



STRATEGIC ISSUES IN BIOTECHNOLOGY, PHARMACEUTICALS, AND NEXT-GENERATION THERAPIES

**PHARMACEUTICALS AND
PHARMACY REPORT**
(November 1, 2025)

www.tusap.org

TUSAP
HEALTH PLATFORM

PHARMACEUTICALS AND PHARMACY REPORT

November 1, 2025

ISBN: 978-605-4123-88-9

TÜSAP EXECUTIVE BOARD

Prof. Dr. Kemal MEMİŞOĞLU / Minister of Health of the Republic of Türkiye
Assoc. Prof. Dr. Şuayıp BİRİNCİ / Deputy Minister of the Ministry of Health of the Republic of Türkiye
Prof. Dr. Sabahattin AYDIN / Former Deputy Minister of the Ministry of Health
Op. Dr. Reşat BAHAT / President of OHSAD
Prof. Dr. Haluk ÖZSARİ / Secretary General of the Association of University Hospitals
Assoc. Prof. Dr. Abdullah Emre GÜNER / Istanbul Provincial Health Director
T. Ufuk EREN / CEO of Volitan Global
Feyzullah AKBEN / Chairman of the Board of SATUR
Savaş MALKOÇ / Secretary General of İEİS

PUBLICATION COORDINATOR

Sadık Abdullah FİDAN

EDITORIAL SERVICES

Funda ÇAMÖZÜ

SECTOR COMMUNICATIONS COORDINATOR

Hazal AKBABA

ORGANIZATION VISITOR RELATIONS

Ece KOŞAR

ORGANIZATION CONTACT

Satur Organization and Tourism Inc.
Kore Şehitleri Cad. Yonca Apt. A Blok No:1/5
Zincirlikuyu / Şişli - İSTANBUL
Phone: +90 212 272 61 06

SUPPORT PARTNERS



VISION MEETINGS 43rd MEETING



PHARMACEUTICALS AND PHARMACY

SATURDAY, NOVEMBER 1, 2025

PLACE

Elite World Grand Istanbul



OPENING REMARKS

Prof. Dr. Sabahattin AYDIN
TÜSAP Executive Board Chair

IS IT MORE IMPORTANT TO DEVELOP AN INNOVATIVE MEDICINE OR AN INNOVATIVE WEAPON?

Today's meeting is taking place in a format that differs somewhat from our traditional TÜSAP Vision Meetings. Given the importance and depth of the topics we will be addressing, our meeting will be somewhat longer than usual. Our main theme is "Strategic Issues in Biotechnology, Pharmaceuticals, and Next-Generation Therapies." In my view, this is an exceptionally challenging subject. You may ask, "Why is it challenging? This is our field—we live and breathe these issues." However, whether a subject leads to meaningful outcomes is directly related to the prominence it receives on the public agenda.

When we look at today's communication landscape and the issues occupying our minds, we must ask ourselves how much attention is actually devoted to pharmaceuticals—or, more broadly, to healthcare strategies and solutions. Unfortunately, when we turn on the television or follow the news, the stories we encounter are no longer about preserving life, but about taking it. We live in a world where every day brings reports of mass casualties, wars, and genocides. Humanity seems increasingly surrounded by an expanding ring of fire. You may even have noticed that, in some countries, ministries of defense are being renamed ministries of war. It compels us to ask a fundamental question: Is our world turning to preserve life, or to destroy it?

Our sector is dedicated to preserving life. Every stakeholder present here works toward enabling people to live healthier, better, and more comfortable lives. For that reason, I would like to emphasize that our work is difficult, yet profoundly meaningful. At times I find myself wondering: What has become a greater source of pride for societies today—developing an innovative medicine or developing an innovative weapon? The answer to that question alone reveals much about the priorities of the age in which we live.

Naturally, our country is not immune to these realities. Like the rest of the world, we are affected by these challenges. Considering that Türkiye is currently implementing a period of tight monetary policies, you can appreciate that our work has become even more demanding. I sincerely hope that our Deputy Minister, who will speak after me, will bring us more encouraging and hopeful news from Ankara, allowing us to continue today's meeting in a more optimistic atmosphere.

Today's meeting consists of three main sessions:

1. The session entitled "Strategic Issues in Pharmaceuticals and Next-Generation Therapies" will be moderated by Assoc. Prof. Dr. Şuayıp Birinci, Deputy Minister of Health.
2. The panel on "Financial Sustainability in Pharmaceuticals" will be moderated by Prof. Dr. Nurullah Okumuş, Deputy Minister of Health.
3. The session entitled "New Approaches to Pharmaceutical Licensing" will be moderated by Prof. Dr. Ahmet Ayar, President of the Turkish Medicines and Medical Devices Agency (TİTCK).

At TÜSAP meetings, our fundamental approach is to gather and document not only the views of the panelists but also those of all participants. Today, we will listen to many distinguished speakers; however, your contributions are what we value most. Under normal circumstances, we collect these views through question-and-answer sessions or surveys. Since today's meeting will be quite extensive, we have decided to move these interactive components to the end of each panel session so that we can gather your opinions following every session.

As with every TÜSAP meeting, this event has been made possible through the support of our valued stakeholders. Sanofi is the main sponsor of today's meeting. Roche and Alexion have contributed as Gold Sponsors. Our supporting sponsors include Yerlika, AstraZeneca, Novartis, Centurion, Johnson & Johnson, Humanis, and Proeutica. TÜSAP's principal supporting partners include Roche, Amgen, Yerlika, Bayer, One Dose Health, Johnson & Johnson, Meditel, Biogen, IQVIA, AstraZeneca, UCB Pharma, İEİS, AİFD, and TİSD. I would like to express my sincere gratitude to all of our stakeholders for their valuable support.

I wish you all a productive meeting. With the hope that the bleak picture I described at the beginning will soon come to an end across the world, I extend my deepest respect to you all and express my wish for a world that places the preservation of life and the promotion of health above all else.





OPENING REMARKS

Assoc. Prof. Dr. Şuayip BİRİNCİ
Deputy Minister of Health

JUST AS WE HAVE BUILT A STRONG DEFENSE INDUSTRY, WE MUST ALSO BUILD A STRONG HEALTH INDUSTRY

With his opening remarks, Professor Sabahattin has undoubtedly placed an even greater responsibility on our shoulders. Just as he demonstrated courage during his tenure as Deputy Minister of Health, I will also try to speak candidly about the gap between what is ideal and what is realistically achievable. That said, it seems that a considerable share of this responsibility now rests with the General Health Insurance (GSS) system. Professor, what do you think? Even having GSS represented here today is, in itself, truly encouraging.

A moment ago, someone asked me, "Where are the officials from the Ministry of Treasury and Finance?" Well, to be honest, we are looking for them as well. Occasionally, we happen to come across them in Ankara.

First of all, I do not wish to paint an overly optimistic picture. However, since I am delivering remarks prepared on behalf of our Minister, I will inevitably use a somewhat different tone, and I ask for your understanding. As you know, we have generally spoken from a position somewhere between the public sphere and our personal views. There have even been occasions when we found ourselves disagreeing with our own reflections. Nevertheless, if Professor Sabahattin permits, today I would like to speak more from the perspective of public policy.

This is our 43rd meeting. In other words, we have gone well beyond the traditional saying of "forty-one times, may it be blessed," and continue two meetings beyond that milestone. Intellectually, these meetings represent a decade-long journey, while in practice we have been meeting together for

nine years. Representatives from the sector, the public institutions, and our stakeholders are all here. After every meeting, each of us leaves with new ideas. Sometimes we depart with many unanswered questions, and later you help fill those gaps. At other times, even if we cannot find definitive answers, we gain a better understanding of the underlying reasons. We go through similar processes ourselves.

I have been serving in management roles for approximately 21 years, and I have known many people in this room for a long time. All of us assess these processes with the awareness that we have not always been able to accomplish everything we hoped to achieve in our respective positions. Today we may be making more critical assessments than we did in the past. My grandfather used to say, "When your money decreases, your wisdom increases." I never forgot those words as a child. Lately, we have been repeating them frequently in Ankara as well. Indeed, we are thinking more deeply about how we can achieve better outcomes within this system.

The sector in which we operate is by no means a small one. Globally, it has reached a value of USD 1.8 trillion. It continues to grow every year and is expected to reach USD 3 trillion within the next decade. Naturally, such growth also makes innovation indispensable. Türkiye may not yet have developed innovative approaches that fully meet these expectations, but I would especially like to emphasize that an intensive process of preparation is currently underway.

Growing demand for vaccines, innovative medicines, and personalized therapies is creating strong momentum to move this sector to an entirely different level. Increasingly, the pharmaceutical industry is being shaped by these demands. According to IQVIA data, pharmaceutical expenditure in the coming years is expected to grow primarily in areas such as oncology, autoimmune diseases, obesity, and diabetes. When we examine recently developed molecules, we see that, regardless of licensing or reimbursement processes, people are increasingly choosing these products to remain healthier and improve their quality of life. This has become a new direction for the industry.

From a global perspective, spending on oncology has risen to 13%–16% of total pharmaceutical expenditure and is expected to approach USD 400 billion by 2027. Expenditure on obesity treatments is also growing at an average annual rate of approximately 40%.





Türkiye is expected to experience an even steeper increase. Our country faces a much greater obesity risk than previously anticipated, with obesity being directly associated with approximately 75% of chronic diseases. This presents significant potential for further growth in the years ahead.

In recent years, the global pharmaceutical industry has been shaped by emerging trends that are introducing new dynamics to the sector. What does this mean in practice? We are now witnessing the use of tools such as big data and artificial intelligence in the discovery of new molecules. These innovative approaches are shortening drug development timelines while also making the process more cost-effective. It is now widely accepted that artificial intelligence is driving innovation in the pharmaceutical industry, reducing costs, and improving patient outcomes.

Today, AI algorithms capable of analyzing large-scale datasets can identify potential drug candidates within a very short period. As a result, drug discovery timelines during the preclinical stage have begun to decrease by approximately 25% to 50%. This creates new opportunities for all of us. Perhaps in the future, despite the substantial upfront investment required for these technologies, we will see pharmaceutical costs become more reasonable as a result of the efficiencies they provide.

Artificial intelligence is transforming not only drug development but also clinical trials and manufacturing processes by optimizing these areas. It also facilitates the identification of suitable patients for clinical studies. We likewise aim to utilize these technologies across many areas. Indeed, during the pandemic, AI applications significantly enhanced our capabilities. Today, together with stakeholders such as TÜSEB, the Turkish Medicines and Medical Devices Agency (TİTCK), and our reimbursement authority, we have embraced a public-sector approach that analyzes larger volumes of data and uses these insights to promote innovation and cost-effective solutions.

Research shows that 85% of biopharmaceutical companies have begun making extensive use of artificial intelligence and big data applications. In particular, technologies such as generative AI and machine learning are improving efficiency and greatly facilitating the development of next-generation pharmaceutical technologies.

In the post-pandemic period, the support provided by countries for healthcare spending and domestic manufacturing has become a strong indicator of growth in the pharmaceutical sector. At the same time, we know that no matter how civilized the world may appear, when faced with a global crisis, countries tend to prioritize their own national interests. This creates significant disadvantages, particularly for countries with lower socioeconomic development, weaker technological infrastructure, or insufficient domestic manufacturing capacity. We have even witnessed cases in which countries have seized medical supplies belonging to others at airports. Such examples reveal how, in times of crisis, the concealed face of civilization comes to the surface. They also offer a sobering reminder of how, even in a highly developed world, war can become the dominant priority and how humanity's destructive tendencies can be directed toward different ends.

According to 2023 data, pharmaceutical sales account for approximately 1.3% of global gross domestic product. In Türkiye, this figure is approximately 0.9%. While maintaining fiscal discipline in pharmaceutical expenditure is essential, we must also ensure that these expenditures serve as a catalyst for investment within the sector. Our common objective should not simply be to procure medicines at affordable prices, but also to strengthen the pharmaceutical industry and develop reimbursement policies that

enable greater investment in research and development. From the perspective of public administration, sector representatives may hold different views, but I would like to emphasize that, under the current circumstances, we are striving to adopt the approach that comes closest to the optimal solution.

When formulating pharmaceutical policy, economic accessibility is only one part of the equation. Equally important is the ability to become a competitive player in the global market. Looking at pharmaceutical sales per capita, countries such as Switzerland, Canada, Germany, and Austria exceeded USD 750 per person in 2023. In Türkiye, by contrast, the figure stands at approximately USD 120 per capita. Mexico and Colombia are slightly below our level. This clearly demonstrates that we have not yet reached the point we aspire to attain.

Türkiye has made significant advances in the pharmaceutical sector over the past 23 years. In 2017, our export-to-import coverage ratio stood at 20%; by 2024, this figure had increased to 37%, representing an 85% improvement. Similarly, in the medical devices sector, the export-to-import coverage ratio has risen from 22% to 47%. Statistically, these figures point to substantial progress. While we may not yet be where we aspire to be, the data clearly indicate that we are moving in the right direction.

The value of Türkiye's pharmaceutical market has grown by 61.3% in U.S. dollar terms between 2015 and 2024. Although we often perceive that "the sector is deteriorating," the data suggest otherwise. Naturally, this growth has also been driven by the increasing demand for healthcare services and the rising burden of disease, both of which continue to grow each year. In Türkiye, the disease burden increases by approximately 4% annually. Measured in Turkish lira, pharmaceutical expenditure has increased nineteenfold over the same period.

We are a country with decades of experience in manufacturing in accordance with international quality standards. Türkiye is home to 885 pharmaceutical establishments and 17 manufacturing facilities,





producing more than 16,000 products. The sector provides employment for approximately 45,000 people and exports to 185 countries, with South Korea ranking as our leading export market. Of course, these figures should not lead us to complacency. Nevertheless, they are a source of motivation. Just as we have strengthened our defense industry, our fundamental objective remains to establish a similarly strong position in the health industry.

In line with Türkiye's 2053 Development Vision, our foremost priorities include establishing an effective pricing mechanism, ensuring the availability of medicines in the market, maintaining affordable access to pharmaceutical treatment, and developing core strategies that support rational pharmaceutical policies.

Some policy measures may appear to have had short-term adverse effects on the sector. However, we evaluate the entire process from the perspective of clinical outcomes. Following the implementation of the Family Medicine Regulation, Türkiye has witnessed a significant reduction in the use of antibiotics, gastric protective medications, and nonsteroidal anti-inflammatory drugs. Utilization of these medicines declined by approximately 40% to 50% in primary care, with smaller reductions observed in secondary care. At the same time, the decrease in antibiotic use did not result in longer hospital stays or increased mortality. On the contrary, antibiotic use in secondary care also declined by 11%, mortality did not increase, and the average length of hospital stay became shorter.

These developments are of critical importance in combating antimicrobial resistance, which is responsible for approximately 42,000 deaths annually through direct and indirect causes. Although our policies have led to a modest decline in the sector's market share, this approach is fully aligned with our public health priorities. We will continue our efforts in this direction. We certainly want the pharmaceutical sector to become stronger, but we also believe that this strength must evolve in harmony with the medical needs of our healthcare system.

While biotechnological medicines are ushering in a new era of treatment, biosimilar products are making access to these innovative therapies more sustainable. The increasing prevalence of chronic diseases, rising treatment costs, and the expiration of patents for biologic medicines are accelerating the maturation of this market. This presents an important opportunity for Türkiye. Pharmaceutical companies are increasing their strategic investments to develop next-generation therapies and secure a position in this expanding market. In parallel, we aim to provide greater support to the domestic pharmaceutical industry.

Globally, the biotechnology market reached USD 1.5 trillion in 2023 and is projected to grow to USD 3.8 trillion by 2030, representing an average annual growth rate of approximately 14%. As Türkiye, I must acknowledge that we have not yet reached the position we aspire to in this field. As of 2023, North America accounted for the largest share of the biotechnology market at 40%, led primarily by the United States. However, the Asia-Pacific region is expected to experience much faster growth in the coming years.

From a technological perspective, DNA sequencing accounted for more than 17% of the biotechnology market in 2023. This clearly demonstrates that biotechnology has become not only a strategic investment area for the future but also one of today's most critical sectors. The growing importance of personalized medicine and the increasing number of orphan drug formulations are creating new

opportunities for biotechnological applications. Furthermore, incentives for innovative biotechnology companies are strengthening overall market dynamics.

As Türkiye, we are shaping our vision accordingly. I would particularly like to emphasize that, as the Ministry of Health, we have made significant progress in this field and are making a determined effort to advance it further.

As of 2023, a total of 155 biotechnological medicines are available on the Turkish pharmaceutical market, including 130 reference biotechnological products and 25 biosimilars. The total sales volume of biotechnology products in Türkiye stands at approximately USD 1.6 billion. By comparison, the figure exceeds USD 300 billion in the United States. In countries such as Germany, France, and Italy, biotechnology sales are approximately USD 10 billion. This comparison clearly shows that our country has not yet reached the desired level in this field.

Biotechnological medicines account for 16% of Türkiye's pharmaceutical market, whereas the average across OECD countries is approximately 32%. This underscores the considerable effort still required to advance biotechnology in our country. Likewise, Türkiye has yet to achieve the desired share of global biotechnology patents. While we had only a single biotechnology marketing authorization in 2008, the number of applications had reached 35 by 2023. In 2024, marketing authorizations were granted for a total of 381 medicines, comprising 358 conventional products and 23 biotechnological products.

These developments reflect not only the growth of the sector but also an ongoing transformation toward a more sustainable and value-added pharmaceutical industry. An 8% growth rate, contributing TRY 3.7 billion to the economy, clearly demonstrates the strategic importance of the biotechnology market.

The President of TÜSEB is also with us today, and I know these issues will be discussed further during the panel. I do not wish to go into detail regarding the structural changes implemented at TÜSEB, but I would like to emphasize the importance we attach to supporting clinical research. In this regard, I consider the contribution of the Social Security Institution (SGK) to be extremely valuable, and I would like to express my gratitude publicly. By undertaking responsibility for covering healthcare expenditures associated with clinical research, SGK has assumed a significant commitment. We have introduced the necessary legislative arrangements to support this initiative, and I believe it represents an important opportunity for both Türkiye and the pharmaceutical sector.

I firmly believe that the discussions we will have today will make a meaningful contribution to the advancement of healthcare in our country. I would also like to emphasize that the ideas emerging from meetings such as this, although not always directly, do influence the decisions we make at the central level. Every issue we reflect upon together within this intellectual ecosystem ultimately shapes our decision-making processes, often in ways we do not immediately recognize.

In the past, we have often said, "This is how the sector views the issue," or "This is where we are weak." At times, however, concerns such as "Will the public sector react negatively?" or "Could this affect my professional relationships?" have prevented some criticisms from being expressed openly. Yet every opinion you share here creates new awareness for us and forms part of the intellectual foundation upon which we build our transformation. That is why I regard these meetings as exceptionally valuable.

Please know that we are genuinely open to every perspective and that we carefully consider all criticism. While working at the center does not always allow us to appreciate field realities as deeply as those of you directly engaged in them, I firmly believe that gatherings such as these provide a platform for open, honest, and constructive dialogue, helping all of us grow and mature together.

With that, I hope today's meeting will continue in this same spirit and on this shared intellectual foundation. Thank you all sincerely for your patience and attention.

PANEL-1

STRATEGIC ISSUES IN PHARMACEUTICALS AND NEXT-GENERATION THERAPIES

(R&D, Biotechnology, Next-Generation Medicines,
Investments, Incentives, Localization)

MODERATOR:



Assoc. Prof. Dr. Şuayıp BİRİNCİ
Deputy Minister of Health

SPEAKERS:



Cem ÖZTÜRK
Regional Head of Eurasia,
Sanofi
Chair of the Board of
Directors, AIFD (Research-
Based Pharmaceutical
Companies Association)



**Prof. Dr. Rana
SANYAL**
Faculty Member,
Boğaziçi University



Farid BİDGOLİ
General Manager,
Roche Pharmaceuticals
Türkiye



**Dr. Hasan Ersin
ZEYTİN**
General Manager,
Yerlika Biopharma



Derya KÖKER
General Manager,
Alexion Türkiye



Moderator: Assoc. Prof. Dr. Şuayip BİRİNCİ
Deputy Minister of Health

In this first session of the TUSAP Vision Meeting, we have come together to discuss a critical topic that will shape Türkiye's future in healthcare and technology: "Strategic Issues in Biotechnology, Pharmaceuticals, and Next-Generation Therapies."

Healthcare is no longer merely a field of public service; it has become a matter of national security and strategic competitiveness. Today, we stand on the threshold of a major global transformation. From AI-assisted drug discovery to genetic therapies, this new era calls for tangible steps toward realizing a vision of an independent and resilient healthcare system in Türkiye. Our fundamental objective is to position Türkiye as a productive, innovative nation and a regional leader.

WE ARE PURSUING SCIENTIFIC DISCOVERIES TO IMPROVE HUMAN LIVES

Cem ÖZTÜRK

*Regional Head of Eurasia, Sanofi Chair of the Board of Directors,
AIFD (Research-Based Pharmaceutical Companies Association)*

First of all, it is truly an honor for us to be here. These platforms provide an environment where the right steps are taken, ideas are openly discussed, gradually take root in our minds, and ultimately lead to tangible outcomes. For that reason, participating here is extremely valuable to us.

As you all know, Sanofi is a global company. With annual revenues of approximately USD 44 billion, we continue to operate in more than 100 countries worldwide. I am responsible for the Eurasia Region. Türkiye is an exceptionally important country for us because we manage our Eurasian operations from here. This region encompasses 17 countries stretching from the Middle East to the Caucasus and Russia.

Why is Türkiye so important? It is a key hub for us because of its young yet rapidly aging population, healthcare consumption per capita, robust healthcare infrastructure, modern hospitals, and strategic geographic location. For these reasons, we have established Türkiye as a regional hub. Our objective is



to further strengthen and expand our global leadership in immunology within Türkiye.

Sanofi is generally recognized for its work in vaccines. However, we also make substantial investments in cardiovascular diseases, immunology, and rare diseases. One of the greatest strengths of platforms such as this is that they create opportunities to build a strong ecosystem. As Sanofi, we attach great importance to being an active part of that ecosystem and contributing to its development. No matter how large a company may be, meaningful progress cannot be achieved unless the right stakeholders are brought together.

A few moments ago, the discussion touched upon the relationship between war and healthcare. The question was raised: "Which is more valuable—developing a weapon or developing a medicine?" As sobering as that question may be, it also reminds us of the profound importance of the sector in which we operate and the vital contribution it makes to humanity.

The Importance of R&D and Clinical Research

We currently have approximately 83 ongoing projects in the fields of immunology and biotechnology. These initiatives are being pursued with the aim of transforming people's lives and creating a healthier future. Our work spans a wide range of areas, from an acne vaccine to rare diseases, multiple sclerosis (MS), type 1 diabetes, and cancer therapies.

Of these 83 projects, 38 have progressed to the drug development stage. We are also making substantial investments in clinical research in Türkiye, where we currently have 66 ongoing clinical trials. I would particularly like to emphasize why clinical research is so important:

Approximately 60% of what we refer to as the "value chain"—from the discovery of a medicine to its production—comes from research and development (R&D). Of that R&D component, approximately

60% consists of clinical research. By comparison, manufacturing itself contributes only about 15% of the total value.

Manufacturing is, of course, critically important from the perspective of national self-sufficiency. However, complete localization of manufacturing is not feasible everywhere, because achieving the necessary scale of production is essential for economic sustainability. For this reason, the value of clinical research is truly immense.

Sanofi'nin Dönüşüm Vizyonu: AI Destekli Biyofarma Şirketi

*100 yıllık bilimsel miras,
yapay zekanın gücüyle yeniden yazılıyor!*

Sağlık Ekosistemini Dönüştüren Projeleri Destekliyoruz

*Sağlık alanında girişimcilik için gelişmesini destekliyoruz;
yenilikçi fikirlerin sürdürülebilir iş modellerine
dönüştürülmesi için girişimcilere destek oluyoruz.*

PharmOp Care4Rare

Challenges Facing the Sector and Proposed Solutions

Although investment in clinical research has increased in Türkiye in recent years, the number of clinical studies has declined. One of the primary reasons is the difficulty of bringing innovative medicines to market. No matter how robust your clinical research infrastructure may be, if you are unable to introduce innovative products to the market, you inevitably lose your competitiveness.

The defense industry is undoubtedly of strategic importance. However, investments in healthcare must be given the same level of priority.

In this context, we believe that global companies such as ours have a responsibility to provide greater support for innovation and the start-up ecosystem. With this in mind, we launched a program called PharmUp approximately five years ago. The idea was inspired, in part, by my mother, who called me every day asking, "Haven't you found a treatment for COVID-19 yet?" That prompted us to ask ourselves, "If we cannot develop it ourselves, how can we support start-ups that might?" And that is how the initiative began.

Our first PharmUp program attracted applications from 73 innovative start-ups. Today, that number has grown to more than 300. We collaborate directly with some of these companies, while helping others secure international investment.

Our goal is not simply for Sanofi to expand its presence in Türkiye. We want Türkiye to develop its own molecules, strengthen its R&D capacity, and reinforce the broader vision of "A Producing Türkiye in Healthcare." In this regard, we are also following developments in Akyurt with great enthusiasm. The transfer of technology for our Hexavalent Combination Vaccine—the first such technology transfer in the world to take place in Türkiye—and its implementation in Akyurt represent a tremendous source of optimism for us.

Türkiye's emergence as a regional hub for pharmaceutical manufacturing and innovation is significant not only for the country itself but also for global companies such as ours. It offers the potential to become an alternative manufacturing base to China and India.

An Aging Population and the Importance of Early Diagnosis

When we examine Türkiye's demographic profile, we see that the proportion of the population aged 65 and over has now exceeded 10%. Over the past five years alone, this figure has increased by approximately 1.5 percentage points.

***"Moderator:** Yes, the increase is indeed significant. Approximately 54% of this population lives with four or more diseases. Such individuals consume, on average, ten times more healthcare resources than the average citizen. The population aged 65 and over is projected to reach 13.8 million by 2030 and 27.7 million by 2060.*

In other words, one in every four people sitting in this room today will be over the age of 65 in the near future. When we consider the impact this demographic will have on healthcare expenditures, the value of investing in early diagnosis and immunology becomes abundantly clear.

In this regard, I would like to mention an important project we are conducting in collaboration with Ankara University. On average, it takes eight years to reach the correct diagnosis for a rare disease—and this is not unique to Türkiye; it is the global average. A patient who first visits a family physician with abdominal pain may wait approximately eight years before receiving the correct diagnosis.

We asked ourselves whether this could be changed. By combining Ankara University's database with Sanofi's expertise, we are developing an algorithm designed to enable much earlier diagnosis. If we can reduce this diagnostic journey from eight years to one, patients could gain seven additional years of improved quality of life while the healthcare system would realize substantial cost savings.

Should this project succeed, it has the potential to become a pioneering model not only for Türkiye but for the world.

Projects of this nature cannot be carried out by Sanofi alone, nor by academia alone. That is precisely why bringing stakeholders together on platforms such as this is so important.

Artificial Intelligence and the Financial Imperative

Research and development has become an indispensable component of the pharmaceutical industry. Sanofi invests €8 billion in R&D each year. However, drug development is such a challenging process that a product receiving an investment of €20 billion may ultimately fail to reach the market because of a minor adverse effect identified during Phase III clinical trials.

Artificial intelligence has now become an indispensable part of our lives. It dramatically increases the likelihood of identifying the right molecular combinations and reduces the margin of error in patient selection. At Sanofi, we use artificial intelligence in approximately 70% of our small-molecule discovery activities. This has reduced our costs by around 15%. For a company investing €8 billion annually in R&D, a 15% reduction represents a substantial amount of funding that can be redirected toward the development of innovative medicines.



In short, we are entering a highly promising period. With its infrastructure and digital health databases, Türkiye has the potential to become one of the leading countries in this field. However, investment in healthcare must increase substantially.

One of my personal aspirations is this: NATO requires its member countries to allocate 5% of their budgets to defense. I wish there were a similar mechanism for healthcare, whereby countries would be required to dedicate a certain percentage of their gross domestic product each year to innovation and research and development.

Moderatör: *We are the heirs of a civilization that places a healthy generation above all else. In our country, health prevails over war. Rest assured, we may even allocate more than that. Now I would like to invite one of the distinguished academics whom we know well in the field of R&D, a long-standing contributor to this ecosystem, Prof. Dr. Rana Sanyal, Faculty Member at Boğaziçi University. We would be pleased to hear your views on the strategic issues surrounding pharmaceuticals and next-generation therapies, including R&D, biotechnology, next-generation medicines, investments, and incentives.*

This session is being recorded and broadcast. Our reports are shared publicly in accordance with the principle of transparency. To date, we have not encountered any issues in this regard. We can ask our colleagues who prepare the reports to confirm this: Has anyone ever instructed them that "these statements are not appropriate for official public language" and therefore should be omitted? I certainly have not. As you can see, no public official has intervened to prevent these remarks from being included in the report. Therefore, I would like to emphasize that everyone should feel completely free to express their views.

FROM BASIC SCIENCE TO THE CLINIC: THE JOURNEY OF DEVELOPING AN INDIGENOUS MEDICINE – STRATEGIC CHALLENGES AND PROPOSED SOLUTIONS

Prof. Dr. Rana SANYAL

Boğaziçi University Faculty Member



I have been a faculty member at Boğaziçi University for the past 21 years. Before that, I spent ten years in the United States, where I completed my doctoral studies and gained experience in the private sector. I worked in pharmaceutical research and drug development. After returning to Türkiye, I initiated pharmaceutical research activities at the university.

By the way, I am an organic chemist. As we progressed through the stages of our research—saying, "Let's test it in cells, then in animal models"—we began to recognize significant infrastructure gaps. To address these deficiencies, we established a research center, and that is how the journey evolved. The center, the Boğaziçi University Life Sciences and Technologies Research Center, is now 15 years old.

Once the outcomes generated by this center convinced us that we could effectively utilize this infrastructure and develop innovative products, we founded a start-up called RS Research in 2015. At RS Research, our work focuses on cancer. We are dedicated to developing targeted cancer therapies.

These are among the most advanced forms of what is commonly referred to as "smart drugs." They are nanobiomolecular therapeutics that carry both a biotechnological component and, to use a military analogy, a "bullet" designed to destroy the tumor once it reaches its target. This "bullet" may consist of either a cytotoxic agent or a radiopharmaceutical. We have pursued this research using different platforms and delivery systems.

The research itself was always rooted in basic science. However, once basic science reached the stage of innovation, commercialization became the next step. Supported by venture capital and investment funding, the company set out to complete all the clinical development stages required for this molecule.

Since this was a novel molecule, we also needed to complete preclinical animal studies. Initially, we were unable to conduct these studies in Türkiye, so our first experiments were carried out abroad. (Today, GLP- and GCP-compliant facilities are available in Türkiye.) Once those studies were completed and we concluded that the molecule had become a viable clinical candidate, we began working with the Turkish Medicines and Medical Devices Agency (TİTCK). At that stage, the question became: "Can we actually bring such a molecule to patients?" This inevitably brought manufacturing requirements to the forefront.

By manufacturing, I mean the following: this is a synthetic chemical molecule consisting of a polymeric material carrying a cytotoxic agent, with an additional bioconjugation component involving a biomolecule. In other words, unlike biotechnological products manufactured using living cells, this is a synthetic manufacturing process. As a result, both its analytical characterization and purification become considerably more complex. Once those stages were completed, we aimed to convert the synthesized compound into a lyophilized product.

Since we anticipated that only limited quantities would be required for clinical trials, we also had to establish a manufacturing facility in Türkiye. As part of this ecosystem, we have now built a facility capable of both synthesis and fill-finish operations, producing clinical-grade lyophilized cytotoxic products.

Once these materials became available for clinical use, we initiated a Phase Ia clinical trial in oncology, treating patients individually. While some patients had previously participated in global pharmaceutical



company studies, our objective was to initiate this entire clinical trial in Türkiye and recruit all participants locally. At one point we even said, "Why don't we write the clinical protocol ourselves?" It turned out that this was also a first. Working together with the TITCK, we successfully accomplished that as well, and the Phase I trial began. After a long journey, we have now reached the final stage of Phase I.

Critical Needs and Recommendations for the Development of the Sector

Moderator: *Professor, I do not want to interrupt you, but Mr. Cem, as a representative of a company currently marketing products, understandably presented a more cautious and optimistic perspective. As an entrepreneur, however, you are in a unique position to share what could have been done better throughout this journey. In particular, what improvements would have enabled you to reach your goals more easily? What shortcomings exist in the current processes, what are the sector's deficiencies, and in which areas could Türkiye have provided a more enabling environment?*

Throughout this journey, we have had to undertake many tasks that a start-up probably should not have to take on—such as establishing our own manufacturing facility. Yet that is precisely what enabled us to stand alongside the 66 companies currently conducting clinical research in Türkiye as a company conducting its own clinical trial. The companies participating in the remainder of this session—Mr. Cem, Mr. Hasan, and the others—will each present their own experiences as well. Why are meetings like this so important? Because we have demonstrated that it is possible. We have succeeded in developing a new medicine.

Yes, artificial intelligence can certainly generate significant efficiencies, but those gains amount to only about half of the total investment required to develop a new drug. Therefore, my expectations of AI have their limits. Beyond a certain point, we will still need systems capable of taking a molecule all the way to where it needs to go—and I believe we will continue to play an essential role in that process.



I would like to begin with your grandfather's saying because I truly liked it: "When we have less money, we become more resourceful." To accomplish all of this, we can compare the amounts invested by major global pharmaceutical companies with those invested by start-ups; the FDA has published data on both. Looking at those figures, one could say that ingenuity flourishes on the start-up side. I took that personally. We are genuinely trying to do something smart. In fact, we have no choice. We are driven not only by innovation but also by necessity. If we fail to make the right decisions, we simply will not survive.

We are witnessing a global shift in drug development toward the start-up ecosystem. Comparisons are often made between healthcare and the defense industry, and our Deputy Minister referred to this as well. There are indeed similarities—for example, the emphasis on developing "national products." Likewise, both sectors have large multinational companies developing products.

However, there is one fundamental difference: the market for these products. When a defense product is developed, you may choose not to sell it to every country and may impose restrictions on its distribution. Medicines are entirely different. When you develop a pharmaceutical product on a global scale, your goal is to make it available everywhere. This creates a different kind of international reputation and enables Türkiye to build a global standing that differs from its reputation in the defense sector. There is generally no reason to restrict market access. From the perspective of Türkiye's global reputation, this is of tremendous importance.

Requests and Recommendations for Clinical Research

Mr. Cem also touched upon clinical research. What can we do here, and what do we want? Let me move on to our requests:

1. TÜSEB and the Scope of the Support Legislation: A new regulation was introduced together with TÜSEB's support for clinical research. I believe this is a very positive development for Türkiye. However, we also need to move to the following point: even if you are not receiving support from TÜSEB, if you are developing something in Türkiye, why should you be penalized simply because you did not receive funding? In other words, even if no funding has been provided, if you are developing something in Türkiye, we would very much like to be subject to the same support legislation that applies to clinical research.

***Moderator:** We have also had detailed discussions with the General Health Insurance (GHI) side on this issue. Covering the costs of clinical research as part of healthcare expenditures constitutes a very significant financial burden. For this reason, it was initially decided to focus support on certain strategic projects. Even this represents a highly valuable starting point. Your feedback is valid; however, ultimately, I do not believe that TÜSEB, the Ministry of Health, or the General Health Insurance Directorate would refrain from supporting a critical and strategic product. No one would want a highly valuable product to fall behind in Türkiye because of budgetary constraints. However, it may be very difficult to cover every product. If other products also enter the Turkish market together with partners in Türkiye, evaluating and filtering such requests would be valuable. Since our resources are limited, this type of restriction was introduced. Let me once again recall my grandfather's saying. Due to budgetary constraints, the General Health Insurance Directorate initially proposed financing clinical research from within the global budget. However, the GHI side responded positively to our feedback on this matter. We also believe that there will be no objections from the Ministry of Treasury and Finance. We hope to see clinical research financing removed from the global budget, demonstrating that the Ministry of Treasury and Finance has also assumed responsibility in this area.*

Yes, we will certainly draw quite a lot from your grandfather today. I am not speaking on behalf of all global companies. I am speaking on behalf of a company that has developed a medicine in Türkiye, successfully brought it from basic science to the clinical stage, and currently has one product.

2. Clinical Protocol Development (EMA Model): The European Medicines Agency (EMA) has such a practice: developing the protocol together. I am referring to an approach they describe as "co-creation." So, what can we do through the Turkish Medicines and Medical Devices Agency (TİTCK)? I am referring to developing protocols for clinical research from the very beginning of the process—not the stage where I have already submitted my protocol and then ask, "What do you think of this?" This is my request, and I would very much like you to initiate it. How wonderful it would be if we could develop our Phase II protocol together. We currently have a substantial pipeline of clinical research projects underway. Our first molecule is completing Phase I. We are planning another Phase I application within the coming year. Let us review that protocol together—not after it has been submitted, but by developing it together from the outset. That is my request.



3. Performance Criteria and e-Nabız Integration: Enrolling patients in clinical research. This is a request that concerns all of us, everyone in this room involved in clinical research. Let patient enrollment in clinical research become a performance criterion in the public sector. Can we make this a performance criterion in public hospitals? There is already a form of performance criterion, but patient enrollment in clinical research is an area that we must always accelerate. While we are on this subject, there is also the issue of matching patients for clinical research through e-Nabız. This information does not need to be shared with the company. When this information is conveyed to the patient's physician and you say, "There is a suitable clinical study for your patient," we are talking about something that would immediately facilitate the patient's early access to treatment.

Moderator: *This is a highly valuable proposal. We can implement it immediately. I will take ownership of this issue without delay.*

However, since I am the one proposing it, perhaps you could initiate my protocol first.

Speaker (Mr. Cem): *Don't roll it out across Türkiye; start from a single site only. We would be happy to participate in the pilot.*

Moderator: *This is an excellent proposal. Let's begin with Professor Rana. Are you ready? As soon as you submit your algorithm, we can see the number of eligible patients in the system and generate alerts for physicians. This is an application that we can implement very easily.*

Thank you. That happened very quickly.

4. The Challenge of Early Access and the Leverage Effect: Early access to medicines is extremely important in Türkiye. Everyone in this room has already read and is familiar with the FDA report, particularly with regard to oncology medicines, where time is of the essence. Unfortunately, the number of new medicines introduced into Türkiye over the past two years is zero. In other words, among the medicines approved by the FDA and the EMA, not a single one has entered the Turkish market within two years.

What do we need to do about this? Yes, we need funding. If we had more financial resources, we would also be able to bring in more products. However, alongside the reasons these medicines are unable to enter the market, we should also consider that we have medicines of our own. Once we begin supplying our own medicines to the world, then, in addition to the financial benefits, when a country says, "This is an excellent medicine; we want it," perhaps it could also serve as leverage for saying, "Very well, then when that medicine from your country becomes available..." This is something that could be considered.

Moderator: *Are you referring to medicines that have received marketing authorization, or does your assessment also include medicines supplied through the foreign drug program?*

From abroad... Specifically, I believe medicines supplied through the Turkish Pharmacists' Association are not counted in the FDA report. I think Mr. Ümit, who knows the FDA report inside and out, should answer that.



Moderator: Because medicines are also supplied through the foreign drug program. Unfortunately, court rulings have also become a means of drug procurement. Hopefully, the General Health Insurance system (GSS) will resolve this issue soon.

Yes, but let's also acknowledge that it is not a good model.

Moderator: Regarding access to innovative medicines in Türkiye, figures as low as "around 6%" are frequently mentioned in public discussions. However, when the actual data are examined, it is evident that this rate rises to as much as 45% through mechanisms such as the foreign drug supply program. Although this method is far from ideal, it demonstrates that access to innovative medicines is, in fact, being provided. I am making this point not to defend ourselves, but to present another aspect of the current situation.

Participant (Mr. Ümit): The issue examined in the foreign drug study is as follows: The study does not look at medicines that have marketing authorization. If a medicine has been authorized by the EMA, it is effectively considered authorized throughout Europe. What the study examines is reimbursed medicines. In Türkiye's case, both foreign medicines and... that is, both 4A and 4C are included... foreign medicines that are reimbursed. That is because the comparison is based on reimbursement. In those countries, the corresponding medicines are reimbursed. The comparison is not whether they are on the market, but whether every patient prescribed that medicine can obtain it under the reimbursement system. If access is obtained indirectly, it is not counted, and naturally court decisions are not included. As far as I know—and Mr. Eren can correct me if I am mistaken—payments made pursuant to court decisions do not appear as pharmaceutical expenditures in either the budget of the Republic of Türkiye or the budget of the Ministry of Labour and Social Security. Instead, they are recorded as personal payments made to individuals. Therefore, I believe it would be worthwhile for everyone conducting research to determine that figure and find out how many medicines are being paid for through that mechanism. That is an entirely separate issue. Neither we nor anyone else has access to those data, nor is it possible for us to calculate them.



Participant (Mr. Eren): Mr. Minister, those medicines are included within our total healthcare expenditures, but not within our pharmaceutical expenditures. However, they are included in the total healthcare expenditure of TRY 960 billion recorded in 2024. Court-ordered payments have decreased substantially in the recent period with the expansion of reimbursed procurement. The results of the related efforts are already becoming evident. In fact, the critical question is this: Medicines that received FDA or EMA approval within the last two years may not have entered Türkiye, but which of those medicines were truly practice-changing or groundbreaking? How many of them did not reach Türkiye? I ask this because these medicines do undergo evaluation. We conduct the assessments, but our reimbursement committee—the scientific committee—may conclude that, "At this stage, there is no need to use this medicine." A medicine may have received approval within the past year or two, but approval alone is not our sole criterion. What is important is the actual contribution that medicine makes to patients. Is it truly groundbreaking? Does it fundamentally change clinical guidelines? Or is it simply an alternative molecule that still requires additional clinical evidence?

May I respond to that? Because I can answer from a completely impartial standpoint. I represent a company that sells none of these medicines. I am neither with AIFD nor with Sanofi.

I consider it my responsibility to provide you with a list identifying which medicines were truly critical, which would have become first-line therapies, which entered other markets but could not reach Türkiye within the first five years, and which have still not reached Türkiye over the past decade. I say this with great regret: unfortunately, we currently have medicines that have profoundly changed clinical protocols and transformed patients' lives, yet we have been unable to introduce them into Türkiye even within five years.

Participant (Mr. Eren): The reason I mentioned this is that there are also medicines such as etomidate, a basic anaesthetic agent that should be used as a first-line option, which may at times be unavailable in the country. Being innovative or recently authorized is not, by itself, our only criterion. As you rightly said, if a medicine is truly groundbreaking, significantly alters clinical guidelines, and still fails to obtain reimbursement, then that becomes a much greater responsibility and a much greater burden for us.

Moderator: Professor, I will bring representatives from the Ministry of Treasury and Finance to our next meeting. Please don't be too hard on Mr. Eren—he shares the same perspective as we do. In fact, we now understand more clearly why representatives from the Ministry of Finance are not here today.

Speaker (Mr. Cem): I would like to contribute to this discussion. In my opinion, everyone who has spoken here is right. First of all, I would like to thank Professor Sanyal, because, as she mentioned, there are truly remarkable innovative medicines.

These data are among the key indicators companies like ours consider before making investment decisions. In the past, when approximately 20% of the medicines approved by the FDA in the United States entered the Turkish market, this was not regarded as a problem because the vast majority of the highest-priority medicines were already reaching our country. Rare and exceptional cases could still be accessed through court decisions.

However, once that figure declined to 3–4%, the inability of innovative medicines to enter the Turkish market became a serious issue of discussion, affecting the entire ecosystem.

Before making an investment, an international investor or a major pharmaceutical company examines several fundamental criteria:

- What percentage of the gross domestic product is allocated to healthcare?*
- What proportion of that healthcare budget is allocated to pharmaceuticals?*
- Is there a realistic opportunity to introduce innovative medicines into the Turkish market?*

When all these indicators are considered, we unfortunately continue to rank last among OECD countries.

I must state very clearly that I have worked at Sanofi for 22 years. Ten to fifteen years ago, we had operations in around 100 countries. Today, that number has fallen to 65. As costs increase, global companies are compelled to choose the countries in which they will invest. Whether Türkiye is regarded as a key market is assessed on the basis of these key performance indicators (KPIs).

As a result, Türkiye is gradually losing its competitiveness. Moreover, every delay in reimbursement decisions sets us back by at least three years, because even after a positive reimbursement decision is made, it takes a minimum of three years for the medicine to become available in Türkiye.

I do not accept the argument that these low access figures can be explained by saying, "These medicines are not coming because we don't want them," or "We did not consider these medicines worthwhile." There are undoubtedly medicines on that list that we would very much want to see introduced into Türkiye.

Since this is the current reality, we must support clinical research far more seriously and much more vigorously. Supporting clinical research at the earliest stages will enable our patients to gain access to medicines. The figure in the FDA report points to a real issue. Whatever the reason may be, we must first acknowledge that reality and then decide what kind of strategy we should adopt in response. My principal recommendation is to expand and strengthen clinical research. There is already a desire to increase clinical research, and this situation provides an additional justification for making that decision.

5. Pricing Regulations for Locally Developed Medicines: Although this falls outside my own area of expertise, it is an issue that many companies in the sector understand very well. In Türkiye, we have not yet implemented a pricing process for a medicine that has been developed in Türkiye and will receive its first price approval in Türkiye. We urgently need legislation to regulate this process.

Of course, when we develop a global product, there is always the option of saying, "Don't obtain a price in Türkiye—go and obtain the price in the United States first." However, why would we choose such a delay? Many countries, such as South Korea, have already established pioneering practices in this area. We also know that the initial pricing decision subsequently serves as a reference for many other countries.

For this reason, we need regulatory mechanisms governing pricing and the subsequent reimbursement policy. One of the products we have developed is currently continuing its clinical development. Since it is a cancer treatment, it will complete Phase III. However, do not imagine that this process will take "another ten years or so." The product we are discussing has the potential to reach the market even on the basis of Phase II data. Products of this kind are on the way, and therefore the necessary legislative infrastructure must be established without delay.

Moderator: *You raised some excellent points. I have been given quite a bit of homework. As for making this a performance criterion in the public sector: yes, this can be done. I will also bring this proposal to the attention of our Minister, because I believe it is a very good suggestion. Although it is not directly related to clinical research, there is already a scientific publication score within the*

academic incentive system. We could incorporate it into that scoring system and, without making any legislative changes, convert it into a performance criterion. I believe our Minister will strongly support this proposal, and I will present it to him.

THE DRIVING FORCE OF TRANSFORMATION IN HEALTHCARE: INNOVATION AND VALUE CREATION FOCUSED ON TÜRKİYE'S NEEDS

Farid BIDGOLİ

General Manager, Roche Pharmaceuticals Türkiye

It is a great honor and source of excitement for me to come together with you once again in such a vital session as Strategic Issues in Pharmaceuticals and Next-Generation Therapies.

Some of you may remember; exactly one year ago, on this platform, I had my first TÜSAP experience, and today I am very happy to be among you once again and to meet with these valuable stakeholders of the healthcare ecosystem.

Today, as you can also see on the screen, under the title “The Driving Force of Transformation in Healthcare: Innovation and Value Creation Focused on Türkiye’s Needs,” I will share with you Roche Türkiye’s strategic role, vision, and commitment in this major transformation.

As I begin my speech, I would like to start with an interesting anecdote that shows how deep-rooted and strategic our bond with Türkiye is.

Roche’s presence in Türkiye is much more than a simple commercial relationship; it is the product of a deep partnership whose foundations are based on the foresight of Mustafa Kemal Atatürk, the founder of the Republic of Türkiye.

There is a striking fact that shows how strong a negotiator and visionary the Turkish nation is: the first request for strategic cooperation negotiations between Roche and Türkiye came directly from the Government of the Republic of Türkiye.

Following Atatürk’s initiatives, this relationship, which began in the 1940s with the supply of opium, one of Türkiye’s strategic resources at that time, to Roche for the production of high-quality medicines, has today gone beyond being merely a company that brings medicines and has transformed into a strategic partner that focuses on local needs and brings data-driven innovation and next-generation therapies to Türkiye.



This deep-rooted history is the strongest proof of how permanent and value-creation oriented our presence in Türkiye is.

Now let us take a closer look at how this deep partnership shapes today's transformation in healthcare.

First, let us look at patient focus, which is our fundamental purpose: In the last 10 years, we have reached more than 12 million patients with our innovative treatment and diagnostic solutions. To make the size of these figures more concrete, approximately 6 million units of our medicines touch patients' lives every year, and by performing 1 billion diagnostic tests annually with Roche kits and devices, we support patients in rapidly reaching the correct diagnosis.

The driving force behind this impact is our R&D and our confidence in Türkiye.

Over the last 10 years, with a momentum increasing by more than 800%, we have made a total investment of 4.1 billion TL in Türkiye. This is not only a financial commitment, but also an indicator of our belief in Turkish science and healthcare potential. Thanks to this investment:

- We collaborate with approximately 1,500 research centers,
- We enable more than 63,000 of our patients to gain early access to innovative treatments through clinical studies.

In addition, our investment of approximately 200 million TL in physician training and scientific meetings shows the importance we attach to the development of our human resources.

Yes, all these metrics reveal the scale of our operation in Türkiye and its positive impact on patients. However, as a General Manager, I also know very well that despite all these investments and efforts, there can still be difficulties in access to certain innovative treatments.

At this very point, I would like to share our core message beyond the numbers: True success should be addressed as a success story.

As a pharmaceutical company, the promises we make or the investments we make alone can create an impact only up to a certain point. However, when the healthcare system works at full efficiency and in harmony with every unit, including legal regulations, investment incentives, funding mechanisms and sector cooperation, we can create a truly lasting and revolutionary positive impact not only on 12 million people, but on the entire population of Türkiye.

We can better make sense of the vital importance of the system working with all its components through a concrete public health issue. This issue is Breast Cancer, which has strategic importance on Türkiye's health agenda and is unfortunately one of the greatest threats to our women.

Breast cancer is not only the most common type of cancer among women, but also ranks second among cancer-related deaths.

- Worldwide, one woman is diagnosed with breast cancer every 14 seconds.
- One in every 8 women carries the risk of facing this disease during her lifetime.
- When we look at Türkiye, the incidence rate points to a high rate of 43.4 per 100,000 women. These figures show us that this disease requires a comprehensive and national struggle.



However, within all this challenging picture, the strongest message that gives us hope is also here: Breast cancer can be completely cured when diagnosed early and treated.

I would like to draw your attention to the most striking statistic here. This is evidence showing why we need to act quickly and correctly in our healthcare system:

- If a woman is diagnosed at Early Stage I, the 5-year survival rate is 100%. This means an excellent outcome for our patients and almost complete recovery.
- However, when the disease progresses and reaches Advanced Stage III, the survival potential rapidly declines to 74%.
- When the disease becomes metastatic, that is, when it reaches Stage IV, this rate unfortunately shows a much more dramatic decline.

This picture does not only show us statistics. It also proves that early diagnosis and access to the right treatment create the difference in life between 100% and 74%. This is the fundamental reason why, as Roche, our focus on next-generation therapies and diagnostic solutions carries a humanitarian responsibility beyond innovation.

We have seen the burden created by diseases such as breast cancer and the value of early diagnosis. So why is bringing solutions to these problems and investing in next-generation therapies not only a medical issue, but also a critical matter of Social Value? Why should our focus be on the role of women?

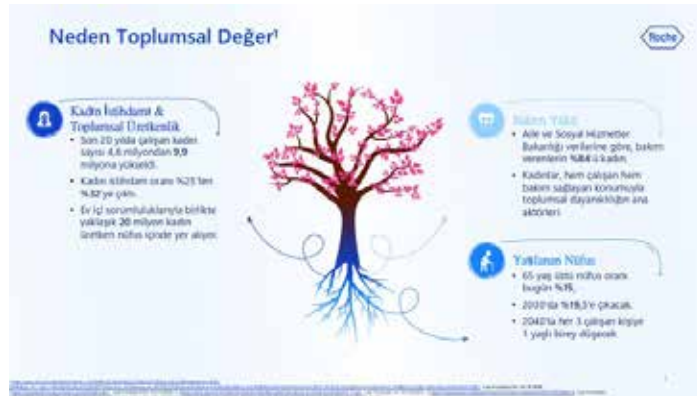
Women form the roots and the fabric of life of this tree, both economically and socially. First, let us look at the dimension of economic productivity:

- Over the last 20 years, the number of working women has almost doubled, reaching 9.9 million. The increase in the employment rate from 25% to 32% shows that women are the main driving force of economic growth.

However, the role of women in society is not limited only to the economy. They are also the main actors of our social resilience. According to the data of the Ministry of Family and Social Services, 84% of official caregivers in Türkiye are women. Women generally put themselves in the background and prioritize the health and well-being of everyone in the household and around them. Our strategic view is this: If we pay attention and care to these roots (women's health), the leaves and branches of society (our general well-being) will naturally become stronger and grow.

This situation turns into a strategic challenge, especially when combined with the reality of the Aging Population in Türkiye:

- Our population over the age of 65 is increasing rapidly and is expected to reach 19.5% in 2030.



- The most critical projection is that by 2040, there will be 1 elderly individual for every 3 working people.

Our women, who add so much value to society and carry the burden of care, unfortunately face the risk of becoming dependent as they age. As far as I can see, women care about others much more than anyone else in the world. Therefore, our strategic priority is to keep this valuable population healthy and economically active for a longer period.

Healthy women mean a lower care burden, higher productivity, and therefore a more resilient national economy. Facilitating access to next-generation therapies is the key to achieving this strategic goal.

We have a responsibility to look at the entire patient journey in Breast Cancer, from diagnosis to treatment, from a holistic perspective.

Our vision of Social Value Leadership in the Fight Against Cancer requires us to focus strategically on every stage of this journey:

1. Awareness: The journey begins with the most critical step, namely Awareness. If we remember that early diagnosis raises the survival rate to 100%, supporting screening and awareness-raising efforts is the first and most valuable step.
2. Diagnosis: The second stage is the process of rapid and accurate Diagnosis. Roche's global strength in the field of diagnostics (IVD) plays a critical role in increasing the quality and speed of diagnostic processes. Accurate diagnosis is the key to the newest treatment.
3. Treatment: The third stage, Treatment, is the area where our next-generation innovative medicines come into play and where we improve the patient's quality of life and survival. Ease of access is of vital importance here.
4. Follow-up: Finally, the Follow-up stage. Continuous monitoring and support of the patient after treatment, and remaining alert against the risk of recurrence in order to maintain long-term survival and quality of life, are also within our area of responsibility.

For us, Social Value Leadership requires investing in and producing solutions not only for one part of this journey, but for the entire chain extending from the patient's first suspicion to continuing life as a healthy individual. Our strategic focus is to ensure that no link in this chain is broken.

Let us take a closer look at the Awareness stage, the first and perhaps the most critical step of the patient journey. If we remember that early diagnosis in breast cancer means 100% survival, every effort at this stage means a direct investment in our national welfare.

In this social value journey, we focus on three main strategic areas to increase awareness:



1. Expanding Screening: Creating Concrete Impact

- First, we support the expansion of screenings, which are the most important tool for early diagnosis.
- We have been working in cooperation with KETEMs for many years and have been supporting the Bahçeşehir Screening Project of the Breast Health Association (MEMEDER) for ten years. Thanks to this continuous support, approximately 10,000 women have been screened with mammography. Such screening projects are the only way to detect cancer while it is still at Stage I and to maximize patients' chances of survival.

2. Supporting Knowledge: Empowering Healthcare Professionals

- Another pillar of awareness is empowering the actors on the front lines of the healthcare system: Supporting Knowledge.
- In cooperation with the Turkish Surgical Association, we organize training programs for our family physicians working especially in our eastern provinces, where access is difficult. Family physicians are the first point of contact with the patient; their knowledge of current approaches to breast cancer and proper referral is a vital link in the early diagnosis chain.

3. Supporting Through Technology: Reaching Large Audiences

- Finally, we increase awareness by using next-generation tools: Supporting Through Technology.
- Through our digital campaigns such as “Kadın Eli Değsin” and “Merakına Yenilsin,” we inform women about breast self-examination and the entire patient journey by using websites, social media platforms and mobile applications. Digital tools provide us with the opportunity to reach millions who cannot be reached through traditional methods.

This threefold strategy, namely expanding screening, refreshing physicians' knowledge and using technology to reach large audiences, represents the concrete steps we take at the awareness stage in the fight against breast cancer.



In the Age of Artificial Intelligence (AI) we are in, we see that demand for hospitals and healthcare services has increased dramatically. In order to meet this demand burden and improve the quality of diagnosis, we need to integrate Artificial Intelligence-based diagnostic methods into our systems.

As Roche, we also use methods that will facilitate and accelerate women's breast cancer diagnosis through digital technologies and platforms. Our strategic solution is to create a national platform that eliminates geographical barriers:

- Digital Radiology and Pathology: By digitalizing diagnostic imaging and pathology data, we enable

complex data to be shared quickly, securely and easily. Together with our multidisciplinary teams, we actively use digital pathology.

- Virtual Tumor Board Platform: The most strategic part of this process is our central platform that brings diagnostic data together. Thanks to this platform, a physician anywhere in Türkiye can transfer case data here and request access from a physician at the center or from another specialty hospital.

This platform has two main benefits:

1. Multidisciplinary Quality: Regardless of geographical location, the case can be brought to a Tumor Board (Virtual Tumor Board) in order to receive the most accurate and up-to-date diagnostic consensus.
2. National Access and Standardization: This is our commitment to standardizing diagnostic quality nationwide and delivering the best expertise to every patient in the shortest possible time.

With this platform, we not only support diagnosis, but also ensure that patients coming from the awareness stage can access Stage I diagnosis wherever they are. Let us not forget that the success of next-generation therapies depends on accurate and rapid diagnosis.

Traditional approaches unfortunately create a major time burden for our patients, especially for our women with breast cancer. For traditional Intravenous (IV) Applications in the hospital, the patient has to spend between 4 and 7 hours in the hospital, including administration and monitoring, together with travel and waiting times. This is a serious inefficiency and challenge for both the patient and the healthcare system.



At this point, we carried out a strategic paradigm shift in treatment management. We moved the treatment from Intravenous (IV) administration to Subcutaneous (SC) administration, which is much more practical and faster.

- As you can see on the screen: while Intravenous administration in the hospital takes approximately 3.5 hours, with the new Subcutaneous Application, this duration can be reduced to a total of 20 minutes in healthcare centers.
- Especially thanks to our partnership with TITCK (Turkish Medicines and Medical Devices Agency), we significantly shorten this waiting and administration time, optimizing the patient's hospital experience and total journey time.

However, we are taking this transformation one step further: Home Healthcare Services. This is not only about saving time, but about fulfilling our Social Value commitment that we mentioned in the previous slides.

Why home care?

- Let us not forget that women are the ones who carry 84% of the caregiving burden in Türkiye. They have to take care of their children and elderly parents, and going to the hospital is a major logistical barrier for them.
- In addition, they may not want to leave home due to personal difficulties such as hair loss related to chemotherapy. Home care gives them both full access to treatment and the freedom to maintain their social and personal roles.

The results of the home healthcare projects we have implemented with the support of institutions such as the Istanbul Provincial Health Directorate are striking:

- In just 1,000 patients, a total of 25,000 hours of time savings is achieved for the healthcare system and patients.
- This means approximately 60 hours per patient.



This is a concrete example of how innovative treatment directly contributes to the patient's social life and to society's economic cycle, in other words, how it is the "Driving Force of Transformation in Healthcare."

For us, success is not only making a medicine accessible; it is focusing on personalized healthcare planned according to the patient's medical and personal needs. This holistic approach enables us to make a major difference by bringing together the Medical Journey, the Supportive Process and the Social Role.

Especially through the combination of early diagnosis, smart medicines and the right diagnostic tests (such as HER2), Türkiye truly has a groundbreaking potential in this field prospectively.

Here is the concrete and proud result of this effort:

With innovative treatment approaches targeting the HER2 receptor in early-stage breast cancer and planned according to the medical and personal needs of patients, 3,859 cases of metastasis have been prevented in Türkiye.

This striking figure is not the success of a medicine alone, but proof of how life-saving Diagnosis made at the right time, Personalized Treatment and the cooperation of the entire system can be.

What does this mean? Thousands of women did not experience the most difficult and destructive stage of the disease, namely metastasis.

They were able to continue carrying the caregiving burden of their families, continued to contribute to the economy, and reached the 100% survival potential achieved when detected at Stage I.

When we consider the magnitude of the productivity lost in metastatic cancer and the economic burden, the value this progress adds to society and the economy is immeasurable.



- On a Patient Basis: Thanks to early diagnosis and current treatment approaches, we can gain an average of up to 27 additional years of life for each woman whose metastasis is prevented. This is not an ordinary increase in longevity; it is a meaningful increase in life expectancy, adjusted for productivity and quality.
- In Total: With these 3,859 metastasis cases that we prevented over a ten-year period, we create a total of 100,000 years of gained life years (Quality-Adjusted Life Years – QALYs and Health Adjusted Life Years – HAEYs).

These 100,000 years are active and healthy years that patients spend outside the hospital during their treatment processes, contributing to their families, their surroundings and, most importantly, the economy.

The critical point here is the concept of Productivity-Adjusted Life Year (HAEY). A woman who overcomes breast cancer:

1. Can Return to Work: She continues to contribute actively to the economy, and productivity loss is prevented.
2. Maintains Her Social Role: Instead of becoming dependent on others, she continues to maintain her social roles that form the roots of her family and society; she continues to provide benefit in indispensable roles such as motherhood, parenthood, sisterhood and being an aunt.

This means that Survival, Quality of Life and Productivity are an inseparable whole. The investment we make is not only about treating a disease, but about creating an economic and social cycle that strengthens society from its very foundation.

Distinguished guests, the final and most important output of the innovation in Awareness and Diagnosis, the practical solutions in Treatment Management, and the productivity we add to the lives of our women is shown on this slide.

We can clearly see what our Social Value-Oriented Approach means for a Sustainable Future.

We examine the economic impact created by the 3,859 metastasis cases we prevented through the iceberg analogy. This is not only about avoiding healthcare expenditures, but also about actively contributing to the economy.

In total, we create a massive Economic Impact of 32.5 Billion TL:

1. Healthcare System Cost Savings (25.4 Billion TL): This is a major saving achieved from the high costs of advanced-stage cancer treatment, unnecessary hospital visits and bed occupancy rates. Think of Istanbul traffic and the intensity in hospitals; this figure means the easing of a major burden on the system.
2. Non-Medical Cost Savings (4.2 Billion TL): This saving is the recovery of the time and resources spent by patients and their caregivers.
3. Income Continuity (2.1 Billion TL): This is the income continuity provided by women who return to working life after overcoming breast cancer. When our women can return to the system, their contribution to the national economy increases rapidly.
4. Tax Contribution (750 Million TL): This is the additional tax contribution provided to the state together with increased productivity.



This 32.5 Billion TL is not only a saving; it is a resource that can be reinvested in Türkiye's future. This saving can be directed to highly valuable areas, such as supporting 50,000 women entrepreneurs or providing scholarships to 250,000 female students.

My Closing Message will be very clear and direct:

Türkiye is on its way to becoming a rapidly ageing population. In the next 10 years, people's dependence on others will increase. Therefore, by contributing to health today, we reduce dependence and strengthen the most productive and most resilient segment of society: our women.

Let us not forget: Contributing to health means contributing to the value of the nation.

Moderator: Mr. Farid, speaking of women, as a friend of yours who recently lost his mother, I applaud the women in this room.

Because one in every 5 women, 22%, used to present with stage 4 and stage 5 cancer in Türkiye. In breast cancer, thanks to these screenings and programs in Türkiye, currently one in every 200 women presents with breast cancer at level 4-5, at the final-stage level. We have shown in a very short time how effective preventive approaches to cancer are in Türkiye. I would also like to thank my colleagues, who are the representatives of this effort, in their absence. I thank both the sector and my teammates working at the Ministry of Health and in the healthcare sector. Let us also remember them here.

SUSTAINABLE GROWTH PERSPECTIVE IN THE DOMESTIC BIOTECHNOLOGY ECOSYSTEM

Dr. Hasan Ersin ZEYTİN

General Manager, Yerlika Biopharma

I have been working in the biotechnological medicines sector for 31 years. Approximately 10 years of this period were spent in the United States; my doctoral and postdoctoral studies focused on cancer immunotherapy and gene therapy. Many of the products we were working on at that time have now gradually begun to enter the market.

I have been in Türkiye for 23 years, and throughout this period I have continued to work in the field of biotechnology. Thanks to the opportunities provided to me by my previous company, I had the chance to contribute to many important initiatives. In 2007, we conducted a Phase 2 study with a biotechnological product and established the largest pharmaceutical production facility in the field of biotechnology. We developed a vaccine for COVID and brought it up to Phase 2. In short, we have had many different experiences in this field.

For the last two and a half years, I have been working at Yerlika. Yerlika is a company established in Türkiye in 2016 and supported by foreign investors. They have approximately 30 biosimilar products sold in their own countries and in other markets where they operate. When I received the offer, I said, "I



have one condition for coming to your factory in Türkiye: Will you carry out technology transfer, or is there no need for me to come?” Because I strongly believe in the importance of production. Thankfully, they stood behind the promise they made. Over the last two and a half years, through technology transfers that had not previously been carried out in Türkiye, we have started to produce our products domestically.

Sağlığa olan tutkumuz,
hayallerini ötesinde...

TÜSAP-43
İlaç ve Eczacılık Vizyon
Toplantısı

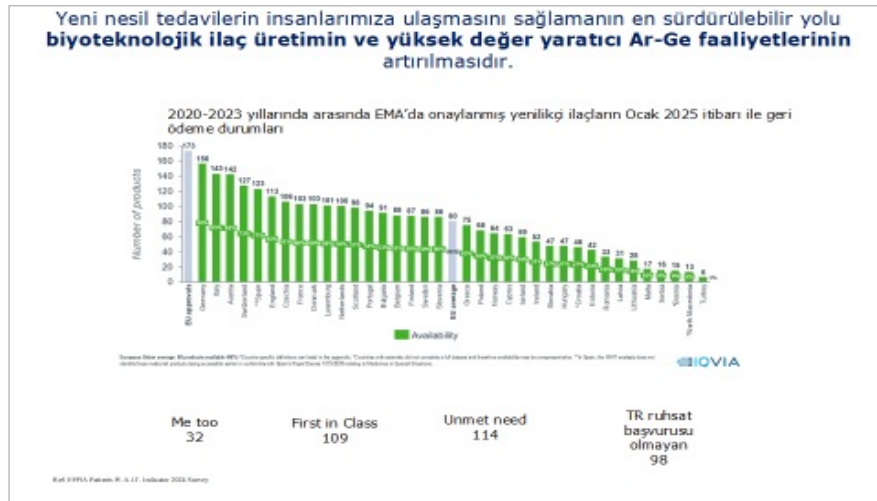
1 Kasım 2025

Biyoteknoloji, ilaç ve yeni nesil
tedavilerde Güncel ve Stratejik
Konular Zirvesi

Dr. Hasan Zeytin







I have been using this slide for approximately 7–8 years. I do not want to talk about access; my main purpose is to understand the modalities of these 173 innovative medicines. I look at this and proceed based on this data to understand what kind of products these medicines are and where we should be heading.

I truly believe this: If you do not manufacture, if you do not invest in R&D, you will always have difficulty in accessing innovative medicines. Bring as many clinical studies to Türkiye as you wish; unless production is carried out here, ultimately you will have to buy from abroad. This leads to a major foreign trade deficit.

As a habit coming from my scientific background, I examined these molecules one by one — Mr. Ümit and his colleagues must have looked at them as well, perhaps others too. The picture that emerges is as follows:

- 32 of them are what we call “me-too” medicines; in other words, medicines similar to products that were already on the market and patented.

- The point I would like to emphasize here is this: I am not presenting this data for the access discussion; my aim is to see the modalities, that is, the types of these products and where we need to head. However, another interesting and noteworthy piece of data is this: The list includes 98 products for which no marketing authorization application has been submitted in Türkiye. In other words, the fact that the company does not submit a marketing authorization application in Türkiye is also one dimension of the access problem.

Yenilikçi ilaçlar olarak nitelendirilen ilaçların % 40 biyoteknolojik yöntemlerle üretilmektedir.

Ana model/ler (Sayı)

Kategori	Sayı
Kimyasal	200
Biyoteknik	100
Biyoteknik	10

Biyoteknolojik ilaç modelleri (sayı)

Yöntem	Sayı
Antikorlar (Antibodies)	5
Genetik	5
Enzim	15
Monoklonal antikorlar	20
Farmak	5
Farmak (Farmak)	5
Genetik	5
Kültür (Kültür)	1
Farmakolojik Biyoteknoloji	1

Monoklonal antikorların pazar hakimiyetleri önümüzdeki yıllarda devam edecektir.

Yerlika
Biyoteknoloji

Kat: 2024, Patente, R. 3.12. Endüstriyel 2024, Nanyang

Monoklonal antikorlar sadece onkoloji ürünler değildir, geliştirmekte olan ürünler içinde de en fazla çalışılan moleküllerdir.

Category	Description	Subclasses	Number of positive products by phase
Antineoplastic	Anti-proliferation of antibodies that recognize specific targets	Anti-CD	2,479
		Anti-EGFR	155
		Anti-HER2	121
Protein and protein	Protein or its derivatives are used to increase or decrease existing biological processes in a cell or tissue system	Recombinant	1,393
		Cell therapies	1,103
Cell therapies	Manipulation of immune cell function and regeneration to achieve existing diseases	CD47-anti	493
		CD20-anti	343
		TCR	181
		CD45-anti	19
		T cell	15
Gene therapies	Introduction or modification of DNA integrated into cells	Gene augmentation	108
		Gene editing	17
Nucleic acids	Agent of gene therapy, gene editing or RNAi	CRISPR-Cas9 therapies	143
		siRNA	127
		mRNA	129
		Antisense oligonucleotides	89
Other non-oncological	Protein or its derivatives are used to increase or decrease existing biological processes in a cell or tissue system	Recombinant	17
		Antisense	11

Legend: Phase I (Green), Phase II (Blue), Phase III (Purple)

Source: Evaluate Pharma, Q3 2023

Note: ADC = antibody-drug conjugates, siRNA = small interfering RNA, CAR-T = chimeric antigen receptor-transduced natural killer cell, CD47 = cluster of differentiation 47, mAb = monoclonal antibody, PROTAC = proteasome-targeting molecule, TCR = T-cell receptor therapy, TIL = tumor-infiltrating lymphocyte.

Trends in Biotechnology and Import Dependency

I am talking about the field of biotechnology. In this context, we need to look at the subgroups and submodalities of innovative medicines. When you examine them, you see the following: monoclonal antibodies constitute the majority of this group. When you look at the product portfolios currently under development by companies, you also see that monoclonal antibodies will maintain this dominance in the coming years.

We talk about gene therapy, we talk about ADCs; however, from the perspective of production, it is seen that the products that will be used most in the coming period will again be monoclonal antibodies. When you look at the medicines whose clinical and preclinical studies are ongoing, and those that have been approved, the same picture appears. In biotechnological medicines, we see that many companies are working most intensively on monoclonal antibodies.

Therefore, the direction of the market is evolving toward this area. If Türkiye is to take a strategic step, we believe that we need to focus on this field.



When we look at the Turkish market, we see that as of 2024, total spending on biotechnological medicines has reached the level of 2.4 to 2.5 billion dollars. There are currently 158 biotechnological molecules in Türkiye. According to IMS data, these 158 molecules are registered among medicine groups.

By comparison, there are approximately 4,500 molecules among chemical medicines, and their total value can also be seen in the table. Therefore, we can say that biotechnological medicines are both increasing numerically and forming a market that is gradually growing in terms of value.



Do we see this? Over the past five years, cumulatively, we have spent a total of 10 billion dollars on these products. If this development continues in the same way, by 2030 we will be talking about a budget of approximately 18 billion dollars.

However, there is an important point here: 99.9% of these products come from abroad. Therefore, we need to ask ourselves the following question: Do we have such a budget? I know that Türkiye is a large and strong country, but this burden in pharmaceutical expenditures is gradually increasing. We need to focus on how we can prevent this burden and how we can reduce it.



Here, we also need to ask the following question: Alright, we import these medicines, but where do we import them from? When we look at the data, we see that approximately 60% of these products come from European Union countries, whose regulations we are required to comply with. In other words, this money actually goes directly to Europe.

We continue to implement their regulations, and within this framework, we continue to purchase medicines from the same countries. We need to look at this situation carefully, because it is a very critical point. If no change is made here, the process will continue in the same way, and 18 billion dollars will again flow abroad in this manner.



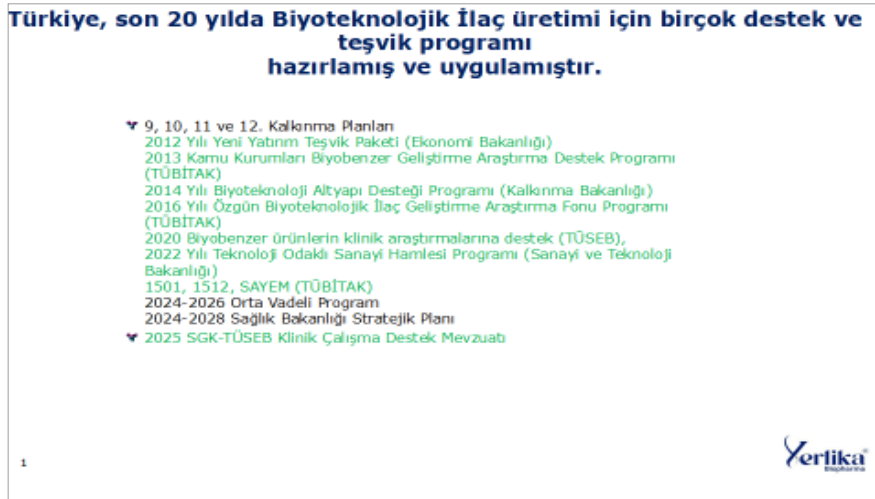
Production Capacity and the Ineffectiveness of Incentives

We need to talk about production, because as I stated earlier, I come from a manufacturing company and I truly believe in the contribution of production to health. I attach great importance to the added value provided by production.

This visual shows biotechnological drug production capacity in the world in liters. As of last year, global production capacity reached 15.6 million liters. In other words, all countries around the world are making serious investments for the production of biotechnological drugs — I underline this, they are making investments for production to take place.

When we look at Türkiye's situation, we only have a facility capacity of 10 thousand liters. If we do not make a fundamental change here, if we do not take new strategic decisions, we will face serious difficulties in this area. My dear General Manager, otherwise we will have to pay much more money for the import of biotechnological drugs.

Moderator: He has already submitted it to the Ministry of Treasury and Finance. There is nothing to be done. He says the Ministry of Treasury and Finance should think about it.



In fact, we are aware of this situation; for years, even for more than 20 years, we have been acting with this awareness. When you look at all the development plans and the incentives provided, you can clearly see this. In addition to the incentives provided by the Ministry of Health, the Ministry of Industry and the Ministry of Economy, including the most recent incentive provided by the SGK in 2025 for the reference product in clinical trials, numerous support programs have been implemented in Türkiye for this field.

To speak frankly, I really do not know whether there is another country with such a comprehensive incentive system. It is discussed a great deal, but Türkiye has taken serious steps in this regard; these incentives should also be given their due credit. Companies have benefited from them.

Ülkemiz biyoteknolojik ilaç üretim tesisleri olan ama biyoteknolojik ilaç üretmeyip ithal eden çok zengin bir ülkedir.

Güncel durum						
Şirket	Yatırım Başlangıç Tarihi	Kapasite (Litre)	Ticari Seri Üretim (yıl)	Tür / Üretim Sistemi (Expression system)	Proses Validasyon Üretim	Rekabetlendirme için Üretim
Yerlika Biopharma	2017	500	20	Memel		
Yerlika Biopharma	2014	2000	40	Memel		
Yerlika Biopharma	2014	600	20	Memel		
Yerlika Biopharma	2014	800	20	Memel		
Yerlika Biopharma	2017	4700	40	Memel		
Yerlika Biopharma	2018	200	20	Memel		
Yerlika Biopharma	2014	1500	20	Memel		
Arven	2007	50	40	Bakteriyel		
Arven	2014	50	40	Bakteriyel		
Arven	2014	4000	40	Bakteriyel		
MediKye	2010	50	20	Memel		
IBO	2017	50	20	Memel		
SUMUM	2018	50	20	Memel		
		14250	360			

Eğer bütün tesisler full kapasite çalışırsa ülkemizde yaklaşık 360 seri ticari üretim yapılabilir.

Türkiye'de son 7 yılda hiçbir yatırım yapılmamıştır.
En son yapılan yatırım 2017-2018 yılında başlatılmıştır.

1
Belli Kapasite Bilgisi

Yerlika
Biopharma

Biotechnological Medicine Production: Capacity and Taught Helplessness

The table you see shows the status of companies investing in the production of biotechnological medicine raw materials in Türkiye. Without naming the companies, I would like to touch upon a few critical points:

1. Capacity: Compared with figures such as the 10 thousand liters I mentioned in my previous speech, the capacities of these facilities and
2. Commercial Production Series: When this existing capacity, established through incentives, operates at full capacity, according to my calculations, approximately 360 commercial production series can be carried out annually in our country. This may mean 360 series of a single product or one series of 360 different products. Every scenario needs to be evaluated, but this potential exists.

However, despite this existing capacity, I would like to draw attention to the table: For the last seven years, there has been zero investment in biotechnological medicines in Türkiye. No one is investing.

Moderator: I would like to hear the reason for this situation.

The expression “learned helplessness,” used by a bureaucrat when describing this situation, had caught my attention. I call this “taught helplessness.”

Moderator: What should we do?

Are the existing facilities operating? Arven, one of the well-known companies engaged in commercial production, was operating. As our own company (Yerlika Biopharma), we submitted a marketing authorization application this year with our own production. However, when we look at the general picture, this is the status of biotechnological medicine production in Türkiye. As you can see in the table, mammalian cell-based facilities exist, and these facilities are capable of production.

**2024 yılında ülkemizde en fazla satışı olan 25 molekül'ün 23'ü
ülkemizde üretilebilir.**

Molekül	Kuru	USD	USD KUTU	TR'de tecrübeli kuvvet	Patent Durumu
AMUNOGLUTININ BAGE	580.000	\$178.927.255	\$545	Var	Yok
NEFOLINAM	432.502	\$172.131.952	\$120	Var	Yok
PROBESOLINAM	73.943	\$69.257.227	\$1.340	Var	Yok
CHARTOLINAM	120.932	\$71.492.510	\$908	Var	Yok
ADAMOLINAM	590.026	\$61.514.155	\$124	Var	Yok
AMUNO OLAPONE	6.280.993	\$57.894.123	\$14	Var	Yok
POLYTRONIN ALFA	594.025	\$55.725.113	\$111	Var	Yok
AMULOCINAM	82.005	\$51.002.415	\$458	Var	Yok
ALBAMIN	190.648	\$50.830.354	\$87	Var	Yok
OLAPOLINAM	837.153	\$49.414.530	\$81	Var	Yok
CHARTOLINAM	17.348	\$47.898.235	\$1.705	Var	Yok
AMULOCINAM	381.851	\$38.490.955	\$112	Var	Yok
AMUNO HUMAN PARILLOMULUS TYPE (S)	470.499	\$37.127.415	\$78	Var	Yok
AMULOCINAM	699.709	\$35.949.595	\$85	Var	Yok
AMUNO AGPAT	3.044.259	\$35.202.710	\$9	Var	Yok
AMULOCINAM	182.188	\$35.547.890	\$105	Var	Yok
AMULOCINAM	490.982	\$33.725.151	\$72	Var	Yok
AMULOCINAM	340.752	\$33.200.990	\$85	Var	Yok
AMULOCINAM	279.504	\$32.799.452	\$115	Var	Yok
AMULOCINAM ALFA	277.555	\$31.991.930	\$114	Var	Yok
AMULOCINAM	483.691	\$28.206.910	\$58	Var	Yok
AMULOCINAM	595.438	\$28.550.229	\$45	Var	Yok
AMULOCINAM	214.225	\$25.991.939	\$124	Var	Yok
AMULOCINAM (AMULOCINAM)	32.005	\$25.495.714	\$794	Var	Yok
AMULOCINAM	300.618	\$24.421.906	\$77	Var	Yok

1



The 25 products sold in Türkiye in 2024. I ask which of these can be produced by these facilities? One of two issues is: Does the facility have the infrastructure to produce this? The second is whether these products have patents. If they have patents, you cannot produce them anyway. Türkiye is currently in a position to produce 23 of the 25 best-selling biological products. It has the facility, and there is no patent. We need to look at the issue in this way. We need to look at how we can use the existing facilities.

In this table, you see the 25 biological products with the highest sales in Türkiye in 2024. We analyzed whether these products can be produced in our existing facilities based on two main criteria:

- 1. Technical Infrastructure:** Does the facility have the infrastructure to produce this molecule?
- 2. Patent Status:** Are the patents of these products still in force? (Products with ongoing patents cannot legally be produced.)

As a result of this analysis, it is seen that Türkiye is currently in a position to produce 23 of the 25 best-selling biological products.

Criterion	Status	Explanation
Facility Adequacy	Available	Existing facilities can technical-ly carry out production.
Patent Status	Not Present in Most	The patents of the vast majority of the products have expired.

Therefore, we need to look at the situation as follows: there are facilities in Türkiye, and there is no patent (in other words, the patent barrier has been removed). What we need to focus on is the question of how we can actively use these existing facilities.



Türkiye'nin Önde Gelen Biyüretim Merkezi

- 1 — 2016
Kuruluş
- 2 — 2019
Üretim tesisi açılışı
- 3 — Çerkezköy
Çerkezköy OSB
- 4 — Biyoteknolojik İlaç GMP Sertifikası
? Biyoteknolojik İlaç Üretimi İmni



Yerlika Biopharma, ekipman ve insan altyapısı ile aktif olarak çalışan ve sadece biyoteknolojik ilaç üretimi yapan yerli bir şirkettir.

• Nitelikli İş Gücü:

- 80 tam zamanlı çalışan
- %70'i 5 yıldan fazla mesleki tecrübeli
- %17'si M.Sc. ve PhD diplomalı

• Üretim Altyapısı ve Kalite Standartları:

- Monoklonal Antikor, Protein, Viral Bazlı Gen Tedavisi, Peptid, Aşı Üretimi yapabilecek alt yapı
- Hücreden itibaren doluma kadar üretim yapabilecek cGMP onaylı 1.750 m² temiz oda
- Bütün üretim hattı için EU GMP onayı için başvurusu

• CDMO ve Proses Geliştirme Uzmanlığı:

• Biyolojik ürünlerin ölçek büyütme ve rutin üretimi için üretim, kalite, regülasyon ve müşteri hizmetleri sunabilen.



1

Yerlika Biopharma: Türkiye's Leading Biomanufacturing Center

I would like to provide brief information about our own company, Yerlika Biopharma. We are a domestic company that operates actively with its equipment and human infrastructure and produces only biotechnological medicines.

Our campus is located in the Çerkezköy Organized Industrial Zone. Our company was established in 2016, and the production facility became operational in 2019. Our facility has GMP (Good Manufacturing Practices) certification, which is the international quality standard in biotechnological medicine production, and we carry out production in accordance with these standards.

Qualified Workforce and Production Infrastructure:

We are currently working at an intensive pace, day and night, with a team of 80 people. The qualified structure of our team is as follows:

- 70% hold Master's (M.Sc.) and Doctorate (Ph.D.) degrees.
- More than 70% have over 5 years of professional experience.

Our Production Infrastructure and Human Resources: Our production infrastructure has been established to cover all types of products that can be produced in mammalian cell systems. We have

the infrastructure and human resources to produce monoclonal antibodies, proteins, viral-based gene therapies, peptides and vaccines. I would especially like to state that we have the capacity to produce all types of biotechnological products in mammalian cell-based systems.

CDMO and Process Development Expertise: In addition, by undertaking an important role for the ecosystem, we are a company capable of offering CDMO (Contract Development and Manufacturing



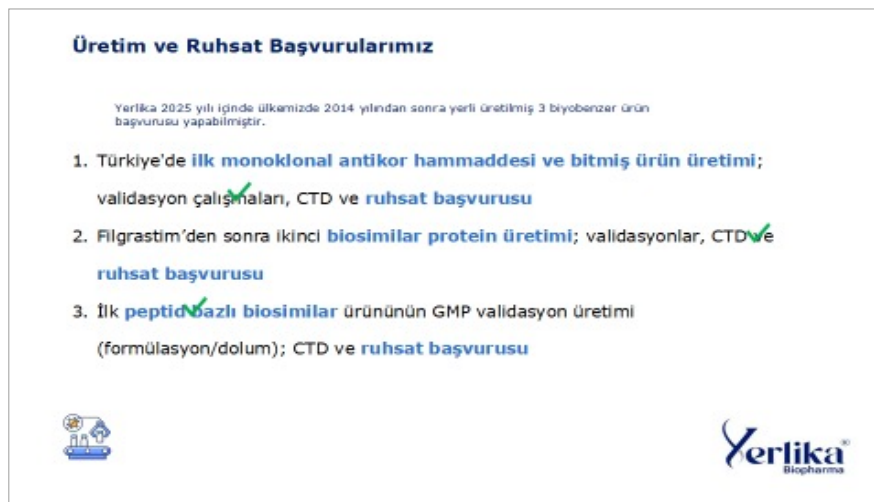
Organization) services to other universities and companies for biotechnological medicine production.

You can see the product modalities and our production capability, which I mentioned in the previous slide, in greater detail in this graph. The blue bars in the graph show the number of molecules approved in Türkiye in 2024.

As can be seen, as Yerlika Biopharma, we have the infrastructure and experience to produce most of the different types of biotechnological medicines:

- **Monoclonal Antibodies (Mab):** We are able to produce them.
- **Proteins:** We are able to produce them.
- **Vaccine:** If it is produced in mammalian cell systems, we are able to produce both the vaccine raw material and the finished product.
- **Insulin and Peptide:** We do not have the infrastructure to produce the raw material of these products. However, we are able to provide filling (finished product) services for such products.

In summary, this system, which is capable of producing most of the different types of biotechnological medicines, is a domestic company based in Çerkezköy that is currently active and providing services in Türkiye.



Our Production and Marketing Authorization Applications: Yerlika's Concrete Achievements

Over the last 2.5 years, as a company, we have achieved very important successes.

After Arven's biotechnological/biosimilar marketing authorization application in 2014, no other company submitted a marketing authorization application for a domestically produced biosimilar in Türkiye until 2025. In this context, as Yerlika Biopharma, we are proud to have achieved a first since 2014.

As Yerlika, in 2025, we will be able to submit applications for three domestically produced biosimilar products in our country for the first time since 2014.

1. Türkiye's First Monoclonal Antibody Raw Material and Finished Product Production: In our own facility, we carried out the entire production process, starting from the cell stage through to the finished product, prepared the marketing authorization dossier (CTD), and submitted our application.
2. Second Biosimilar Protein Production After Filgrastim: After Filgrastim, we produced the raw material of a second protein product in the biosimilar category, completed the validation studies, and submitted our marketing authorization application.
3. GMP Validation Production of the First Peptide-Based Biosimilar Product: For a peptide-based product, we completed filling/formulation production in our facility and process validations for products for which we cannot produce the peptide but can carry out filling, and submitted our marketing authorization application.

I consider these achievements to be a very important step on behalf of my company. These are studies carried out for the first time since 2014. Hopefully, in the coming years, other companies will also undertake similar initiatives. Cooperation is of vital importance for the ecosystem, and although we are a small company, we continue to work very hard and remain a part of the ecosystem.



Strategic Collaborations and Clinical Research Initiatives

Our company's recent strategic steps and achievements:

1. TÜSEB "Producing Health" Protocol: Yerlika Biopharma is the first pharmaceutical company to sign the "Producing Health" protocol launched by TÜSEB last year. Under this protocol, we pledged

to support medicine development studies in Türkiye in collaboration with TÜSEB. We hope to encourage other companies to participate in this initiative.

2. 2. First Phase 1 Clinical Study in a Biosimilar Product: For the first time in Türkiye, we are about to initiate a Phase 1 clinical study for a biosimilar product. We have received our TITCK approvals; following the completion of the import process for the reference product, we aim to start clinical studies before the end of this year. This will be the first clinical study to be conducted in Türkiye for a biosimilar product.
3. 3. Support for the Development of a Domestic Gene Therapy Molecule: There is an original gene therapy molecule against cancer that was discovered by one of our academics. For this molecule, which was brought to us after the basic science stage, we carried out process optimization and the production of process series at our facility in Çerkezköy. Preparations are currently underway for the product to proceed to preclinical and clinical studies, and preclinical studies will begin in the coming days.
4. 4. CDMO Service for European Union Clinical Studies: We received a request from another business partner asking whether we could carry out production for them because they would be conducting clinical studies in Europe. We responded positively to this request and completed the production at the filling stage in our facility. The clinical studies of this product in the European Union are currently ongoing.

Türkiye'nin en fazla prosesi valide edilmiş hücre hattına sahibiz.

Molekül	Süreç	Üretim Yeri
Eptacog Alfa	Onaylı pazarda	İthal
YB-Mab 1	Ruhsat sürecinde	İthal
YB-Mab 2	Ruhsat sürecinde	İmal
YB-Mab 3	Ruhsat sürecinde	İthal
YB-Mab 4	Ruhsat sürecinde	İmal
YB-Protein 1	Ruhsat sürecinde	İmal
YB-Peptid 1	Ruhsat sürecinde	İmal
YB-Mab 5	AR-GE sürecinde	İmal
YB-Mab 6	Proses Geliştirme	İmal

VALIDE

Yerlika

Having the Highest Number of Process-Validated Cell Lines in Türkiye

Now I would like to give a concrete answer to the question “What can we do?” The cell line, which is the starting point of everything in biotechnology, is of great importance. We are currently the company with the highest number of process-validated cell lines in Türkiye.

In the table, you can see the list of our products for which marketing authorization studies are ongoing. For these products (YB-Mab 2, YB-Mab 4, YB-Protein 1, YB-Peptid 1, YB-Mab 5 and YB-Mab 6), marketing authorization applications have either been submitted or they are at the R&D/Process Development stage.

We are in a position to manufacture all of these products in our own facility (those marked as “Manufacturing” in the table). We are talking about domestic production. If our financial conditions improve in the coming period, we will rapidly continue the domestic production of these products.

Türkiye'nin biyoteknolojik ilaçta dış ticaret açığını azaltması, var olan biyoteknolojik ilaç üretim kapasitesinin en az %50'sinin ticari ölçekte faaliyete geçirilmesi ile sağlanabilir.

Boyle bir hedef ancak yeni finansal mekanizmalar ile desteklenen, başka ülkelerde üretilmiş ve valide ürünlerin var olan tesislerimize teknoloji transferi ile mümkün olabilir.



Conclusion and Strategic Recommendation: Reducing the Foreign Trade Deficit

As for the answer to the question “What can we do?”:

Türkiye's reduction of its foreign trade deficit in biotechnological medicines can be achieved by putting at least 50% of the existing biotechnological medicine production capacity into operation on a commercial scale.

The most important step Türkiye must take to achieve this target is the following: ensuring that existing facilities begin commercial-scale production through technology transfer as soon as possible. Our facilities exist, and we have technical competence. What we need is to accelerate technology transfer processes for the active use of these facilities.

The answer to the question of how this process can be implemented is as follows:

1. New Financial Mechanisms: Certain new financial supports are required in order to achieve this target.
2. Technology Transfer: Products that have been produced and validated in other countries should be brought to our existing facilities through technology transfer.

This approach will both reduce the foreign trade deficit by increasing domestic production and bring the existing idle capacity into the economy.

Doğru finansman ve teknoloji transferiyle Türkiye, 5 yılda bölgesinde biyoteknolojik ilaçta oyun değiştirici olabilir.

Neden Teknoloji Transferi Öncelikli Olmalı:

- Üretim tesisleri mevcut ama finans ve bilgi eksikliği nedeniyle aktif kapasite var.
- Teknoloji transferi olmadan yerli molekül geliştirmek yıllar alıyor.

Finansman Gereksinimi:

• Ortalama teknoloji transfer maliyeti (klinik çalışmalar dahil) : 3-5 M USD / molekül

Finansman Modelleri:

1. Devletin Teknoloji transferini Ar-Ge Destek programlarına alması
2. Devlet Destekli Yatırım/Geliştirme Kredileri:
 1. Teknoloji transferini pahalı ve riskli gören firmalara uygun finansman sağlanması.
3. “Türkiye Biyoteknoloji Girişim Grubu” (TOGG Benzeri Model):
 1. Sanayi liderlerinin oluşturacağı konsorsiyum
 2. Devletin finansal yükümlülük azaltması
 3. Mevcut tesislerden üretim hizmetleri alır
 4. Vizyonu yalnızca biyoteknolojik ilaç üretmek olur



Strategic Transformation and TOGG-like Model Proposal

Here, I would like to move on to the explanations that will realize the vision that “Türkiye can become a game changer in biotechnological medicines in its region within 5 years.”

1. Why Should Technology Transfer Be Prioritized?

I am not saying that we should give up on R&D studies, but we already have established facilities. Technology transfer is a much faster and easier system compared with product development. Through technology transfer, we can move products to commercial scale as soon as possible. Considering that production facilities exist but have idle capacity due to a lack of licensing and know-how, this is a necessity.

2. Financing Requirement and Models

Technology transfer requires serious financing. The average technology transfer cost, including clinical studies, is around 3–5 million US Dollars per molecule.

In the current situation, the Ministry of Industry and Technology supports only R&D studies, not technology transfer processes. We believe that this situation needs to change rapidly.

The financing models we propose are as follows:

- State Support: The state should include technology transfers in R&D support programs.
- Special Loans: State-supported investment/development loans can be provided for companies that see technology transfer as expensive and risky. This will prevent financing difficulties.

3. Türkiye Biotechnology Initiative Group (TOGG-like Model)

Perhaps it may seem like a dream, but a TOGG-like system also needs to be established in the field of biotechnology. In Türkiye, as a priority, a consortium should be formed by bringing together industrial leaders who know this business and want to invest.

This consortium should activate the existing idle facilities as soon as possible by saying, “I will use these facilities for these products, and these will be my products.”

Ruhsat Streci:
Üretimden pazara hızlı geçişi kolaylaştıracak yeni bir bilimsel kurul, yerli biyoteknolojinin
önünü açacak en kritik katalizator olabilir.

Biyoteknolojik ürünlerde ruhsat onay süreci daha kısa ve basit yapılabilir.

Çözüm: Yeni Bilimsel Komisyon Kurulmalı:

- Sadece yerli üretilen biyoteknolojik ürünler için özel komisyon
- Sadece yerli ürünlerin hızla pazara sunulmasını hedeflemek
- Bilim insanları ve TITCK ürün geliştirme sürecine baştan dahil olur.

Beklenen Etki:

- Ruhsat süreci %40'a kadar kısalabilir
- Üretim → Ruhsat → Pazar zinciri hızlanır
- Yerli biyotek ürünlerin ihracata hızlanır





Marketing Authorization Process and Accelerating Domestic Biotechnology

The marketing authorization process is a critical issue for our sector. It is essential to establish a new scientific commission that will make the marketing authorization approval process for biotechnological products shorter and simpler.

Proposed Solution: Establishment of a New Scientific Commission

This commission should focus only on marketing authorization studies for domestically produced biotechnological products. The main objective of such a structure should be to ensure that domestically produced products are rapidly introduced to the market. In addition, scientists and TİTCK (Turkish Medicines and Medical Devices Agency) should be involved in the development process of these products from the very beginning.

Expected Impact:

- The marketing authorization period may be shortened by up to 60%.
- The chain from production to marketing authorization, and from there to market access, will be accelerated.
- The export of domestic biotechnological products will become easier.

Closing Message

For me, today has the nature of a final word. As a company, our main objective is to become a Turkish biotechnology company carrying out commercial production by using 100% of its capacity by 2028.

Moderator: *Perhaps it would not be an early announcement to say this: as the Ministry, we have developed a new policy proposal regarding biosimilar medicines, and we have also discussed this issue with the Ministry of Treasury and Finance.*

A move that will give the sector breathing room and that everyone views positively is coming soon. You will see it when the policy becomes clear and all the details emerge. Particularly regarding biosimilar medicines, steps will be taken that will increase the confidence of both foreign investors and domestic investors.

I see here that everyone has a consensus on this issue. I can already say that a good opportunity will open up. I do not want to go into details; however, our approach is to implement a much stronger policy that primarily prioritizes domestic production. I can confirm that an approach will come that will eliminate the sector's concerns such as, "Can we recover our investment in this competitive environment?"

STRATEGIC ISSUES IN PHARMACEUTICALS AND NEXT-GENERATION THERAPIES

Derya KÖKER

General Manager, Alexion AstraZeneca Rare Diseases Türkiye



I have been working under the umbrella of Alexion for the last 10 years of my 30-year career. Alexion is a biotechnology company focused on rare diseases. I would like to briefly share the founding story of our company, as I believe it may be of interest to Prof. Dr. Rana Sanyal: just like Professor Rana's initiative, Alexion is also the product of a process in which a professor from Yale University worked on monoclonal antibodies for many years. Although the professor's first project failed before reaching the market, at the end of the day, I personally witnessed that scientific discovery transform into a company on a global scale.

We currently operate in more than 70 countries. In Türkiye, we have been active since 2010, that is, for 15 years. All of our medicines have been developed for rare diseases, and for each medicine, we first submit a marketing authorization application. We are often asked, "You have been here for 15 years and you have only one reimbursement; is this information correct?" Our answer is: Yes, it is correct. We currently have four medicines with marketing authorization. Three of these four medicines are life-saving treatments that would lead to fatal outcomes if patients did not receive them. Our fourth medicine is a product that provides significant public benefit compared with the existing therapy.

That said, I believe that the pharmaceutical sector has an important role in generating added value. In this context, I would like to share the support we provide:

- **Early Diagnosis Support:** We provide 2 million dollars in diagnostic support annually. We continue this investment every year in order to accelerate early diagnosis processes and support controlled distribution risk management. In the field of rare diseases, this figure is quite high.
- **Clinical Research:** In rare diseases, the success rate of a medicine is generally below 6%. Despite this, we are conducting 8 active clinical studies in 23 hospitals in Türkiye. This is a very good rate for our sector.
- **Early Access Programs:** To date, we have provided support worth 3 billion TL under humanitarian early access programs (EAP).

Recommendation for Reimbursement Processes

At this point, I would like to present a recommendation regarding the process after clinical research. As required by regulation, companies are obliged to provide those medicines to patients until the product enters the market. For example, we are currently providing free product supply to our country for one medicine after clinical research, and we have been doing so for 10 years.

My recommendation here is as follows: after clinical research is completed, I believe that a priority can be provided for these products in reimbursement processes, or at least a facilitation in reaching reimbursement negotiations. This would be encouraging both in terms of uninterrupted patient access and the recognition of companies' long-term contributions.



Economic and Social Burden of Rare Diseases

Here, I will touch upon a few figures on the screen, because I see rare diseases not only as a clinical diagnosis, but also as an important economic topic. This is particularly true for our country.

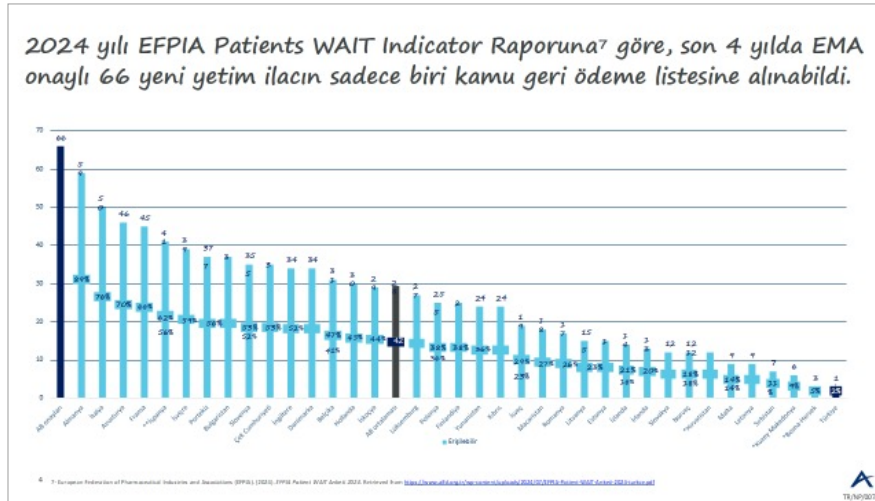
When we look at the prevalence and incidence of diseases, although the numbers may appear to be in the hundreds of thousands, as you can see here, they affect millions of people. This data is taken from the latest Ministry of Health study (approximately 5–6.4 million people in Türkiye live with rare diseases).

For reasons we know, especially factors such as consanguineous marriages, these patients have to consult many specialists for many years until they receive a diagnosis. The average time to diagnosis is 5 years, and the number of specialists visited during this period reaches 8.

Here, I see it as a responsibility to share the story of a mother I met through a patient association: The mother had said that since her child was born, “Every time I changed the diaper, the child cried and screamed...” The child was born with an enzyme deficiency and the bones were not developing properly. Sometimes even the rib cage bones did not develop, and the child lived with these pains. The mother said, “As a mother, I already felt that there was something seriously wrong with my child.” This family lived through these pains with their child for exactly 10 years, went from doctor to doctor, and at the end of 10 years, a pediatrician in our country made the diagnosis. Yet this was a disease that could have been diagnosed very easily with low ALP (alkaline phosphatase). I wish this low ALP would appear on screens in hospitals, just like emergency alerts. These patients truly struggle with very heavy burdens and difficult years.

For this reason, the economic burden of rare diseases is 6 times higher compared with common diseases.

I will not go into too many figures, but I would like to draw attention to an important point: When you look at the preventable cost during the period until a disease is diagnosed, you see that this figure can reach up to 500,000 dollars (the range of total preventable cost for a patient during the period until diagnosis is 86–517 thousand dollars). Unfortunately, these studies have not been conducted in our country; they are global data. However, we hope to see such local studies in our country as well.



Türkiye. That medicine also has an importance between life and death. I have great respect for the work done in this regard. However, I would also like to state clearly that we can do better things and use the resources we have more efficiently.

Nadir Hastalıklar Klinik Olduğu Kadar Ekonomik Bir Konu Başlığıdır

Sonuç-bazlı Finansman Modeli	Erken Tanı Kapasitesi
Erilim halinde, risk paylaşılır, etki kanıtlanır ve değer ortaya çıkar. • Önceliklendirme: Pediatrik hastalar ve yaşamı tehdit eden, alternatifsiz endikasyonlar 30-60 gün içinde koşullu onaya alınır. • Risk paylaşımı: Başlangıçta taban indirim ve sonuç-bazlı ödeme ile tedaviye başlanır. • Kanıt üretimi: 12 ay boyunca gerçek yaşam verisi toplanır; etkililiğe 3-5 yıllık anlaşılmaya geçilir, etkisizse firma geri öder. Kamu için anlamı, eşitlik ve toplum sağlığını artırırken bütçe öngörülebilirliğini güçlendirmektir. Endüstri için anlamı, klinik değeri kanıtlandıkça sürdürülebilir ve ölçeklenebilir bir geri ödeme zemini ile öngörülebilirlik ve yatırımın artırılmasıdır.	• Genetik test erişiminin yaygınlaştırılması ve sonuç sürelerinin kısaltılması, • Klinisyen ekranlarında otomatik "kırmızı bayrak" uyarıları ve karar destek algoritmaları, • e-Nabız entegrasyonu, • Ülke çapında yeni doğan tarama panellerinin genişletilmesi, • Multidisipliner referans merkez ağlarının kurulması için endüstri ile teknik, finansal ve operasyonel iş birliği yapılabilir.

5

TRANSİTE

Outcome-Based Financing Model Proposal

Indeed, the statement of our elder whose valuable views we shared, “When our money is scarce, our minds increase,” is also valid for this process. Acting with this principle, we have focused on developing a project within our own organization over the last year. We invite all stakeholders who would like to contribute to this project, which we are conducting in collaboration with the Rare Diseases Federation and Hacettepe University Health Economics and Policy Center.

As an output of this project, I would like to present an Outcome-Based Financing Model proposal here today. Our main objective is to share the risk with the public while accelerating access. As a company, we are ready to share this risk so that the effectiveness of the medicine can be seen concretely. Let us not forget that a price is assigned in return for a value. Where value is not concretely proven, it is natural to talk about a cost.

Moderator: We are also discussing this as TITCK. Because there are many medicines that we use but from which we do not obtain results.

We are ready to be a pilot. Because when you see the value of the patient, you cannot call a treatment applied to that patient “expensive.” However, of course, prioritization is required. If we are talking about strategy, as you all know, it is the art of being able to give something up. When you cannot give anything up, it is not possible to foresee a strategy.

This model is purely a proposal, only as an example:

1. Prioritization: Starting with prioritizations such as pediatric patients, life-threatening conditions or indications with no alternatives, conditional approval is obtained within 30–60 days.
2. Risk Sharing: Initially, a base discount may be applied. If there is a budgetary constraint for the year, an upper limit (cap) may be set, and if the budget is exceeded, it may be reimbursed.



3. Evidence Generation: Real-world data collected in Türkiye over 12 months is analyzed. If it is proven to be effective, the process moves to an agreement of at least 3–5 years, not a short-term one; if it is ineffective, the company makes reimbursement.

This model will increase investment predictability by creating a reimbursement basis that we can implement immediately today, that is beneficial for the public sector and industry, and that is sustainable and scalable as clinical value is proven. I believe that rare diseases are an economic topic rather than merely a budgetary constraint.

Moderator: *Of course, when your resources are limited, it is not easy to distribute everything fairly and use what is appropriate.*

Of course, we are ready for this as well. Prioritization is very important for us as much as it is for you. I would like to give the following message: As the industry, we are ready to cooperate here on every matter, financial and operational.

Moderator: *Assoc. Prof. Dr. Şuayıp BİRİNCİ*

I sincerely thank all participants for their valuable contributions. I observe that a shared vision and a constructive perspective have emerged in the panel. Personally, I must state that I have been enlightened by the information presented. I am very pleased that everyone has expressed what was on their minds with such transparency. Perhaps there are also shortcomings that have not yet been voiced; I would very much like to hear them as well.

The main purpose of organizing these platforms is to listen to possible problems and shortcomings, to see what we can do with public authority regarding these critical issues, and how we can further improve our ecosystem. We would like this constructive dialogue to continue in the coming period as well, because we greatly benefit from such feedback.

We also want the sector, independent of the duties we carry out, to see these platforms as a solution partner. Everyone is represented equally on the TUSAP Executive Board. Apart from the opening speech in the morning, I am here with my own personal experience and identity. If it is asked whether I make an assessment independent of my public duty; of course, being aware of our public responsibility, we may use a diplomatic language in our statements. However, our main purpose is to display a solution-oriented approach with our original identity, in the same mental environment as you. I once again thank everyone who contributed with this approach.

PANEL-2

FINANCIAL SUSTAINABILITY IN PHARMACEUTICALS

(Healthcare Budget, Pricing and Reimbursement)

MODERATOR:



Prof. Dr. Nurullah OKUMUŞ

Deputy Minister of Health, Ministry of Health

SPEAKERS:



**Assoc. Prof. Dr.
Eren USUL**

SGK - General Manager of
General Health Insurance



Dr. Ümit DERELİ

AIFD - Association
of Research-Based
Pharmaceutical
Companies
Secretary General



Dr. Sami TÜRKOĞLU

TİSD - Secretary
General of the Turkish
Pharmaceutical Industry
Association



Savaş MALKOÇ

İEİS - Secretary General
of the Pharmaceutical
Manufacturers Association
of Türkiye



Moderator: Prof. Dr. Nurullah OKUMUŞ
Deputy Minister of Health, Ministry of Health

When we speak of pharmaceuticals, our fundamental objective is, of course, human health. However, pharmaceuticals also transform into a commercial product in the course of the process. Until they become a product, there are long-term R&D activities, product development, production at the final stage, and ultimately the processes of supplying them to the market.

The supply side is of vital importance for the sector to remain standing. Because this process affects many stakeholders, from new product development and raw material supply to employment. On the supply side, there are two main purchasers:

- 1. State: It undertakes a large proportion of pharmaceutical purchases.*
- 2. Citizen: It comes into play especially in high-cost medicine groups described as catastrophic expenditure.*

Considering current economic conditions, market conditions and the global competitive environment, we never want the sector to face financial constraints. On the contrary, we aim to provide more financial support and resources. However, the justifications, reasons and criteria for this support must be clearly determined within the framework of the current economic picture.

In this panel, we will discuss how we will establish this delicate balance, how we will ensure financial sustainability, and how we will develop our policies along this axis.



THE CENTRAL ROLE IN FINANCIAL SUSTAINABILITY: THE BALANCE BETWEEN HEALTH AND ECONOMY

Assoc. Prof. Dr. Eren USUL

SGK - General Manager of General Health Insurance

The issue of reimbursement in healthcare is one of the most important and fundamental problem areas not only for us, but for all countries and on a global scale.

As General Health Insurance (GSS), we are in the most challenging position within this task. On one side, there are the demands of Health Services and the medical community, while on the other side of our table, there are the macroeconomic balances and constraints of our Ministry of Treasury and Finance. We are in a position that remains between these two justified sides and is responsible for ensuring this coordination. We perhaps define this as the most difficult task.

Because every stakeholder is right when viewed from their own perspective. Health authorities, the medical community, pharmacists and manufacturers; each presents undeniable justifications when viewed from their own standpoint. Scientific facts and reports express issues such as “how much can be saved by avoiding complications” or “what can be gained through early diagnosis steps” in an extremely clear and strong manner. There is a concrete reality on this side.

However, when we turn our direction to the other side, namely cost management and the macroeconomic picture, the Ministry of Treasury and Finance also has its own macro realities and figures. When we listen to their constraints, we do not find it difficult to agree with them either.

Therefore, remaining between the medical sector/health sciences and economic and financial management is an extremely challenging task. Both fields are highly assertive and are two separate disciplines that are certain of their own truths. Our fundamental effort is to bring these two disciplines together at a common point and to try to provide what is needed, within economic measures, in an equitable manner.

Quality of Reimbursement and the Importance of Data Infrastructure

This point is quite critical for the sustainability of the system. Apart from fundamental problems such as exchange rates, pharmaceutical pricing and current reimbursement restrictions; even if we had a great deal of money, regardless of the resources we allocate, the most important area would still be the high-quality execution of reimbursement processes.

Even if the share of Gross National Product (GNP) spent on pharmaceuticals today were 4%, 5% or more, as in high-spending countries such as Germany, we would still have to discuss a high-quality reimbursement system. Unless we establish the infrastructure of a high-quality reimbursement system, solving the other main problems will become more difficult. Therefore, I believe that we should primarily focus on this area.



The Problem of Use, Monitoring and Evaluation

The first and most important criterion of a high-quality reimbursement system is the proper follow-up of the use, monitoring and evaluation stages.

Of course, we have massive and detailed data systems such as Medula and e-Nabız. However, the real question is this: “Do we have high-quality data?”

The difficulties we have recently experienced in the reimbursement processes of medicines such as immunotherapies clearly reveal this situation. We know the general number of lung cancer patients in the system. However, when we go down to sub-breakdowns, such as non-small cell and squamous subtypes, we cannot access detailed data.

As long as we cannot access these sub-breakdown data, we have difficulty taking steps and adopting an economic approach regarding innovative medicines developed for those subtypes.

Therefore, whether we call it value-based, outcome-oriented or a higher-quality reimbursement system, in order for this system to be established, we must first have command of these detailed data and ensure monitoring and evaluation of the process from beginning to end. This is one of the fundamental issues we need to solve.

Objectivity in Reimbursement Decisions and the Professionalization of the System

When we present an objective justification to our Ministry of Treasury and Finance in reimbursement systems, their approach to this issue is not negative.

As concrete evidence of this: Over the last year, the cost to GSS of the medicines we included in reimbursement, despite not being in the budget, is approximately 30 billion TL. When these figures are presented to our Ministry of Treasury and Finance together with the data, it is seen that they are not distant from the issue. The most critical part here is to identify the need correctly and present it with concrete data.

Transformation of the Decision-Making Process

We are trying to assume this objective identification role more and are carrying out our work in this direction. The evaluation and needs assessment in reimbursement processes must take on a more professional and institutional structure.

Unfortunately, in the current situation, our decision-making processes proceed from the upper level to the lower level, based on the personal knowledge, expertise and experience of our General Managers, Presidents and Deputy Ministers.

However, what should happen is that policies should be determined from the bottom and flow upward. Our R&D units and institutes at the lower level need to become somewhat more active, work more effectively, and reach a position where they can produce policy for senior management.

With this perspective, we are trying to reshape the reimbursement system in a way that allows the evaluations and studies carried out at the lower level to flow upward. This is the most important transformation we desire.

Common Mind, Dynamism and Improvement Targets

When creating reimbursement policies, we try to build a common mind together with all our stakeholders. We closely follow international developments and indices such as the “Wait Index” mentioned in the previous panel.

Together with all our public stakeholders such as the Ministry of Health, including TİTCK, the Ministry of Treasury and Finance, and the Presidency of Strategy and Budget, we follow these developments and try to create policies accordingly.



Analysis of Pharmaceutical Access Figures

In our analyses regarding the criticisms on pharmaceutical access, when we look at cross-sectional periods, for example the 2019–2020 period, the root causes of the barriers to access vary:

- Of a total of 167 medicines, 120 not receiving marketing authorization is due to other reasons.
- 93 of them never received marketing authorization.
- 20 of them received marketing authorization but never applied for reimbursement.
- Of the remaining 47 medicines, 18 were included in reimbursement, 9 resulted negatively, and the process for the remaining 18 is ongoing.

The root causes of these figures are also being analyzed meticulously.

Overseas Treatments and Monitoring of Domestic Production Capacity

We also closely monitor overseas treatments. Which patient went for proton therapy, which one went for CAR-T cell therapy; not only the treatment cost, but all expenses including the patient's journey, such as flight tickets and similar costs, are seen figure by figure together with our Minister.

In addition, as stated in the previous panel, work is also being carried out on how much we pay for which biotechnological medicines, which domestic manufacturer can produce which molecule, and which company with capacity can produce which molecule. There are plans and programs regarding these; while some are declared, some are strategically left to time.

Vision

The reimbursement process is a very active and dynamic process, and we are trying to keep pace with it. The root causes and solution proposals are clear and are continuously expressed by the sector as well.

However, our greatest objective is to maintain and further advance the quality healthcare service provided in our reimbursement processes, without losing this dynamism and without allowing it to fall even one step back. As all public stakeholders, our concentration in this direction is complete. We have no doubt that we will emerge from this situation stronger and move to better points. We are in a better position compared with the previous year, and together with all our stakeholders, we foresee that we will be in an even better position next year.

Financial Burden of High-Value Treatments and the Role of SGK

Moderator: *Our General Manager, Assoc. Prof. Dr. Eren USUL, provides us with very significant support on this issue. He has undertaken the part of this field that carries the heaviest and most difficult workload.*

Because on one side, as the Ministry of Health, we say, "We need these and those treatments; we must provide them to our citizens," while on the other side, the sector places significant pressure on him regarding the inclusion of these treatments in reimbursement based on their financial dimension.

Our fundamental duty is to manage this process at the most optimal level and, by taking the health of our citizens as the basis, to ensure that these vital medicines are made available to citizens by evaluating the economic means and financial strength we have.

Today, a significant transformation has taken place in the pharmaceutical market:

- From a level that was previously high in terms of boxes but lower in terms of value;
- We have now entered a cross-relationship that is low in terms of boxes but very high in terms of value.

When we consider the financial burden created in the field particularly by biotechnological medicines and gene-based therapies, the importance of this panel becomes clear once again.

FINANCIAL SUSTAINABILITY CRISES IN HEALTHCARE AND PHARMACEUTICALS

Dr. Ümit DERELİ

*AİFD - Association of Research-Based Pharmaceutical Companies
Secretary General*



I. Resource Problem in Healthcare Expenditures: The Reality of 4%

Although the title of this session is actually “Financial Sustainability in Pharmaceuticals,” this is a subheading. Its main heading should be “Financial Sustainability in Healthcare.” Because if we cannot ensure financial sustainability at the upper level, this will gradually have a negative impact on sustainability in pharmaceuticals and ultimately on the sustainability of healthcare services.

At this point, it is necessary to make a very important observation on which we must all agree: Türkiye allocates insufficient resources to healthcare as a whole.

- **OECD Average:** %9.8
- **Expenditure in Türkiye:** around 4%.

Türkiye’s Ministry of Treasury and Finance and the Presidency of Strategy and Budget need to become aware of this reality. It is not possible to sustain such a generous healthcare service provision forever while allocating such limited resources. If other OECD countries such as France, Germany and Switzerland were able to manage this, they would undoubtedly want to do so.

Nominal Comparison: While our national income per capita is around 15,000 dollars, France allocates 12% of its income of 50–55 thousand dollars to healthcare, and Germany allocates 11–12% to healthcare. We, on the other hand, allocate only 4% of 15,000 dollars. Mathematically, it is not possible to sustain this service. We must accept this reality and say, “There is a problem here, and we will work to improve it.”

II. It Is Painful to Talk About the Exchange Rate, Not the Price

While we could be discussing high value-added issues, biotechnology, next-generation therapies, how the sector can be developed, and how it can attract clinical research, it is very painful that, in the end, we keep coming back not even to the price, but to the exchange rate.

I have been the Secretary General of AİFD for more than 10 years. In Türkiye, we talk about the exchange rate: “What will the pharmaceutical conversion rate be?”

This situation sends very wrong messages abroad:

In official documents from the United States Department of Commerce, the term “Arbitrary” is used for the pricing mechanism in Türkiye. Although each time we cross this out and send it back as “sovereign pricing,” in the eyes of the United States, the pricing here is arbitrary.



Indeed, everyone here is waiting for a development regarding the exchange rate, and in meetings where we do not hear anything about the exchange rate, we begin to question our reason for existence. This is a reality, and we should not be afraid of this reality.

III. The Need for a Value-Based Approach

As Mr. Eren also stated, we still cannot measure the value of the output, that is, the health outcome. Since we cannot control the output, we try to control the input, namely the price, at the very beginning, at the marketing authorization stage.

However, the price used as the basis for marketing authorization is the price used as the basis for marketing authorization. The reimbursement part should be handled separately in the Medical Economic Evaluation Commission, and the price should be determined in proportion to the value produced by the medicine.

We now need to start implementing this “value-based” approach. We have lost a great deal of time, but we should not abandon it simply because we have lost time. We must continue from where we are by transforming this system. The price used as the basis for marketing authorization should also be treated as the list price, and we somehow need to move away from a position where people speak about us as arbitrary.

IV. Sector Participation in Pricing Studies

Finally, the pharmaceutical sector itself must be directly involved in all kinds of pricing studies being carried out. As marketing authorization holders, we are a party to this regulation. While a regulation is being prepared through which our list prices are determined, we are not merely a party whose “external opinion” will be sought after the study has been completed.

I would like to state openly and with all due respect: We are a party that must be involved at every stage of the study.

I. Speed of Access vs. Budget Share: The Priority of the Social State

Moderator: *When we look at it in terms of per capita income, yes, approximately 4% of our national income is allocated as a resource to health. However, it should be underlined that this ratio ranks at high levels within the budgets of other ministries.*

Of course, I have no doubt that the share allocated from our country’s health budget to the medical device and pharmaceutical sector should be even higher. However, this budget share should not be directly linked to outcomes.

Comparison of Speed of Access: *In many European countries, you cannot access healthcare services as quickly and easily as in Türkiye. In the United Kingdom, you see waiting times for a dentist appointment extending for months, even years. From this perspective, despite such a low budget share, we can comfortably say that we are in a better position than many European countries in the delivery of healthcare services.*

II. US Pricing and Social Policies

Frankly, I do not accept the term “arbitrary” used by the United States of America for our



pharmaceutical pricing. If you sell the same medicine for 365 dollars in the United States and provide it to citizens in Türkiye for 35 dollars, this is not arbitrary; it is a social practice carried out for the health of citizens.

- **High Cost in the US:** In the United States, policies in the process from pharmaceutical R&D to production reflect high costs onto citizens. In return, it is seen that citizens experience major difficulties in accessing medicines and healthcare services. I say this based on my observations; when you live there, if you contract a disease, you may face the risk of losing your wealth and your home. In order to receive fully equipped healthcare services, you have to take out more than one health insurance policy and still make large contributions out of your own pocket.
- **Social Access in Türkiye:** Access to healthcare services in Türkiye is almost unavailable anywhere else in the world.

Therefore, let us not be unfair to our country. In terms of access to healthcare services, we are at a much better level than many European countries and the United States. It is not possible for us to apply the same prices in Türkiye, because we have no chance of bearing this financial burden.

I repeat: These words of mine should not be understood as meaning that I am against increasing the health budget. I believe that we need to increase financial resources in order to ensure the sustainability of the sector.

Mr. Deputy Minister, I agree with your assessment regarding the United States that “it is not a social state” and with your evaluation on access.

However, what I particularly wanted to emphasize by mentioning the ratios was this: We truly need resources to ensure the sustainability of health. Especially when our access to innovative medicines is so far behind, and if access rates are higher than Türkiye even in countries such as Bosnia and Herzegovina, Macedonia and Serbia, whose per capita national income is lower than ours, we need to question certain things.

Unaccessed Products and Guidelines: I would like to add concrete data to a point that our General Manager Mr. Eren drew attention to: 36 of the products that could not access reimbursement are still recommended in the treatment guidelines of National Specialty Associations in Türkiye. We must be aware of our areas for improvement so that we can improve them.

You are right regarding arbitrariness. We also cross out the document coming from the US and send it back by writing “National Sovereign – Sovereign Pricing System” instead.

Moderator: This is entirely a policy created by our country for the health of citizens. I thank you for having stated that what appears arbitrary is in fact policies developed entirely for the health of citizens here.

THE IMPASSE OF THE DOMESTIC PHARMACEUTICAL INDUSTRY: UNIT PRICE AND SUSTAINABILITY

Dr. Sami TÜRKOĞLU

Secretary General of TİSD - Turkish Pharmaceutical Industry Association

I. The Current Point Reached in Access to Healthcare Services

At the point our healthcare system has reached, I believe I am among those in this hall who are most likely to understand what accessibility means from the patient's perspective. Indeed, I completed my residency at an SGK Hospital and served as chief physician.

I come from the days when, after a woman had one breast removed due to cancer, permission was required for referral even when there was a possibility of spread to the other breast; from the days when patients waited at hospital doors to obtain medical supplies and medicines.

The point we have reached, when we think of those days, is an incredible development. This is my personal opinion: I am glad that we have such an abundant and easily accessible system. We will all fall ill one day, and fortunately, these are covered by our state. Thanks to the extraordinary systems provided by the Social Security Institution, citizens can obtain their medicines by providing their Turkish Republic identity number.

II. The Fundamental Challenge of the Domestic Sector: Unit Price

Although these achievements in access are commendable, the sector's duty and fundamental demand concern the unit price of medicines and medical supplies determined by the policies set by the state.

- **Level of the Price:** The calculation of this unit price and the point it has reached are at rock bottom, regardless of which international or national scale you take as a basis. This is our difficulty.
- **Inability to Intervene:** Whether the state determines these policies very strictly or very broadly is not something in which we can intervene; this is at the discretion of the Republic of Türkiye. Personally, I find this approach very appropriate.

However, while there is no problem in the flow of resources to the public sector, universities, and private hospitals through co-payment differences or the global budget, there is no possibility or prospect for us to sell even 1 kuruş above the price announced by the Republic of Türkiye.

Therefore, our fundamental argument concerns this unit price and the methodology by which the unit price is calculated.

III. Future Studies and the Distribution of the Pie

We understand from the messages of our esteemed President and Minister that there are certain preparations regarding our Pharmaceutical Pricing Decree. This is such a study that, at the end of it, the



amount allocated to health from the Gross National Product will gradually increase. However, based on our public-sector experience, if it is assumed that this ratio will not change, will the distribution of the pie then be changed?

It is very important for the sector to be included in the preparation phase of these studies, as Ümit Bey also underlined. We request this emphatically: Let us be included. We already have no chance of changing anything to which the public authority does not say “Yes.”

IV. The Financial Bottleneck and the Suspension of Investments

We have to obtain more resources than the share allocated from the budget. What happens if we do not? This is progressing in a very insidious manner:

- **Supply Problem:** We look at the figures; the supply of a medicine on a box basis has fallen from 10,000 to 3,000. Reversal would be problematic, and it is very difficult to regain the previous supply level.
- **Cost Burden:** The domestic pharmaceutical industry supplies nearly 90% of the market in the country on a box basis. Due to increasing energy and personnel expenses, as well as the costs of highly qualified human resources, the sector has reached a bottleneck.
- **Suspension of Investments:** Most investments in digitalization, R&D, and internationally linked investments have been suspended. Those other than the essential ones are on hold. The indicator of this will not be seen immediately; however, greater difficulties may be experienced in 1-2 years

V. Call for Urgency

The Ministry of Treasury and Finance should not be viewing this situation from outer space. We are truly in very serious difficulty, and as the sector, we also struggle to explain our problem.

The last thing we would want is to have to gather immediately and do something because of an extraordinary supply shortage. This would be a bad scenario to explain both externally and internally.

We are a sector that touches all 95 million people. Therefore, making savings or restrictions in this area means going backward from the level of healthcare service we have reached due to budgetary reasons.

We now need to talk about other things with this distinguished audience, with our professors in this hall. Constantly talking about prices cheapens this work and lowers the motivation of human resources. We are tired of it as well. We are sure that the Ministry of Health shares the same feelings with us; however, in order for the Ministry of Treasury and Finance to understand this emergency, we need to take our methodology one step further.

We Are in the Same Boat: The Political and Human Consequences of Low Prices

Moderator: Sami Bey, then let us invite you and your team to a meeting where medicines are not discussed and an entirely different topic is addressed; perhaps it would be easier to manage.

However, we all agree on one matter: We are, in fact, all in the same boat. When the boat takes on water from somewhere and sinks, we will all be trapped under it. As Ümit Hocamız also mentioned at the beginning of his speech, sometimes it is necessary to look at the issue from the opposite direction.

The Political Consequence of Low Pricing

You also reminded us of your SGK days. We know very well those days when even a piece of cotton was on the agenda, changed the political conjuncture, and created pressure on citizens. Ultimately, when you cannot provide medicines, medical devices, or consumables, the system collapses completely from the bottom to the top. Therefore, we are aware that we are in the same boat.

In your speech, I felt the following: I experienced a similar situation at the meeting on October 29 as well. When you moved to one side, you felt as if you were on the opposing side. However, having come here today, we too are in the same boat.

Comparative Cost Reality: The fact that per capita pharmaceutical expenditure is at the same level as Bangladesh is a matter that needs to be reflected upon. Therefore, protecting the sector financially and ensuring its survival are necessary in terms of sustainability, which is our title.

Consensus on the Necessity of Increasing Prices

We agree, as all public institutions, primarily our esteemed Minister, our President of the Turkish Medicines and Medical Devices Agency (TİTCK), our General Directors, and our Department Heads, that this sector must survive.

It has been discussed that, for this sector to survive, medicine prices need to rise to more reasonable and sustainable levels. If this is not done, inaccessible medicines will have consequences for public health, and they will certainly also have a political consequence.

In the current picture, we, as the Ministry of Health, are also among those who say that medicine prices need to rise to much more reasonable levels in terms of sustainability. Because when production stops, when you cannot protect health, and when you cannot provide medicines to citizens, this will certainly have a consequence.

We should not view this situation only as a political necessity. I believe we should also be aware that we are obliged to do this from a humanitarian standpoint.

THE PRICE SYSTEM IS NOT WORKING: MULTIPLE AUTHORITIES AND A DOWNWARD TREND IN THE PHARMACEUTICAL INDUSTRY

Savaş MALKOÇ

Secretary General of İEİS - Pharmaceutical Manufacturers Association of Türkiye)

Esteemed Deputy Minister, after these valuable speeches, I find myself in the difficulty of saying something new, as we share similar perspectives; however, I would first like to state that I fully agree with the previous speeches.



I. Multiple Authorities in the Public Sector and the Problem of Ownership of Medicines

Esteemed Minister, those exciting meetings in Ankara that you mentioned excite us as well. However, there is one issue there that we cannot make sense of: multiple authorities. Who is the owner of medicines? Unfortunately, we have not been able to receive this answer in recent years.

- **Sole Authorized Institution:** Although TITCK (Ministry of Health) is the sole authorized institution in determining medicine prices, why do we have to go each time to other public units such as the Ministry of Finance and now the Presidency of Strategy and Budget, as if we had committed a wrongdoing, and try to prove why the sector cannot survive and cannot invest?
- **Evolution Toward a Finance-Oriented Perspective:** The Ministry of Finance is, of course, a valuable unit concerning money. However, it is not healthy for industrial, pharmaceutical, or education policy to be determined according to the budgetary concerns of the Ministry of Finance. The balance has been disrupted, and in recent years, this balance has evolved too much toward a finance-oriented perspective. We are uncomfortable with this situation.

II. Social State Policy Is Being Placed on the Sector

Our state has made a choice: to provide citizens with medicines and healthcare services at the most affordable price from the perspective of a social state. We have no objection to this.

However, our problem is this: The state is trying to carry out this social policy largely through the private sector.

- **Economic Burden:** By constantly suppressing medicine prices, the cost of providing citizens with cheap medicines has economically been placed largely on the sector.
- **Benchmarking and Exchange Rate Illusion:** Our pricing system is based on the prices of the 5 countries with the lowest prices. A medicine that costs 10 Euros in Greece is said to be provided in Türkiye for “2 Euros.” Moreover, this 2-Euro price is calculated based on the pharmaceutical exchange rate taken as 21.67 TL and returns to us as 14.73 TL together with discounts.

We respect the state’s preference; however, this preference must be made on the condition that sufficient financing is allocated. The financial sustainability of our companies is as important as the financial sustainability of the public sector.

III. The Erosion of Prices in the Face of Inflation

The reason why our complaints have increased in recent years is this: Although the public sector says, “We have given you more exchange rate increases than necessary,” we, as manufacturers, do not feel this.

Price/Cost Comparison for the Last Three Years (2022-2025):

Indicator	Increase Rate
Minimum Wage	%682
Producer Prices (PPI)	%694
Consumer Prices (CPI)	%556
TRY/Euro Exchange Rate (Suppressed)	%432
Pharmaceutical Exchange Rate	%373

This table clearly shows that the financial sustainability of the public sector is, of course, important; however, under these conditions, it is not possible for our companies to survive financially.

Even without going into the details of input costs such as vehicle rental and personnel expenses, the situation is critical. There is no one in our sector working for minimum wage; everyone’s salary level is high. This is precisely why we advocate for Türkiye to become a country with a say in pharmaceuticals: because we provide young, qualified employment and high value-added exports. However, we only hear this vision in words.



IV. The Paradox of Blaming a Sector That Invests

When we say, let us at least prevent this sector from dying and keep it standing, let alone developing it, we receive questions from public bureaucrats such as: “You complain this much, but how are you making these investments?”

A sector that should be thanked is almost being blamed because it invests, supplies medicines to the market, and does not leave citizens without medicines. This creates concern in us that such a perception has emerged in the public sector: “This means there is no problem, everything is going well. You are also investing, and you are also supplying medicines. Then you can continue as you are.”

I have to say very clearly: This pricing system is not working. It has not been working for the last 3-4 years. The public sector’s annual interim decisions to update the pharmaceutical exchange rate are also a de facto acknowledgment that the system is not working.

V. Demand for Urgent Action and Predictability

- 1. Revision of the System:** Predictability cannot be offered to us through a system that does not work. It is clear that the pricing system in February is not working. This system must absolutely be changed without delay.
- 2. Consultation and Participation:** I agree with my colleagues. Please proceed in consultation with us. After a change is made in the public sector, reversing it takes many years. Before causing greater harm to the sector, please implement a pharmaceutical pricing system suitable for the conditions of the day. We respectfully request that you do this not only with public institutions, but by taking our views during the preparation phase.
- 3. Investments Are Stopping:** In this uncertainty and lack of predictability, it is very difficult for the private sector to invest and enter new areas. It is being discussed in boards of directors that companies feel somewhat guilty for making investments.

The public sector must stop viewing medicines merely as a financial item and a burden on the budget. There is also a real sector side and a patient side to this. We are in a period when even the United States prioritizes the pharmaceutical sector and there is a major global race in biotechnology and biosimilars. Unfortunately, we are far behind in this race.

VI. Conclusion and Concrete Production Data

A pharmaceutical sector stuck on the pharmaceutical exchange rate does not deserve this, esteemed Minister, nor does this distinguished audience. As a sector, we also do not deserve the following: We need clear legislation that will ensure predictability, in which the rules are redefined, and under which we will not constantly go to Ankara for this issue and go door to door. We keep going around in the same vicious cycle every year.

So, you complain this much, but what is the situation? According to TÜİK figures, the concrete production data are as follows:

- **2024 Production Decline:** Excluding the pandemic period, pharmaceutical production decreased by 7.3% in 2024 for the first time. In the first 8 months, this decline continued at 3.4%.
- **Historical Downward Trend:** Pharmaceutical production has been on an uninterrupted downward

trend for the last 13 months for the first time in its history. During the same period, while there was a 2.7% increase in general manufacturing.

This continuous decline will, after a while, lead the sector to reduce its production and result in greater external dependence.

Our expectation from the public sector is:

- 1. To bring our pharmaceutical exchange rate to a reasonable level as quickly as possible.**
- 2. To urgently ensure that this pharmaceutical pricing system is revised according to the conditions of the day by allocating the most appropriate budget.**

Call for Unified Management

Moderator: The Problem of Multiple Authorities in Financial Management: *You are particularly right on this issue: We, the Ministry of Health, state the rationale and the need; you, the private sector, produce; however, the Ministry of Finance determines the price. In terms of determining the price of a product and managing its cost, in fact, three separate institutions or organizations such as the private sector, the Ministry of Health, and the Ministry of Finance are struggling with one another like the three legs of a tripod.*

Proposed Solution: *In this field, either the authority should be given directly to the Ministry of Finance, or the Ministry of Finance's area should be transferred to the Ministry of Health. We agree that a structure should be established that will both make decisions and manage the financial process, and determine prices, from a single point.*

Esteemed Minister, there is a fact constantly emphasized in Türkiye: The only product whose price has not changed in the last year is medicine.

- If the Ministry of Finance brings the fight against inflation and leaves it solely on the pharmaceutical sector, then there is already a major problem there.
- While everyone in the market can adjust their prices, and while sometimes excessive prices are being discussed, the pharmaceutical sector is told, "No, you cannot increase."
- This sector is subject to the same costs and does not receive anything on a subsidized basis. In fact, it is an advanced-technology sector that must continuously invest.

When the public sector, so that I do not constantly mention the Ministry of Finance, says to this sector, "No, you have not received it for a year, do not receive it again, continue this way," even if we set everything else aside, this is simply not fair.

Moreover, we believe that a sector that should be held most dearly does not deserve this treatment.

Commitment to Urgent Action: Unified Management and Pricing Justice

Moderator: I. The Sector's Creativity and Promise of Support

You are truly creating miracles. You are a sector that manages to survive despite such low prices and constantly increasing raw material costs. We need to provide more support to ensure the development and continuity of the pharmaceutical sector.

Multiple Authorities and Dynamic Pricing: *The problem that the sector refers to as multiple authorities is, in fact, causing the increase you should receive over the course of a year to be delayed. The pricing process needs to be carried out from a single authority. At that meeting, we exerted serious pressure on the need for pricing to change dynamically, not at certain intervals. If the exchange rate changes, that rate needs to be updated instantly so that you are not affected by price increases.*

Thanks to SGK: Despite everything, I thank Eren Hocam from SGK. Although it was not included in the budget, the financing of medicines newly included in the reimbursement scope was provided with an additional budget of approximately 30 billion TL.

We Are Aligned Toward the Same Goal: I repeat: We are absolutely and unquestionably in the same boat, and we serve the same goal. We will provide as much support as we can. I state that I will do everything in my power to ensure that the sector can obtain the reasonable pricing it demands, and I commit to making this effort. I know very well what is being experienced in the field; we are aware of the reality that raw material prices can suddenly double and create costs at the level of millions of dollars.

Suspension of Production: We need to sustain employment. When there is difficulty in financing, if employment cannot be maintained, this situation may go as far as suspending production rather than incurring losses. We do not want this in any way. As the Ministry, we are ready to do our part in this regard, both in terms of legislation and financial sustainability. I agree with your idea of unified management; this would be much more reasonable.

The Bitter Realities of Domestic Industrialists

Participant - The bitterest reality is this: despite the lack of adequate price and exchange rate regulation, Turkish domestic pharmaceutical industrialists are truly fulfilling their responsibility to their country.

However, the worst part is this: despite all these difficulties, the prices obtained are later confronted, through pharmaceutical procurements made by the State Supply Office (DMO), with the objective of purchasing products at the most extreme price.

Production Restrictions: In the pharmaceutical sector, we do not have the option of purchasing raw materials from wherever they are cheaper or shifting labor to where it is cheaper. Because even the slightest change in production means a workload, a problem, and a loss of time for the relevant unit of TİTCK.

The Sector Is Struggling to Survive: What President Savaş and the other participants said is very appropriate. This sector needs to survive. Layoffs have now begun. I returned from the fair in Frankfurt two days ago; compared to last year, 10 companies from the pharmaceutical sector in Türkiye could not participate. This deeply saddened me. While there was high participation even during the pandemic, this situation shows the point the sector has reached.





PANEL-3

NEW PRACTICES IN LICENSING

MODERATOR:



Prof. Dr. Ahmet AYAR
President of TITCK – Turkish Medicines and
Medical Devices Agency

SPEAKERS:



**Specialist Pharmacist
Ömer Hakan ŞİMŞEK**
Head of the Department of Pharmaceutical
Licensing, TITCK
(TITCK Practices and Innovations)



İsmail ÖNCEL
Board Member of İEİS (Sector View)



Prof. Dr. Ahmet AYAR

President of TİTCK – Turkish Medicines and Medical Devices Agency

Although the discussions held so far have been stressful in terms of revealing our current problems, they are extremely helpful in terms of discovering the problem. There is a famous saying: “The solution to a problem depends 90% on agreeing on it.” When we understand the problem, we move closer to the solution.

In this session, we will try to focus on the topic at hand. Issues related to pricing and pricing policy, especially the situation and calculations of the Treasury and Finance in reimbursement... They are not here, and I do not have the authority or sufficient information to speak on their behalf.

However, they are probably making a decision by keeping education, defense, and culture in balance. You have more information than we do; just as you visit TİTCK, you then also visit policymakers related to reimbursement and pricing. I am sure you convey their difficulties, issues, hopes, and calculations.

After answering the relevant questions of the survey conducted here and making a short speech in order to manage the process better, I will give the floor to my Head of the Licensing Department, Specialist Pharmacist Ömer Hakan ŞİMŞEK Bey. He is truly a specialist pharmacist who has worked at the Agency for many years since the moment he took office. In addition, he and his team are very self-sacrificing. At the same time, with his IT capability, capacity, knowledge of medicines and the Agency, and his IT experience, he is a great chance for our country and for my period of administration. I would like to thank him and his colleagues once again in your presence.



TİTCK's Duty and Responsibility

Now, in academic terms, the institution responsible for the process of ensuring public access to safe, high-quality, and effective medicines, at their value and in an accessible manner, is TİTCK.

The rules related to this are universal; this was also emphasized in previous presentations. These are the EMA rules developed and put into practice by the European community. They are highly binding for



Türkiye. It is also partly good that this is the case, because there are no strong departments related to regulation in our academia and society. Thesis studies are rare; hypotheses, ideas, and policy tests are limited. Therefore, reactive decision-making mechanisms are in effect. Alongside this, we have a simple institutional duty that proceeds by adapting the rules of the world's leading regulatory and supervisory institutions, the FDA and EMA, to the conditions of our country.

The Balance Between Speed, Safety, and Reputation

So, what do we encounter here?

Neither we nor you are satisfied with the speed. When it comes to the level of figures, we will be clear; we are clear. You have become tense, you are tired, and this is not a place suitable for saying anything other than serious remarks. But with your permission, I will say something: When I assumed this responsibility, I said, "Is speed the problem? Let us accelerate it." There is a country in South America that issues a license in two hours. Would you like that? How would it be? Let us approve it in two hours. Presumably, for a while, those who receive those licenses would erect a virtual statue of us for this administration.

However, we have concerns. When we do not apply the criteria related to safety, there are serious consequences: the reputation of the sector is shaken. Its potential to sell products to the global market is reduced to zero.

For this reason, I will say one sentence in defense of TİTCK: Most justifiably, the members of the commissions who have worked at the Agency from its establishment to the present day, and who have contributed from outside as commission members, have not allowed a scandal to occur in Türkiye. For this, they definitely deserve thanks in their absence.

However, the requirements for carrying out the existing processes more quickly are also present in the literature: faster patient access to medicines, ensuring competition in favor of the public, the entry of innovative medicines into the country, and their transformation into trade are matters that can create snowball-like positive effects and must be fulfilled. This is also our shortcoming.

Management Approach and Responsibility

For a while, I have been doing the following: Distinguished audience, we do not play games. "Preparing valuable documents is a game. The clock stopped, the file went to you and stopped, it came to me, whatever happened, there was a third correspondence. In order to be successful, I wrote at 5 so that you would not ruin my average, and I removed you." I will not play these games.

Being portrayed as unsuccessful is not at all my dream. Because there is a very great responsibility: providing the people of Türkiye with high-quality, effective medicines; ensuring that the sector receives the return on its investment; sitting in a very large and luxurious office in Ankara with the taxes you pay. I cannot pay the rent for that. I have a very great responsibility.

But I will not play this game for a while: I stopped the clock. You wrote three times, I removed you, I did not open a slot. I may hire consultants for these, and I may work on them myself. I will not do this. Therefore, although we already have no credit, or we do not know our tomorrow, I will also share the truth with you within six months with such figures. It is not possible for us to continue without numbers. Nurullah Minister is here; I am speaking by relying on such goodwill and courage. In the end, he may give an instruction and say, "No, the numbers must also be met." If he says, "The file went there in separate slots, stop the clock from here," my authority to use initiative is also limited. I am an employee of the



state, and I am extremely loyal to my state. I am aware of this. When we do not know, they also remind us, primarily Nurullah Minister, that this is not a place where one can implement one's own wishes and preferences.

Structural Problems and Solutions for Increasing Speed

In order to increase speed, I will share some excuses with you, perhaps so that you may empathize. Solving these is our duty. As we did in primary school, with the logic of "Pool problem: what happens if you turn on one tap?", what can we do if we want to increase speed?

1. Limitation on the Number of Commissions

One of the ways is to establish more commissions.

In the past, those who prepared the Presidential Decree limited the number of commissions to 40. According to one statement, in a field with a volume of around 9 billion dollars, the number of commissions that will evaluate files is limited to 40 in our country and at TİTCK. Unfortunately, I realized this after seven months, and I am currently dealing with it. The Presidential Decree has been changed. If 400 commissions were established in this country for acceleration, what harm would it do to the country? With what reasoning did whoever said 40 say this? The decree states that "no more than this shall be paid."

2. Motivation and Remuneration of Commission Members

I can estimate that there are many academics here who contribute to TİTCK. I also bow respectfully before them in their absence. They are motivated; they do not ask for money.

You know how many pages TİTCK pages, that is, files, consist of, don't you? These are such technical matters. If someone invited me to read those files for 4,000 TL and said that I could not come more than four times in a month, how many months, how many times would I go there saying, "Let this also be a contribution to my state and to our sector"? Without solving this, I cannot ask the commission members who come to me to be motivated, to be fast, and not to open a new chapter in the second or third phase.

I started by defining the problems: You must understand the problem. I said to a Treasury/Finance person who is my friend and has a deep memory in Ankara: "Set aside one day; I will have you read only one of these files, you will only listen. Would you listen to this file for this money?" They will read this to you like a fairy tale.



3. Human Resource Need and Proposed Solutions

To solve this area, I or those who come after me... While I was still speaking about this issue, its turn did not come because of pricing. Our civil society organizations and, possibly, our esteemed Minister need to arrange for academics from universities to be temporarily assigned for six months or one year. Since they do half of their work there and half of it here, they come tired, and they have other work. However, the files of the industry with high added value cannot be evaluated at the expected speed. If there is a more reasonable, creative idea, propose it and let us implement it. Let us also thank you in relation to this.

In the medium term, TITCK needs to make these decisions with its own internal experts.

4. The Role of the Commission and Authority

Now we have gone a little higher. Also, the state has appointed me to a responsible position. Pride swells. During my term, I use this arrogant sentence: We will not allow the atmosphere that “the commissions have dominated the state and TITCK” to exist. They will remain within their limits and provide consultancy. Because TITCK is a board that makes science-based decisions. It cannot make administrative decisions. It does so in exceptional times; when it sustains this outside of exceptions, first of all, it loses its accreditation in the world, and our industrialists become unable to export.

While making these science-based decisions, I will obtain the advisory opinion. I will take the final decision within administrative evaluation and, if necessary, obtain the sector’s response in between and implement it in this way. This is how it already needs to be implemented.

5. Ethical Risks of Commission Members and the Solution

There is also talk of TITCK Commission members, a small number of people who are alleged to have abused their duties and authorities, whose stories have been brought to me, who threatened companies in the past five years, three years, four months, or four years ago. I have not seen it myself, but I am sure it has reached your ears. No one can challenge this sector by wearing this shirt. They cannot establish this dominance.

So what have we done to solve these? A segment of the sector is being provoked through consultants and is engaging in agitation by relying on what it does not know. No one can deny that a major or minor change is needed in this course due to the attitude of some within the commissions and the fatigue of all of them.

What were commissions like in the past? They were fixed. The first commission has five members, and it continues there for one year. The sector member who acts unethically also goes and visits them, applies neighborhood pressure, and tries to wear them down and make friends. They try every way. Why should I put that person in difficulty?

New Practice: Dynamic Commission System

There are no longer fixed commissions in the commissions. My department head said, “Let us do it all at once.” You cannot even do half of it at once. I am in the office; no one, including myself, should cheat. First of all, there must be trust.

There are keywords according to the areas of expertise of the professors. It is clear who should be

on the same commission. We will draw 600 to 1,600 people according to a random number. We will say, you have been assigned to this commission. You have this duty here. This is for one time. In the second instance, it will not be known who will serve in which combination. You may come and obtain the computer records of the draw from me whenever you wish, so that no one can say, “You said so, but you are not drawing; you are doing it by hand.” In this way, we will ensure objectivity. We will also try to prevent commission members from becoming fatigued, like metal fatigue.

It is clear that 4,000 lira after tax, which commission members are receiving, is not the equivalent of this work. To remedy this, we are obliged to provide them the maximum possible compensation and motivate them, including reflecting part of it onto administrative files.

6. Transition Process and Digitalization

Of course, there must be institutional memory regarding files whose evaluation has started and is ongoing. The opinions of those who possess the previous memory continue. We did not stop them in an absolute sense. There was a minor disruption at the ministerial approval stage, but since that date, we have not distributed any new files.

If you are asking how we will pay the price of these two months, I think you are right. However, I believe that this situation will be compensated for through the digitalization of application files and the removal of the limit caused by the restriction of the number of commissions to 40.

At the first or second sector meeting we will hold from now on, I will also present these to you based on figures.

For reasons that some of you know and some of you may not know, we are not continuing as before, and we will not continue as before, due to risk factors that do not deviate from state justice and objectivity, but that lay the groundwork through the human factor. With fixed juries... what were those fixed juries doing? One of my experts takes it and gives three of them there, does he? I have no evidence whatsoever that he did anything, friends. I am not being sarcastic. But could he do it? He could. This is human. You prepare this ground for him. This is human nature; all of them, their biology, does this. Those responsible in the state must minimize these.

Therefore, we have fulfilled the working principles of commissions in a more objective, more dynamic manner, and in a way that can be free from seasonal fatigue during the year.

The greatest responsibility for this delay belongs to me. When I went to the ministry level regarding the renewal of the list, the ministry gave me approval in one day. Primarily Kemal Minister, and all my deputy ministers, constantly instruct us by saying, “Do these extremely quickly; the sector has difficulties, including economic difficulties. Do not add an additional bureaucratic difficulty to these difficulties of the sector.” However, we experienced a pause regarding the technical process. I believe that this pause will increase objectivity, will not lay the groundwork for human manipulation, and will be compensated for in terms of time through the mechanisms that Hakan Bey will explain shortly.

Pricing Policy and the International Reference System

I say I will not speak about prices, but you say, “Let us not come to Ankara frequently. Share it with us. Do we have to come?” We have become accustomed to you; there is now facial familiarity. So if we give that, you will not come. Are you that tired of us? It means that unless we keep this as a secret, no one will come to our doors. For this reason, we will not share this with you for a while longer.

1. Initiative to Correct the Reference System

Of course, in order for an amendment to the regulation to be published at the Presidential level, it is mandatory to obtain the opinions of internal and external stakeholders.

What we are doing, in umbrella terms, is this: It is to repair or rehabilitate the international reference



system, which is one of the theoretical methods of reimbursement and is applied in Türkiye. Mostly to the detriment of the public, leaving the state in a helpless position, this has been gradually distorted and violated over many years. This first needs to be corrected.

We are in the same boat. And theory and science say that, in the medium and long term, for the country's pharmaceutical sector to become stronger, medicine prices must absolutely be above a certain threshold. The value given below that is, for the country, cutting off the branch on which it sits.

As the Ministry of Health, as a bureaucrat under the authority of the Minister of Health, we respect the existing evidence on issues such as medicine prices being at their value, receiving the return on investment in this sector, and adding to this the R&D cost of molecules that result in failure. Our views on pricing are highly similar.

2. Disruptions in the Reference System

But if we cannot establish the ground by repairing the international reference system... I believe it was in Dr. Zeytin's presentation: toward 2029, in a phase when medicines that are low in box volume but high in value will arrive and strain our budget, if our reference pricing remains a patchwork as it is now...

Because I cannot obtain a price from Greece, because Greece purchases in bulk, because it purchases for hospitals and therefore I cannot obtain a reference; because the article forces me, I do not theoretically accept such absurdities as being unable to obtain a price and then going to Egypt to obtain one. We will be clear. Everything will be transparent. We will act in accordance with the international literature.

3. Conventional Medicines and Reassessment

First, we will establish the foundation. After the foundation is established, the share of conventional medicines in the budget and their unit box price are modest.

Again, as TİTCK, just as we prepare this report technically for the relevant levels of our state, we will prepare and submit the report: "Exceptions may be applied to the following items..." In order to fulfill the current value, neither the 40% limit of reassessment nor inflation should be disregarded. The starting point for this should be reset.

Because part of that money will go to the devoted industry that produces in Türkiye; we are aware of this. They will employ workers and pay taxes. I am not a great economist, but when their indirect contributions to the treasury are calculated, good economists will be able to calculate that the money given there remains in the country. We will correct this.

4. Risk of System Collapse

However, if we turn the international reference system into a public thoroughfare and leave it in its current state, if another 158 innovative medicines arrive, the medicine budget and system may collapse. Therefore, the reference system must absolutely be corrected.

5. Steps Taken

If you ask what we have done: We proposed converting it back to its original form. Those who will assume the administrative and political responsibilities related to this will first see it. We shared the impact analysis with them. Then, at a time they deem appropriate... It has been more than forty days,

almost two months since we completed our homework; we will submit this. After that, we will follow the process regarding its applicability.

If you are going to provide feedback to that system, theoretically, say to me, “You have deviated from and differentiated yourself from the examples of the international reference system in the world,” and then we will say, “We made a mistake; let us look at that source and apply the correct version of the defined system bearing this name.” We will humbly accept it. Because this is a system that has been proven in the theoretical world and whose method of implementation is clear.

Bayer is Turkish, it has no relation with Bayer in Germany. The original molecule has no equivalent in our basket of five, it has no relation... These are children’s toys. Ultimately, we have authority, and if we can write this article, the state will not allow it to be circumvented. No one is indispensable. We are pursuing what is right. We are striving to achieve whatever is right for our country and our sector.

THE NEW PHASE OF DIGITAL TRANSFORMATION IN PHARMACEUTICAL LICENSING

Specialist Pharmacist Ömer Hakan ŞİMŞEK

Head of the Department of Pharmaceutical Licensing, TITCK

Like my President, I am not a pharmacist with a licensing background. I have been working at the Agency for 10 years, but until today I have worked in various positions in our Agency, primarily in the Department of Information Systems and in administrative duties. I worked on projects such as the Pharmaceutical Track and Trace System (ITS), the Product Tracking System (ÜTS), and Reçetem. Thanks to our President, in the new process, he also instructed us to work together with our team in order to move to the next stage of digital transformation in the Pharmaceutical Licensing section. As of now, we are working intensively on these processes.



OUR STATUS IN DIGITALIZATION

Our Current Capability: Our Agency has long been accepting applications electronically, in PDF format. The Next Step: Digitalization: By advancing our current level of digitalization, we are making data “structured.” Our aim is not only to receive a document image, PDF, but to obtain machine-readable and processable data, structured data. Strategic Requirement: eCTD v4.0: Structured data is a requirement for compliance with new-generation application standards. It is a preliminary step for data analysis, automation, smart systems, and the development of new technologies, Artificial Intelligence.

Digitalization is a somewhat generic concept; when you look at it from top to bottom, it is a process consisting of many steps.

- **Our Current Capability:** In this respect, our Agency has actually been an institution that abandoned physical documents a very long time ago, that is, nearly 15 years ago, and has been working in a paperless environment. This is the first step of digitalization. We have long been accepting applications electronically, in PDF format.

Strategic Goal: Digitalization (Structured Data)

We also need the next step of digitalization. In fact, “digitalization” may not be exactly the right word, but in Turkish, we need to turn our data into “structured data,” that is, to process and receive data not through the PDF images we receive, but at lower breakdowns and at lower levels.

- **The Next Step:** By advancing our current level of digitalization, we are making data “structured.”
- **Our Aim:** It is not only to receive a document image, PDF, but to obtain machine-readable and processable data.

Strategic Requirements

The requirements of this transformation are as follows:

1. **eCTD v4.0:** Hopefully, we will begin work to transition to eCTD v4.0 in a very short time. We have completed the preliminary preparation to a certain extent. Structured data is a requirement for compliance with new-generation application standards.
2. **Future Technologies:** Together with this digitalization process, with the next step of digitalization, we are currently working on where and how we can use later technologies, including artificial intelligence, and how we can use them effectively. It is a preliminary step for data analysis, automation, smart systems, and the development of new technologies.

Transition to the eCTD v4.0 Standard

What Does eCTD v4.0 Bring

Content is “modular” and reusable - Structured Content Management (SCM) Documents can be reused – The same document can be reused in different applications Bidirectional messaging between applicant and authority - Message Exchange Standard (MES) Use of controlled vocabulary – Definitions and labels become standardized More flexible document updates – Lifecycle management has improved Support for non-PDF content – Different document formats are supported, for example data files Document submission at a finer level of detail – Document hierarchy is more detailed Definition of “context of use” for documents – What they are used for is clearly stated A structure suitable for long-term digital archiving – Sustainable digital system

I estimate that you are familiar with eCTD v4.0. Many of you, especially global companies, already have knowledge of what eCTD v4.0 brings on the global side. We will not go through these one by one.

The Difference Between v3.0 and v4.0

Ülke / Bölge	Teknik Pilot	Güncelli Uygulama	Zorunlu Uygulama
Brezilya (ANVISA)	2026 4. Çeyrek (Planlı)	2027	Belirlenmedi
Avrupa (EMA)	2024	2025	2027
Amerika Birleşik Devletleri (FDA)	2022 - 2023	2024	2029
Kanada (Health Canada)	2026 - 2027 (Planlı)	2027	2029
Güney Kore (MFDS)	Belirlenmedi	2027	Belirlenmedi
Japonya (PMDA)	2021	2022	2026
İsviçre (Swissmedic)	2026 (Planlı)	2027	2030
Avustralya (TGA)	2026 (Planlı)	2027	Belirlenmedi

eCTD v3.0 was published in 2008 and is gradually reaching the end of its lifecycle.

For **eCTD v4.0**, since a somewhat more modular and somewhat more flexible software architecture has been designed, we have seen in our discussions that eCTD v4.0 will be used uninterruptedly for a very long time.

In general, eCTD v4.0 is a somewhat more flexible mechanism, one that goes into somewhat more detailed breakdowns and is planned for a somewhat longer term.

This transition is directly related to the objective we mentioned earlier of obtaining “structured data” and making this data machine-processable.

eCTD v4.0 Global Timeline and TITCK’s Strategy

Currently, except for Japan, which will move to mandatory implementation next year, almost the entire world is now in the development phase, and voluntary practices will begin as of next year.

Perhaps two points should be highlighted here:

- 1. Development Process Length:** It should be noted that the development process of eCTD v4.0 is long. The transition of a country in the world takes three to four years.
- 2. Timing:** We are actually at a very suitable time for transition right now. We intend to transition within the same window and the same interval as the world, even if not at exactly the same time, but at a much closer time, immediately after them.

eCTD v4.0 Transformation

Our vision is not only to transition to eCTD 4.0, the new file submission standard; it is to use this transformation as an opportunity to establish an end-to-end scientific, transparent, and predictable licensing process.

1. Establishing the Technical Infrastructure:

Designing and developing the necessary software and hardware infrastructure. Determining system integration and security standards. Developing a platform fully compliant with eCTD standards.

2. Process Optimization and Stakeholder Management:

Continuing technical studies. Designing the pilot study. Sectoral Preparation: We will follow a proactive communication and training strategy to prepare our stakeholders for this transformation.

eCTD v4.0: Not Just Software, but an Opportunity for Business Process Renewal

Here, it must be stated clearly: eCTD v4.0 is a window for us. We do not evaluate eCTD v4.0 on its own in this way. While transitioning to eCTD v4.0, we want to consider it as an opportunity through which we can renew all of our own business processes as well. Within this scope, our goal is truly to establish a scientific, transparent, and predictable licensing process. I would like to emphasize once again that predictability is very important both for you and for us, and that transparency is very important both for you and for us.

What we are truly trying to do is not actually only transformation to eCTD v4.0. Together with eCTD v4.0, it is to renew the software we currently use from top to bottom with new technologies and a new understanding, and during this process, to be able to reanalyze our own business processes as well.

Transformation Process: Two Main Parts

We actually divide the work into two parts. Although the eCTD v4.0 transformation appears to be a software transformation:

1. Establishing the Technical Infrastructure (TITCK Internal Process)

- The first part of this is establishing our technical infrastructure and carrying out our work related to this.

- 
- In fact, with the permission of the Minister, we have reached the final point. As of January 2026, hopefully if nothing goes wrong, we will technically begin the active development process for eCTD v4.0. Our final moves have been completed; we have carried out the final studies.
 - This first stage will be our software development stage.

2. Pilot Implementation and Sector Transformation (Process Together with the Sector)

- This transformation is not only a software transformation; it is also a transformation that will somehow change the dynamics of the sector and that the sector must carry out together with us.
- With the completion of technical development and the technical infrastructure reaching a certain maturity, in the remaining process, from going into the pilot phase to the process that will extend to voluntary implementation, we will devote intensive time and effort together with you.
- A software project is never only a software project. Sometimes only 30%, sometimes 40%, remains for software development. This is the case even for ITS. What matters is its transition.

Software Development Approach

- A little earlier, a question had come up: We will not purchase a ready-made third-party tool related to eCTD v4.0.
- Because we will develop software through which we will also review our own business processes. We do not want to deal with integration.
- In terms of health informatics, thankfully, as the Ministry, we have a competent perspective. We want both to develop the core side of eCTD v4.0 ourselves, although we may perhaps “outsource” it in some way, and to redevelop our own regular applications ourselves.

What Are We Doing Before eCTD v4.0

- We are analyzing the current situation and needs.
- We are cleaning and standardizing our data.
- We are redesigning our business processes.
- We are carrying out internal software integrations and opening every development we make to the sector.

We have started discussions with international peer institutions.

Work Being Done in the Kitchen and Step-by-Step Outputs

As of now, for six or seven months, as much as possible, we have actually been in the kitchen together with the technical team. We have not really had much chance to meet with you face to face. I also have not been able to meet with you much, but I ask you to excuse me. Because during this period, from our own perspective, we have been carrying out organization, arrangement, and cleaning work in the kitchen. These efforts are still continuing.

But we also want to share some of these with you as much as possible. We do not want to wait until the last moment for any of the eCTD v4.0 transformation and the work we have done before it. We want to share our outputs with you phase by phase.

Concrete Steps Taken for Transparency

1. Process Viewing Screen (August 1 Beta Test): One of these is the screen through which, as of August 1, you began to view the processes of products as a very preliminary version, which we could call the first “beta test.”

- We have some minor problems on this screen, because we are integrating from more than one software system. It should perhaps also be stated that the problems you see there do not actually indicate problems within the Agency, but integration problems.
- Our aim is to increase such screens and such data sharing, and to show the status of the application you have made in a more transparent manner, and perhaps later even their order in the commissions and the elapsed times.

2. Feedback and Communication Channel:

- Thanks to those screens, feedback is coming in. Especially regarding errors on the screens.
- However, by adding file upload options there for the things you want to ask, say, or explain on a product basis, we want to use the communication channel more intensively from there.
- We will continuously make improvements there. With the eCTD Project, we are planning every output we obtain step by step in a way that will be reflected to you.

Status of Licensing Processes

- We write an average of 60,000 letters annually.
- We receive an average of 20,000 applications annually, including variations, transfers, and similar applications.
- There are approximately 2,100 applications in the licensing process.

Workload and Efficiency of the Department of Pharmaceutical Licensing

I do not want to prolong this too much. We also need to share the latest situation with you a little. Yes, are the processes long? They are long. You are right. It must be said with peace of mind: You know our difficulties, and be assured that we are also aware of them. We are not in a position of denying our difficulties. Some of them already need to be solved together with you.

Current Workload Data

However, in order to share our workload with you to some extent, here are the data on what we do:

- We write an average of 60,000 letters annually, belonging only to our Licensing Department.
- We receive nearly 20,000 variation applications annually on average. These come in including licensing and similar processes.
- And we currently have 2,100 application files in the licensing process.

With our current licensing issuance speed, if we asked you for some time and said, let us continue with what we have, we would probably continue working uninterruptedly for five years. Of course, this should not be left this way. If we look at our current issuance speed, this is the situation.

Working Hours and Human Resources Challenges

Truly, I do not think there is such a perception, but let me remind you once again on behalf of my colleagues: With a concept of working hours very different from that of a normal civil servant, especially



during reimbursement periods, as we assume you also witness, we too work continuously, including until midnight.

However, it appears that we need to make this work more efficient. The eCTD v4.0 transformation is one of these. The work we will do regarding digitalization, transparency, and our process evaluations is one of these.

Thanks to our presidents, they continuously increase our number of personnel gradually, but as you know, this does not come in direct proportion. The marginal benefit decreases with the training of each incoming personnel member. In other words, if we doubled the number of personnel right now, the number of licenses would not double. But we are continuously working on that as well.

Priority Actions We Need to Take

- Renewing our software and processes.
- Reconsidering prioritization.
- Standardizing our commission decisions.
- Carrying out all our procedures and processes while remaining in communication with the sectors.

Structural Change and Prioritization Strategy

This is clear: We need to structurally change our existing workload and way of doing business, and various tasks fall to us here. First of all, there are matters that we need to do and, in fact, have already begun to do:

1. Software and Process Renewal: As I mentioned, renewing our software and processes is one pillar of this, eCTD v4.0 and digital transformation.

2. Reactivation of Licensing Prioritization:

- We want to reactivate licensing prioritization, to review prioritization again in a much more reasonable manner, with very different algorithms, perhaps by receiving your views and ideas and working together with them, and to put it back into effect.
- In this form, we hope that we will at least be able to implement various faster pathways and faster procedures, such as the plans regarding biosimilars mentioned by our Minister Şuayıp.

TİTCK's Expectations from the Sector and Common Problem Areas

Our Expectations from the Sector

- The time spent in the sector is, on average, similar to the time spent on our side.
- Deficiencies and errors in the submitted files.
- Difficulties experienced in the market entry of licensed products.

1. Demand for Standardization and Quality

In line with the requests coming from you, and you are right, the fact that our commission decisions sometimes diverge from standards is also a problem for us. We do not want additional chapters to be

opened. We want to make commission decisions more standard, more understandable, and more ICH-compliant. In this respect, there are many tasks that fall to us.

2. Delays on the Sector Side

However, we also have various requests and expectations from you, or areas where we would like to share our concerns with you.

- **Reciprocal Extension of Timelines:** Yes, the time spent on our side is long, that is true, but when we look at the net averages, we can say that the time spent on your side is also not very different from ours in terms of the average. So, of course, it is like the classic “chicken or egg” situation. Sometimes we are delayed, and sometimes you are delayed.
- **Response Quality Issues:** There is also the following situation there: We have problems such as extended commitments, late responses, inconsistent responses, and responses being requested again.
- **File Quality Issues:** In the submitted files, there are sometimes errors and deficiencies that we could not have anticipated, and that even some of our companies accustomed to licensing processes repeatedly make.

The more robust and complete your files are when they arrive, the more comfortable we actually are. Perhaps at this point, I kindly ask you to review your own processes again. If necessary, we must certainly conduct training and joint work on this. On what we expect, what the good examples are, and what the possible problems are.

3. Market Access Problem of Licenses

In fact, the most painful part is... I do not want to give a figure, but we can say this: Of the licenses we have issued so far this year, fewer than half have been able to obtain a price. In other words, the licenses we issue cannot enter the market.

The issue of price is a separate matter. I am saying this independently of the other effects of it that we discussed earlier. As the Licensing Department, this also makes us think from our perspective: “Where are half of the licenses we have issued? What are we doing? How can we further regulate this area?”

As I said, you are right regarding price, SGK, and the remaining processes; I am saying this independently of that. But from our perspective as well, there is also a situation in which your and our joint effort does not turn into much output. Perhaps we need to sit down and discuss these together and review what we need to do.

LICENSING PRODUCTION AND STANDARDIZATION

İsmail ÖNCEL

Board Member of İEİS

I am the Chair of the Licensing Working Group of the Pharmaceutical Manufacturers Association of Türkiye (İEİS). We frequently hold meetings with our colleagues and licensing managers. I had previously presented the main difficulties and the issues raised by our colleagues in the sector to our esteemed President. Now I will briefly proceed from there, but before that, I would like to say something.





The Value of Licensing within the Pharmaceutical Industry

I have nearly half a century of experience in the pharmaceutical industry; in practice, coming from the ground up, together with my management and industrialist experience that I have continued to this day.

Pharmaceutical companies have two areas of activity: one is producing the medicine, and the other is producing the license. The process that begins with R&D and continues with license production ultimately ends with the actual production of the medicine. Producing the medicine is the result.

If you look at the balance sheets of pharmaceutical companies, there are fixed assets consisting of machinery, equipment, and the factory, and there are also the parts consisting of licenses/brands, which have the status of securities and represent the actual value. In the trade, partnerships, or sales of international companies with one another, they look at an existing factory, and they also look at the licenses you have. I can establish the factory; I can establish it in one to one and a half years. That is the easiest process, but until reaching that point, the process that begins with R&D and continues with license production is the part that requires the real effort. In my many years of experience, this is the most valuable part.

Now that most valuable part is also in the hands of TITCK, headed by our esteemed President. Our production is complete, and again it is in their hands, under their supervision and control, but it is very important and essential for us that our licenses are issued in a short time, that the problems we encounter there are resolved in a short time, and that results are reached through practical solutions.

Licensing Speed and Workload

Just now, Hakan Bey mentioned it, and truly, if it has come to this point, then woe to us. Five years for 2,000 licenses... In previous years, as our colleagues in the sector know, there was a year when this Agency issued 800 licenses. But this does not mean that it was done carelessly. There were processes that went through commissions in a similar current structure, underwent analyses, took concrete form, and resulted in licenses. When I think back over the last 10 years, if I am not mistaken, our average as a sector was around 600 to 700 licenses received from the Agency.

Now, Hakan Bey, for this reason, your benchmark should be above 600; it should be 600 if we take the average. If you spread 2,000 over 5 years, that is a very long period. Hopefully, it will not be this way.

Demand for Clarity in Guideline Standards

Now we have 2,000 applications in hand. The applications need to be accelerated. You mentioned it a little earlier, and our President also said it: Now, whom do we take as a guideline? We take EMA; if not EMA, we take FDA. When we cannot find it...

Now this needs to be clarified once and for all. In other words, if my guideline is EMA, then whatever EMA says, my Agency should request information from its sector or request EMA criteria in the standardization of licenses and in files.

We have encountered such things that we submitted the file, and the professor in the commission, seeing it almost as an opportunity to build a career there, asks a question from the Japanese pharmacopoeia. Then let questions come to us from every pharmacopoeia. In other words, if my guideline is EMA, then ask me from EMA. When you cannot find it there, ask from FDA. These need to be standardized.

Moderator: *We will operate the objection mechanism on this issue, and we will not directly submit the additional referee's writing as the commission's report; we will decide these matters in additional*

meetings rather than going into detail here. Now everyone here has been informed. Even if the person who wrote this is the President of TITCK, you will write an objection to anything that has no basis, and you will say: "This is a request outside the legislation presented to us and to which we are subject; we reject it." The mechanism related to this will operate; do not have any concern about that.

But President, do you know what happens here? The letter came, I objected, it came again. That is how those 60,000 correspondences are formed. So many unnecessary letters go back and forth... You look at it, all right, perhaps there are misunderstandings in companies as well, or incomplete information is provided, but there are also cases where the process is prolonged by questions from the Agency that have nothing to do with the matter. That filter there, in other words the process of objection coming and going, also needs to be eliminated. They can very easily reduce 60,000 to 30,000.

1. Requesting Draft Topics

Now, a second point: Information from the sector or certain supplementary items in the file are requested regarding issues that are still in draft form in authorities such as EMA and FDA and have not even entered into force yet. My guideline has not yet put this into force; it is in draft form. The commissions hear it from there and ask questions in this way.

Moderator: *What did we say on behalf of the Agency before you touched upon this? Commissions will not rule over TITCK; TITCK will rule in line with EMA. This is the same as the first item. We will consult on these... As I said, I am speaking a little from above; arrogance comes in, but as long as I am here, anyone who does this will never again be able to serve as a commission member.*

2. Demand for Accelerating Variation Processes

One important matter, in my opinion one of the sector's critical points, is this issue of variations. In variations as well, the variation processes need to be accelerated by taking the EMA criteria as the basis.

For example, there are so many variations... Let me give an example: We purchase raw materials from an Indian company, and the company changes its trade name. We change the documents. It is a very simple process; this is a commercial matter. The factory is the same factory. The trade name change documents have been submitted. Even this is subjected to a procedure as if it were a variation change in the synthesis method. Perhaps a distinction needs to be made there as well. In other words, administrative variations need to be handled quickly. Technical ones need to be handled separately.

Speaker (Hakan): *In fact, similarly, more than one of our teams handles variations. Administrative variations, yes, are sometimes distinguished from normal processes. It should be said that we shared our workload with you, but this was not in the sense of "this is our workload, what can we do?" This is our workload; you should also be aware of it, but it is still we and you who will solve this. We and you need to solve this together in some way. This is not acceptable for us either. That is why we are continuously working. This does not mean that we accept it.*

The reason we shared this was only to be able to tell you, even to some extent, what we are exposed to and what we are experiencing. Regarding these variations as well, we are reviewing the data we have. We will reassess according to them, but sometimes, due to the workload, even a short procedure can wait because it is waiting for the procedures ahead of it. But regarding this, we can meet with you again and discuss various alternatives together with our colleagues.

Dear Hakan, should I understand that we will also meet the EMA criteria for variations, or is this a long-term plan? Let's make sure we receive clear questions, friends. I'm not sure.

Moderator: *We will hold one more meeting, you know...*

All right. Then...



Moderator: But we will also make this final decision on a ship off the coast of Trabzon.

The length of these licensing periods... 210 days...

Moderator: 210 days is not realistic in the short term, and it is not the right term. We will do more than our best. We will also demonstrate this numerically. One of the ways to do this is to increase the number of commissions. It will divide the work, but we are still maintaining our limits. With the commissions in their current state... Why would you limit it to 40? Why not 100, why not 1,000? If the workload comes, if it is 20,000 instead of 2,000, when would you solve this with 40 commissions? Where were you when this decision was made? Why did you not say that this work cannot be done with 40 commissions? Would they not ask? Where were you when it was announced? Can this workload be carried with 40 people? Did you find me?

President, how many years ago was that? Türkiye is developing and growing.

Moderator: It is still in force.

Then it means the laws need to be renewed.

Moderator: You searched for EMA's criteria and found them... Could you not find that this cannot be done with 40 commissions? It means you are satisfied. Let mine go first. Why would you introduce a limit of 40 commissions? What harm would it do to anyone if there were 1,000 commissions? Thankfully, Türkiye has an academic pool. All academics are potential commission members. There are very strong people within TİTCK who know the administrative side.

Why did you not raise your voice when pharmacists were not assigned duties for whatever reason, when they were offended, and when this probably caused them to prepare reports slowly?

Because our ministers have always been physicians.

Moderator: It has nothing to do with that. The ministers are not aware of this. You did not notice this and did not bring it up. And more than 50% of the Agency consists of pharmacists. As the President of the Agency, I made a decision and said: "You receive a differential payment; you cannot serve on a commission." You say, "You limited the commission to 40. You are also saying that half of those inside cannot serve on commissions." If you had shared this, why did you not speak up? I am asking you. Either you will go and ensure that they are also paid, or give me courage, and then I will do it as well. "Tall people cannot serve on commissions." Who remains inside? Do you not know this? Well, do you not also consider the possibility that, because they are not included in commissions, they may become demoralized, slow down the work, and not write reports? Like the blind man eating double dolma, "I will do it if someone does this for me."

President, it seems the tender has fallen to us again.

Moderator: No, I mean if you do not deal with this root cause, EMA's part takes half an hour. I say I have banned it, and you will comply with this. Done. It only takes one instruction. But if I make the decision that the people who will write this report cannot serve on commissions, who will prepare these signatures? Will EMA come and prepare them? Has this been done here? Is this being implemented here?

We expect it from you, hopefully.

Moderator: You have no such request at all. Is it written on those yellow pages you are holding?

Yes, yes. We are hopefully expecting this from you, esteemed President. We are eagerly awaiting these

new commission efforts from esteemed President Ahmet Ayar Bey. We have written it here.

3. Integrity of Commission Processes

President, also regarding these commissions, I saw this in my notes here. For example, a question comes from bioequivalence. It comes from the bioequivalence commission, from pharmacology, and separately from the clinical side. These should be handled in an integrated...

Moderator: *I may not be giving the right answer, but you do not lose time because of that. Whatever is completed is given to you early so that multiple factors can proceed simultaneously. Ultimately, we get stuck at the place called technology. This is so that you are not disadvantaged by it. It does not seem to be against you. You are not happy with it, but instead of collecting all of them, instead of waiting, I think we send what comes in. It is not against you.*

Well, if it will be fast like this...

Moderator: *Faster. Because in the meantime, instead of standing idle, we send you one of the five factors so that you can work on it.*

Technical Demands of the Sector and Institutional Responses

Among the issues we previously presented was reducing the pilot study quantity for products with low batch sizes. For example, reducing it to 5,000 instead of 5,000 to 100,000. We had set certain criteria there. Especially recently, there are orphan medicines and cancer medicines. Each of these involves very expensive substances, and their annual consumption is not high. Their batch sizes are also very low. It would be beneficial for a criterion on these to be communicated to the sector through a study in line with our proposal.

Speaker (Mr. Hakan): *I believe this was also included and discussed in the notes of the sector consultation meeting in previous years. About three or four months ago, we established a team regarding this. They are working on this specifically within our own structure. I hope, with the permission of our President, that we will finalize it as soon as possible. We think it is reasonable and that your requests are meaningful.*

In line with technical proposals, we submitted our recommendations as the Pharmaceutical Manufacturers Association. We worked on it considerably before submitting it.

Moderator: *Will it be concluded soon? (Turning to Specialist Pharmacist Ömer Hakan ŞİMŞEK) We do not give a timetable except to the Minister. This has become something like “there is a fortune awaiting you within three times.”*

Institutional internal practices, as we have just mentioned, being shared clearly with the sector and shortening the time to enter a slot are among the requests coming from our colleagues.

A second issue is EKT practices. We postponed it, postponed it, and said, “We will put it into force on January 1, 2026.” But we still have companies that are not ready.

Moderator: *Have we taken our measures? Friends have worked on it. No grievance will arise in the market. We are aware of the situation. For a while longer, we will soon announce that both will continue together as a dual practice.*

All right, President. The issue of Phase 3 studies for biotechnology products has already been discussed a lot.

Moderator: *The Minister has already made the announcement regarding that. We are regulating the legislation. We are following EMA and FDA. Phase 3 clinical trials will not be mandatory, except for the exceptions that exist in science.*

There is also an important difficulty regarding license transfers.



Moderator: *It will be removed. Everyone with their own license...*

No, no. For example, I sold my license to a company. That company is now the new owner. As I said, a pharmaceutical license legally has the status of a security. I can sell it, I can transfer it. If there are deficiencies in this transferred license, there is the issue of those deficiencies being fulfilled by the new owner, that is, by the party acquiring the license. This is expressed as follows: There is a practice as if you will prepare everything, complete it, and then transfer it to the new company.

Moderator: *We will review that. There is a certain group of licenses in Türkiye; some of them have already had to be taken into scientific review during the objection process, and some of these are also sold through court proceedings. We will not be able to use a very generalizable statement here. There may be exceptions. We will review the situation so that what comes out of our mouth on behalf of the state does not bind us. But as for you, do not sell your licenses; keep them yourselves.*

No, it is like this: Company mergers take place. In those mergers, or partnerships, the transfer of the license becomes an issue. Even if it is not a very general problem, this does occur. The Quality Overall Summary should not be a prerequisite in license renewal. There is a Quality Overall Summary prerequisite.

Speaker (Mr. Bey): Quality Overall Summary (QOS) Requirement:

- The long duration of approval processes, that is, the request that submission of the Quality Overall Summary be made mandatory, is justified.
- License renewal is a very important issue in the world. With license renewal, we question the validity of the license after 5 years. In this regard, we conduct all evaluations again, as if issuing a new license.
- Here, we both question whether everything is up to date and whether the QOS, which is important in terms of quality, has been completed. Whether you have complied with all requirements, whether the file is complete or not, these are checked.
- Doing this only by looking at administrative information is not a very appropriate practice. Renewing a license by looking at a few CVs does not seem very logical to us. We are trying to implement the system applied around the world in the same way.

Moderator: *I think one of the problems there, in addition to submission, is that the approval period is very long. The approval results, these quality document processes, are probably submitted for approval first in license renewal. The long duration after approval... Renewal cannot be carried out, of course, if approval does not come from there.*

Speaker (Mr. Hakan): *I do not think there is a very critical delay there. They work quite well at the administrative stage, but we will review this again. Your problem regarding the overall duration is separate; it already exists, as I presented to you, but we are more comfortable in some areas at this point.*

Participant (TİTCK - Mr. Mesut): *Our colleagues in quality also evaluate technical variations. There is also a very heavy workload there. As far as I know, we have a separate team that prepares the Quality Overall Summary. Therefore, depending on the intensity there, delays may sometimes occur due to the file being heavy. If the file is incomplete, completion is requested. This can also lead to other variations. Ultimately, the prolongation of the matter is actually prolonged because of these. If the file is complete and the Quality Overall Summary has been fully completed, our colleagues issue it immediately after the review.*

These were my main headings.



Panel Closing and Commitments

Moderator: First of all, I would like to thank you for your constructive and developmental contribution. I thank you for your patience. We are obliged to fulfill the rules that bind us with a language and tone that supports you with empathy and understands you. We will pursue this path together. We have identified the points that are candidates for improvement, and we are solving them. We will hold another consultation meeting very soon to solve these points, on which you are right, together. We will also provide written answers to your written questions in a way that reaches everyone. By the end of the year, within a calendar, we will also hold a more focused meeting with the sector and sector representatives somewhere outside Ankara.

PARTICIPANT-1 (Question on the Start Time of Commissions): Esteemed President, thank you very much. You made very good explanations regarding the commissions a little earlier... but I think one thing was missing: When will they start? Because without them starting, it is truly not possible for the licensing period to progress.

Moderator: The evaluation of old files has slowed down, but it has never stopped. Ömer Hakan Bey will answer better regarding the start of new files.

Speaker (Mr. Hakan): We have brought our work to a certain stage. We also carried out software work in the meantime. Hopefully, within a period that is not very long, let me give a time frame of within 2 weeks.

Moderator: I will reduce that to one week. I will go and help him. Now...

Speaker (Mr. Hakan): In other words, within two weeks at the latest.

PARTICIPANT-2: (Question on Commission Memory): I wanted to ask about an issue I could not understand regarding the commissions. You stated that commissions would be formed randomly from a pool. After the first review of our files, if we receive deficiencies and submit our response, will they also carry out the second evaluation?

Moderator: They will do it again; it will have memory. Once a commission is assigned, it will continue with the file. "We will do this additionally..." If someone is lazy, comes without reading, acts carelessly, insists, and, despite being shown evidence, says "this bottle is full" to an empty bottle, they will not continue.

PARTICIPANT-2: (Question on the Implementation of the New Process): Will files whose licensing process has started but which have not yet been evaluated by any commission be affected by this new process? Or will it also be applied to them?

Moderator: It will also be applied to them.

TİTCK SECTOR CONSULTATION MEETING SUMMARY

SPEAKERS:



Prof. Dr. Ahmet AYAR
President of TİTCK – Turkish Medicines
and Medical Devices Agency



**Specialist Pharmacist
Ömer Hakan ŞİMŞEK**
Head of the Department of
Pharmaceutical Licensing, TİTCK
(TİTCK Practices and Innovations)



İsmail ÖNCEL
Board Member of İEİS (Sector View)

I. Evaluations of the TİTCK President (Prof. Dr. Ahmet AYAR) on Structural Problems and Solutions

Problems in Speed and Commission Structure

- **40-Commission Limitation:** The limitation of the number of commissions that will evaluate licensing files to 40 by Presidential Decree is the greatest speed-limiting factor. The aim is to remove this limit.
- **Motivation and Remuneration:** The lack of motivation among commission members and the fact that the 4,000 TL fee they receive does not correspond to the work are fundamental problems. Members should be motivated by being provided the maximum possible compensation.
- **Human Resources:** In order to accelerate the process, academics temporarily assigned from universities for 6 months or 1 year need to be recruited.
- **Role of the Commission:** Commissions will not dominate TİTCK; they will provide consultancy. TİTCK is a board that makes science-based decisions; it cannot make administrative decisions.

Ethical Risks and Dynamic Commission System

- **Risk:** Fixed commission membership lays the groundwork for unethical behavior, neighborhood pressure, and attrition.
- **Solution: The fixed commission practice has been abolished.** A draw will be made by random number from a pool of 600-1,600 people. Members' fatigue and arbitrariness will be prevented.
- **Transparency:** The computer records of the draw will be made available to those who request them.
- **Memory:** For files whose evaluation has started, the assigned commission will continue with the file and will have memory. Members who are lazy, careless, or act deliberately will be removed from the system.

Pricing System and Reference Pricing

- **Purpose:** The aim is to repair or rehabilitate the international reference system applied in Türkiye.
- **Principle:** In the medium and long term, medicine prices must be above a certain threshold for the sector to strengthen. Otherwise, this would be "cutting off the branch on which one sits."
- **Problem:** The current system leads to "patchwork" absurdities such as being unable to obtain a price from Greece and obtaining a price from Egypt instead, and it is disconnected from the international literature.
- **Risk:** If the reference system is not corrected and 158 new medicines arrive, the pharmaceutical budget and system may collapse.
- **Solution:** It has been proposed that the reference system be restored to its original form. The impact analysis has been shared with stakeholders.
- **Reassessment:** For conventional medicines, neither the 40% reassessment limit nor inflation should be taken into account; the starting point should be reset.

II. Digital Transformation in Licensing (Specialist Pharmacist Ömer Hakan ŞİMŞEK)

Digitalization and eCTD v4.0

- **Current Status:** The Agency has been accepting applications in PDF format in a paperless environment for 15 years.

- **New Phase (Digitalization):** The aim is to transform data not only as document images, but into machine-readable structured data.
- **Transition to eCTD v4.0:** The new standard is a requirement for this structured data. This transition is also seen as an opportunity to renew all business processes.
- **Timeline:** The technical development process, active development, will begin as of January 2026. Development will be carried out within the Agency in order to avoid dealing with integration.
- **Pilot Implementation:** Following technical development, pilot implementation will begin together with the sector.

Workload and Transparency

- **Workload:** An average of 60,000 letters are written annually, and nearly 20,000 variation applications are received. There are currently 2,100 licensing application files. It was stated that, at the current pace, these files could be completed in 5 years.
- **Transparency Steps:** As of August 1, a screen for viewing the processes of products has been opened as a beta test. This screen will be continuously developed to show the status of applications, commission order, and elapsed times more transparently.

III. Sector Views and Demands (İsmail ÖNCEL)

The Value of Licensing and the Need for Standardization

- **Legal Value of the License:** Licenses, independent of the factory, have the status of securities in companies' balance sheets and constitute the part that represents the actual value. Therefore, their issuance in a short time is essential.
- **Speed Expectation:** It was stated that the sector previously had an annual average of 600-700 licenses, and an increase in speed was requested.
- **Guideline Clarity:** It was requested that the Agency base its information requests on EMA criteria and avoid asking questions based on draft guidelines or irrelevant pharmacopoeias, such as the Japanese Pharmacopoeia. The Moderator guaranteed that such requests could be rejected through the objection mechanism.

Key Technical Demands

Topic	Sector's Demand	Agency's Response
Variations	Administrative variations, such as title changes, should be separated from technical variations and accelerated in line with EMA criteria.	The demand was found meaningful, and it was stated that the data would be reviewed and the matter would be discussed again with the sector.

Quality Overall Summary (QOS)	The issue of the long duration of QOS submission and approval in license renewal.	The requirement to submit QOS was defended on the grounds that an evaluation similar to a new licensing process is carried out to question the validity of the license, and that it would not be correct to look only at administrative information.
Low Batch Size	In low-consumption products such as orphan and cancer medicines, the pilot study quantity should be reduced, for example from 100,000 to 5,000.	The demand was found reasonable, and it was stated that a special team had been established on this issue and that it would be finalized as soon as possible.
Biotechnology Phase 3	Waiving the requirement.	It was confirmed that this had been announced at the Ministry level and that it would not be mandatory except for exceptions in science.
License Transfers	Deficiencies in the transferred license should be fulfilled by the new owner. The current practice requires the former owner to complete everything.	It was stated that the situation would be reviewed, but that a binding statement could not be made because the matter includes general exceptions such as sales through court proceedings.

IV. Closing and New Commitments

- **Speed Commitment:** Prof. Dr. Ahmet AYAR committed that the Department of Pharmaceutical Licensing would reduce the time for starting new files from two weeks to one week.
- **New Process Timeline** Specialist Pharmacist Ömer Hakan ŞİMŞEK stated that software work for the new random commission assignment mechanism was ongoing and that it would begin within two weeks at the latest, which was reduced to one week by the Moderator.
- **Emphasis on Root Cause:** The Moderator questioned why the sector had remained silent in the past regarding structural root causes such as “40 commissions” and demoralizing decisions such as pharmacists within the Agency not being able to serve on commissions.
- **New Consultation:** It was announced that another consultation meeting would be held very soon to resolve the points found justified. A more focused meeting outside Ankara is planned by the end of the year.
- **Written Responses:** Written responses will be provided to written questions in a way that reaches everyone.





METHODOLOGY

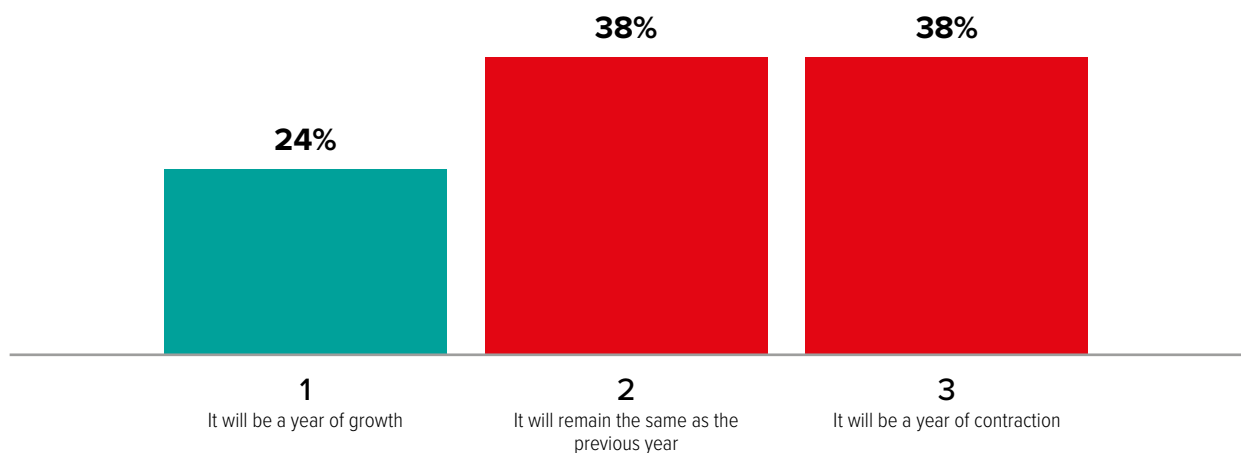
At the 43rd TÜSAP Vision Meeting, held under the theme of **“Strategic Issues in Biotechnology, Pharmaceuticals, and Next-Generation Therapies,”** opinion leaders representing the healthcare sector were asked questions related to the agenda. In a panel setting with two speakers representing the private and public sectors, the result graphs prepared based on the responses of more than 235 senior executives representing the public sector, NGOs, the private sector, and universities were again interpreted by the participants. NGO representatives constituted 17% of the participants, while public executives accounted for 32%. Private sector executives represented 21%, and universities focused on the field of health took their place with a share of 30%.

LOW LEVEL OF OPTIMISM FOR GROWTH IN 2025

Nearly three-quarters of the participants (76%) stated that, in 2025, the healthcare sector would either remain at the same level as the previous year or contract. The fact that expectations of contraction and remaining the same are equal reveals that there is serious uncertainty in the sector regarding growth potential.

1. What is your forecast for the healthcare sector in Türkiye for 2025?

1. It will be a year of growth
2. It will remain the same as the previous year
3. It will be a year of contraction

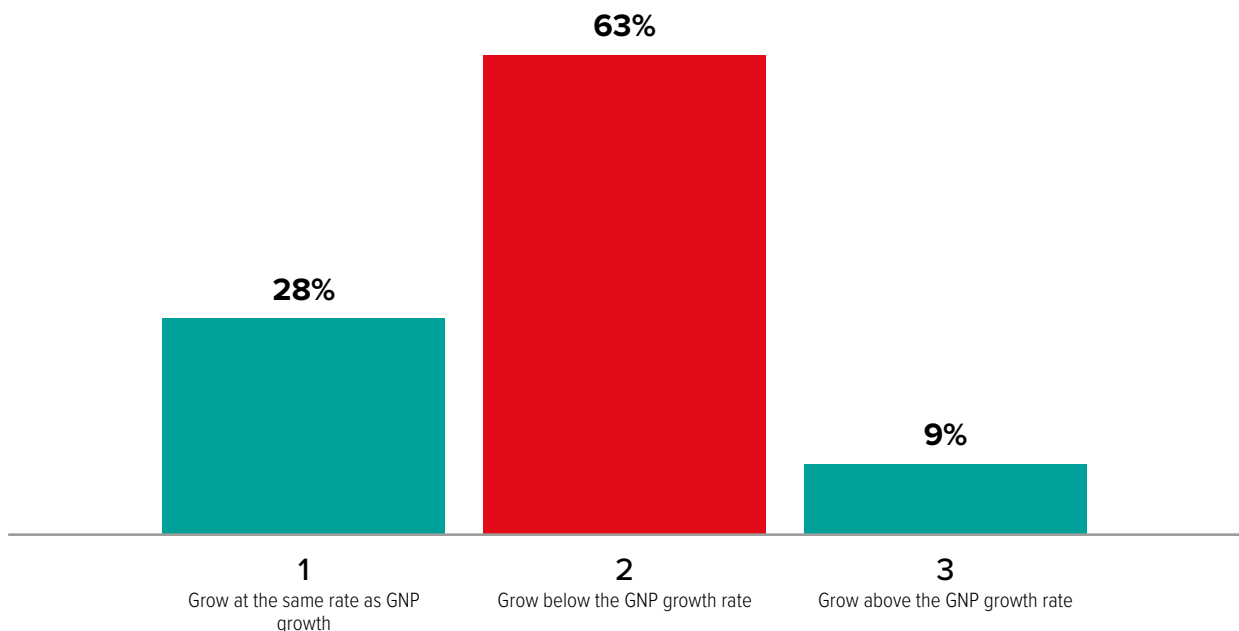


EXPECTATION THAT HEALTHCARE INVESTMENTS WILL LAG BEHIND ECONOMIC GROWTH

More than two-thirds of the participants (63%) foresee that investments in the healthcare sector will remain below the GNP growth rate over the next 5 years. This expectation indicates that investment appetite in the sector is low or that the current investment environment is having difficulty keeping pace with the overall speed of the economy.

2. For Türkiye, over the next 5 years, healthcare investments will:

1. Grow at the same rate as GNP growth
2. Grow below the GNP growth rate
3. Grow above the GNP growth rate

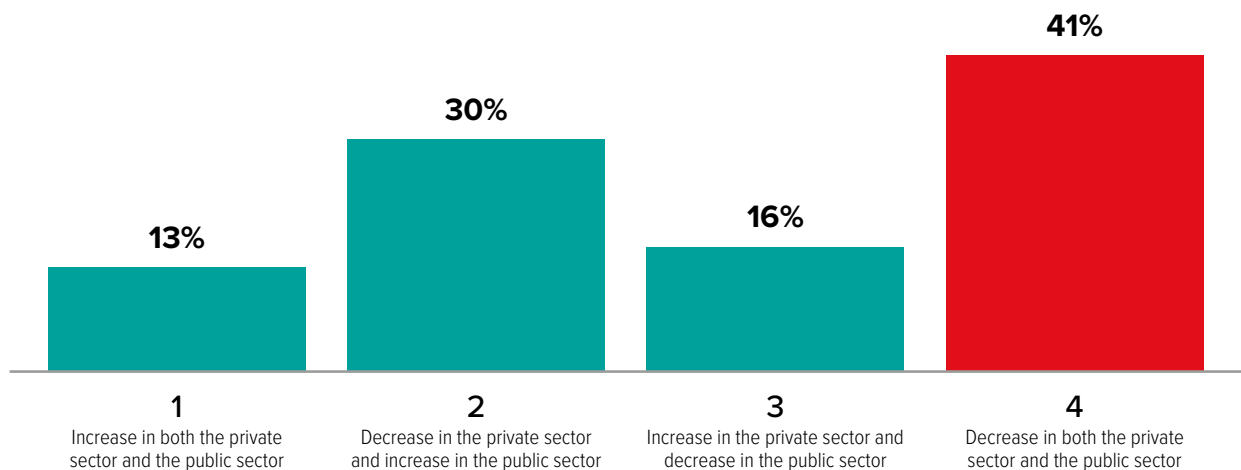


CONCERN OVER THE DECLINE IN PRIVATE SECTOR INVESTMENTS AND EMPHASIS ON THE PUBLIC SECTOR

While the largest share of participants (41%) expects a decline in both sectors, the second-highest rate (30%) foresees a decline in the private sector and an increase in the public sector. In total, 71% of participants share the expectation that private sector investments will be under pressure in the upcoming period. This situation points to a trend in which the investment burden in healthcare services will increasingly shift to the public sector, while the private sector will retreat under current economic conditions.

3. For Türkiye, over the next 5 years, healthcare investments will:

1. Increase in both the private sector and the public sector
2. Decrease in the private sector and increase in the public sector
3. Increase in the private sector and decrease in the public sector
4. Decrease in both the private sector and the public sector



IMPACT OF COST INCREASES ON SECTOR EXPECTATIONS

It was stated that, together with the low exchange rate and increasing costs, the rise in the costs of blue- and white-collar employees in the sector reflects the pessimistic picture. It was expressed that the sector is generally in a good position, but that the state should provide stronger support in terms of trade policy. In this context, the importance of increasing the current support rates to the level of 20-30% was emphasized.

NEED FOR AN EVALUATION OF THE HEALTHCARE SECTOR AS A WHOLE

It was stated that participants are in an environment of psychological pressure in which they remain under the shadow of pressures on pharmaceuticals and the exchange rate, and in which the entire healthcare sector is perceived as being reduced to these two elements. Drawing attention to the fact that the questions cover not only the pharmaceutical sector but the healthcare sector in general, it was emphasized that pharmaceutical expenditures actually have a limited share within healthcare expenditures. For this reason, it was stated that the impact of pharmaceuticals on total healthcare expenditure is not as high as assumed. Based on the experience of the last 22 years, it was expressed that there has been no year in which healthcare expenditures decreased, and that, when the current course is evaluated from a didactic perspective, it is expected to continue in a similar manner.

OPTIMISTIC EXPECTATION FOR GROWTH AND INCREASED INVESTMENT IN THE SECTOR

In the responses given to all three questions, a generally positive outlook was expressed. It was stated that the growth trend in the healthcare sector would continue and that investments would also increase in this direction.

PREVENTIVE HEALTH POLICIES AND STRENGTHENING SOCIAL AWARENESS

In addition to investment planning, it was stated that expanded newborn screening should be implemented rapidly for the healthy generations of the future to be raised. Attention was drawn to the importance of structuring national media and educational curricula in a way that raises awareness about rare diseases. The necessity of reducing consanguineous marriages through national media and television series and addressing preventive medicine more extensively at the societal level was emphasized. In this way, it was stated that fewer resources may be needed for pharmaceutical and healthcare investments in the future.



PREVENTIVE HEALTH POLICIES AND STRENGTHENING SOCIAL AWARENESS

In addition to investment planning, it was stated that expanded newborn screening should be implemented rapidly for the healthy generations of the future to be raised. Attention was drawn to the importance of structuring national media and educational curricula in a way that raises awareness about rare diseases. The necessity of reducing consanguineous marriages through national media and television series and addressing preventive medicine more extensively at the societal level was emphasized. In this way, it was stated that fewer resources may be needed for pharmaceutical and healthcare investments in the future.

THE NECESSITY OF INCREASED AND CONTINUOUS HEALTHCARE INVESTMENTS

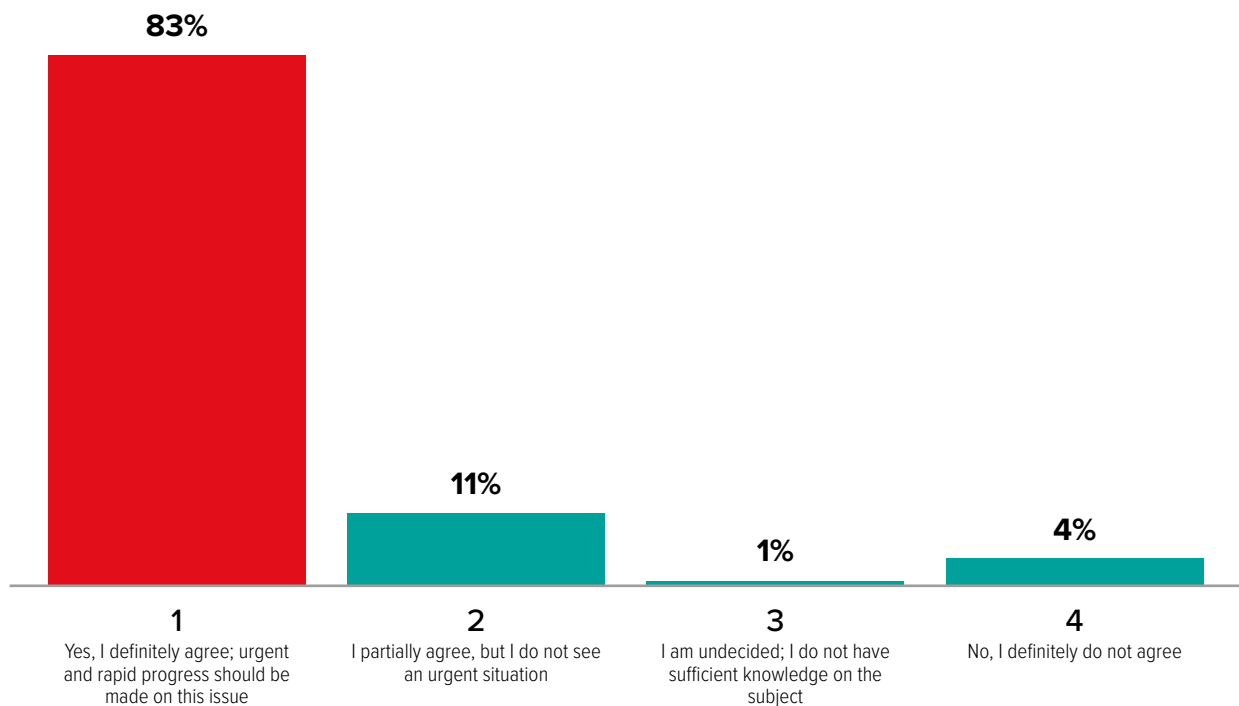
It was emphasized that healthcare investments in Türkiye should increase in both the public and private sectors over the next 5 years. Otherwise, it was stated that the meetings held to date, the awareness created, and the data presented would lose their meaning. It was noted that, in the event of a decline in private and public investments, there could be not only regression but also exits from the sector. It was expressed that sustainability would not be possible if only one reimbursement approval could be obtained for 15 license applications. Nevertheless, optimistic expectations were shared that budgets allocated to health would increase and that a better period would come.

STRONG CONSENSUS ON A STRATEGIC PRIORITY FOR BIOTECHNOLOGY

A very large majority of participants (83%) see biotechnological medicines as a strategic priority area requiring urgent action for Türkiye. This result shows that sector professionals share a strong vision regarding high value-added production, reducing external dependence in pharmaceuticals, and achieving a technological leap. Biotechnology stands out as the most critical and most widely agreed-upon area for the future of the sector.

4. Do you think biotechnological medicines are a strategic priority area for Türkiye?

1. Yes, I definitely agree; urgent and rapid progress should be made on this issue
2. I partially agree, but I do not see an urgent situation
3. I am undecided; I do not have sufficient knowledge on the subject
4. No, I definitely do not agree

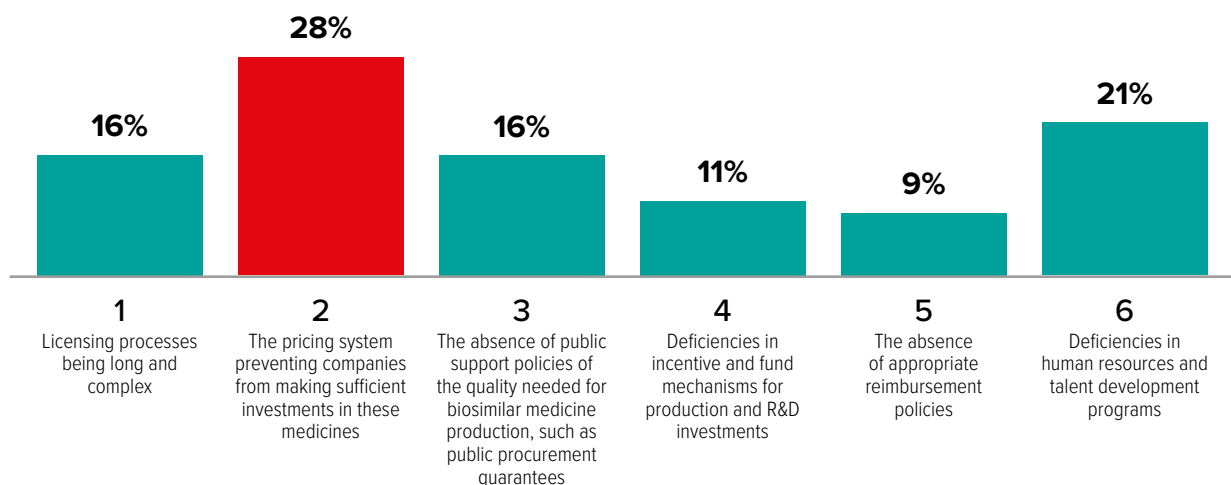


PRICING AND HUMAN RESOURCE BARRIERS IN BIOSIMILAR PRODUCTION

The Pricing System (28%) is identified as the main barrier to the insufficient development of biosimilar products. The second major barrier was stated as Human Resource Deficiencies (21%). In addition, the lack of Licensing and Public Support Policies also accounts for significant shares, each at 16%. This distribution shows that biosimilar development can be possible not only through R&D incentives, but also through a pricing mechanism that secures return on investment and the existence of a qualified pool of experts.

5. Despite R&D and production investments, what is the biggest barrier preventing a sufficient number of biosimilar products from emerging in our country?

1. Licensing processes being long and complex
2. The pricing system preventing companies from making sufficient investments in these medicines
3. The absence of public support policies of the quality needed for biosimilar medicine production, such as public procurement guarantees
4. Deficiencies in incentive and fund mechanisms for production and R&D investments
5. The absence of appropriate reimbursement policies
6. Deficiencies in human resources and talent development programs



UNCERTAINTY OF SUPPORT MECHANISMS IN BIOSIMILAR PRODUCTION

It was stated that public support policies of the quality required for biosimilar medicine production have still not been established and that this issue has been discussed for a long time. It was noted that there is no holistic mechanism regarding which public institution provides what type of support in which area. It was stated that a participant who invested in the field of biotechnology eight years ago observed Korea's success on site and conveyed that the Korean government provides 5 billion dollars of support to the biotechnology sector every year. It was expressed that Türkiye is not expected to allocate a budget on this scale, but that, under the current circumstances, even the amount of budget allocated by TÜSEB is not known within the sector. It was stated that, in its current form, the sector cannot progress only with promises and hopes, and that initiatives limited to individual efforts are not sustainable. It was emphasized that how much support will be provided at the R&D and production stages, when it will be provided, and through which methods should be clarified, and that multi-headedness should be eliminated.

It was stated that multi-headedness such as the Ministry of Industry, TÜBİTAK, support projects, and move projects should be eliminated, and that for biotechnology, a state institution, for example the Ministry of Treasury and Finance, could say, "I am in charge of the money, I am launching this, and the coordination of all of it will be under my responsibility." We do not know from whom we will receive what support.

LACK OF COORDINATION IN BIOTECHNOLOGY SUPPORTS

It was stated that the simultaneous implementation of many institutions and programs, such as the Ministry of Industry, TÜBİTAK, support projects, and move projects, causes serious multi-headedness in the sector. It was noted that this situation causes companies operating in the field of biotechnology to be unable to foresee from which institution and what type of support they can receive. In this context, it was emphasized that coordination in the field of biotechnology should be gathered under a single center. For example, it was expressed that the Ministry of Treasury and Finance managing the process from a single hand by saying, "I am in charge of the money, and coordination will be under my responsibility," could increase the effectiveness of supports and eliminate the current fragmented structure.

THE NECESSITY OF ACTIVATING PUBLIC SUPPORT POLICIES

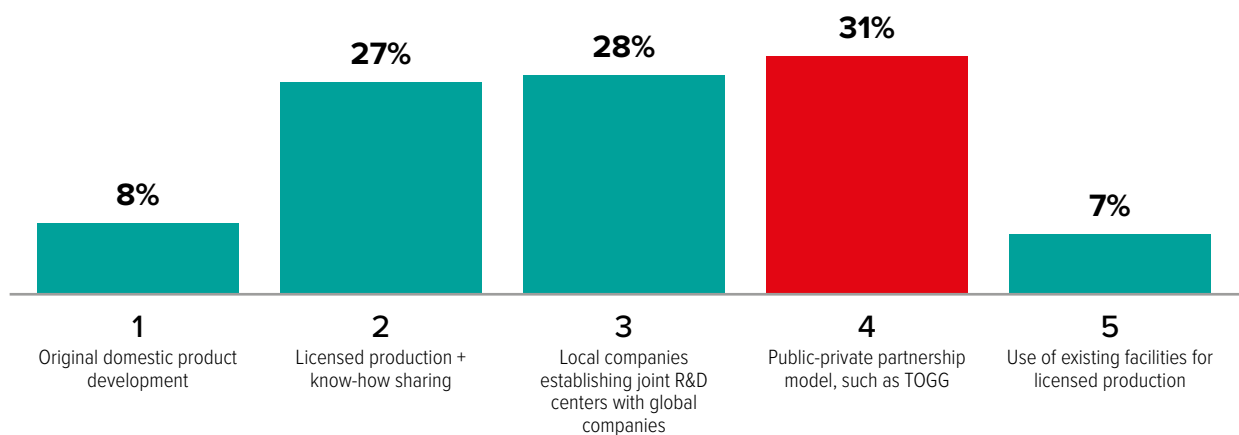
It was stated that there are currently investments of certain scales in Türkiye, but that activating public support policies is of great importance for these investments to be implemented effectively. It was emphasized that activating these policies would provide a general benefit not only in terms of the development of the sector, but also in terms of the national economy and social welfare.

CONFIDENCE IN THE PUBLIC-PRIVATE PARTNERSHIP MODEL IN BIOTECHNOLOGICAL PRODUCTION

Participants point to the Public-Private Partnership Model (31%) as the most effective strategy that will accelerate biotechnological medicine production. Joint R&D centers (28%) and licensed production (27%) also receive high levels of support. These data show that the sector believes a large, coordinated model supported by state assurance, combined with international collaborations, will deliver the fastest results. The long-term and risky path of original development receives the lowest preference.

6. Which of the following is the fastest and most effective strategy for biotechnological medicine production in Türkiye?

1. Original domestic product development
2. Licensed production + know-how sharing
3. Local companies establishing joint R&D centers with global companies
4. Public-private partnership model, such as TOGG
5. Use of existing facilities for licensed production



THE IMPORTANCE OF MODELS BASED ON PUBLIC-PRIVATE AND UNIVERSITY COLLABORATION

Within the framework of the public-private partnership model, it was stated that a structure similar to TOGG could also be implemented in the field of health. Referring to the importance of joint work among universities, the public sector, and the private sector, it was stated that intensive efforts are being made to establish a center in this direction at Marmara University Faculty of Pharmacy and that an important stage has been reached on this issue. It was emphasized that this meeting is an important step in shaping the vision for the future, and all stakeholders who contributed were thanked.

THE NEED FOR STRATEGIC GUIDANCE AND COORDINATION IN UNIVERSITY-INDUSTRY COLLABORATIONS

It was stated that university-industry collaborations have made significant progress compared to previous years, but that the outputs produced at universities should be managed not only with a publication-oriented approach, but also with product-oriented strategies. It was noted that start-up mechanisms and technoparks supporting this process have not been able to provide the desired efficiency due to the ineffective use of the existing infrastructure. It was expressed that universities have many laboratories and accredited centers, but that problems are experienced in the coordination and inventory management of these centers. It was emphasized that, instead of establishing new centers, a high potential could emerge if existing centers are developed and used more effectively. In this direction, recommendations were made to increase university-industry collaborations.

RECOMMENDATIONS ON INTELLECTUAL PROPERTY AND LICENSING MODELS IN UNIVERSITY-INDUSTRY COLLABORATIONS

It was stated that various difficulties are experienced in university-industry collaborations in terms of intellectual property rights, and therefore arrangements such as license partnership and license transfer could be beneficial for the ecosystem. It was noted that an exemplary model on this issue is being implemented at Erciyes University, where the university received an R&D investment and developed a product on behalf of the private sector, starting with license partnership in the process and later carrying out a license transfer. In this way, it was emphasized that both the university generated income and the developed product could be commercialized. Attention was drawn to the need to disseminate such models across the ecosystem and increase support that will encourage similar collaborations.

THE SUITABILITY OF A TOGG-LIKE MODEL IN THE PHARMACEUTICAL SECTOR WAS DISCUSSED

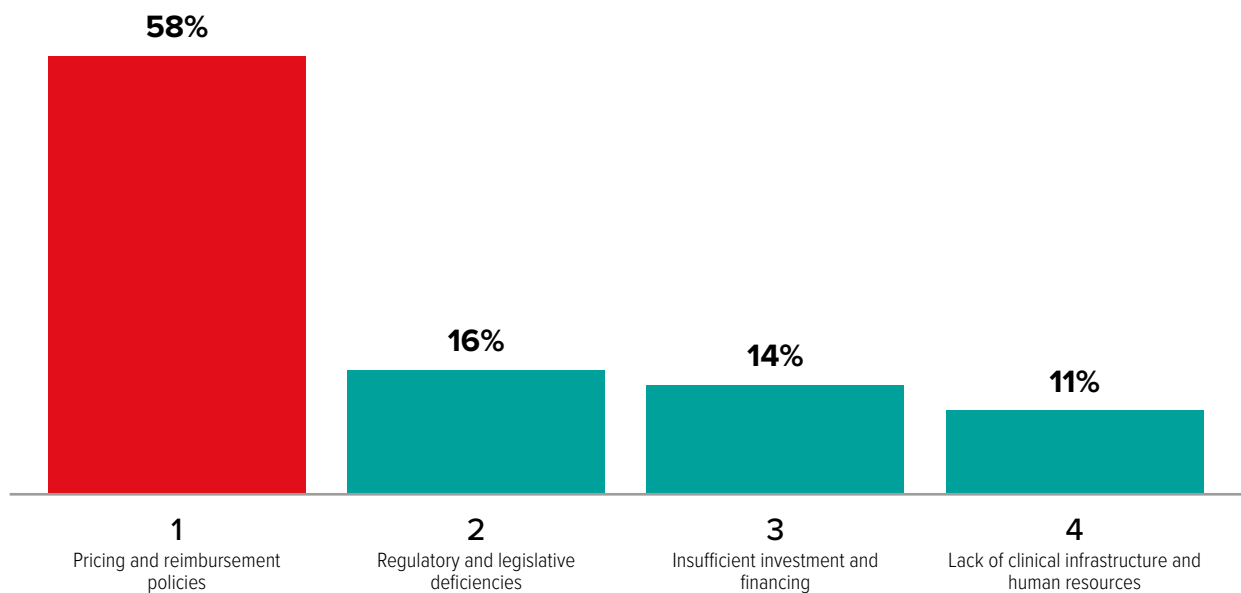
It was stated that a TOGG-like public-private partnership model is not viewed favorably, and that this model arose from the fact that there was no similar manufacturer in Türkiye at the time TOGG was established. However, it was noted that in the pharmaceutical sector, there are already many companies, factories, and production facilities, and therefore the main need in this field is not a new structure, but financial guarantee mechanisms that will enable the existing capacity to be used. It was emphasized that when this assurance is provided to the sector, production and investment processes will function on their own.

THE BIGGEST FINANCIAL BARRIER TO ACCESS TO NEXT-GENERATION THERAPIES

According to more than half of the participants (58%), the most critical barrier to the widespread use of next-generation therapies is Pricing and Reimbursement Policies. The inherently high cost of these therapies creates a major challenge for the sustainability of existing national reimbursement systems. Although other regulatory, financing, and infrastructure deficiencies are important, overcoming financial barriers is seen as the primary condition for access to these innovative therapies.

7. What is the most important barrier to the widespread use of next-generation therapies, such as gene, cell, and mRNA therapies, in Türkiye?

1. Pricing and reimbursement policies
2. Regulatory and legislative deficiencies
3. Insufficient investment and financing
4. Lack of clinical infrastructure and human resources



IT WAS EMPHASIZED THAT MEDICINE AND TECHNOLOGY SHOULD BE INTEGRATED IN NEXT-GENERATION THERAPIES

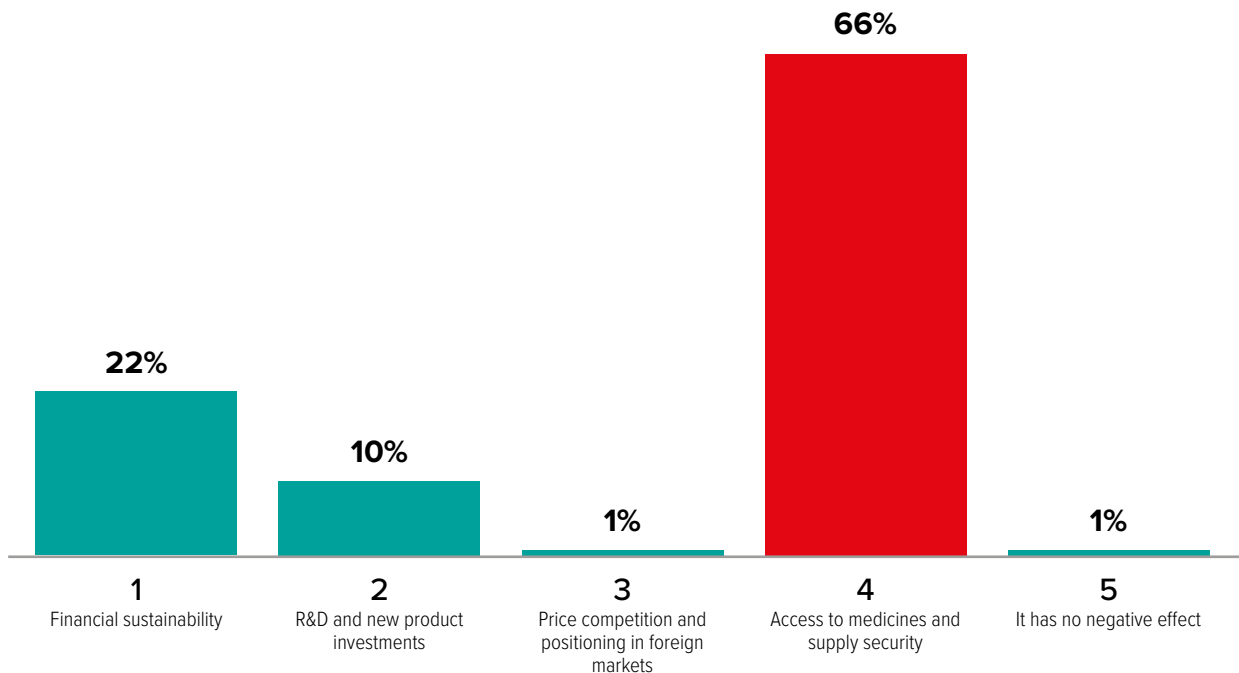
When evaluated from the perspective of companies that have cancer centers and operate in non-pharmaceutical fields, it was stated that treatment models in which medicine and technology are used together in next-generation approaches such as proton therapy, BNCT, or tenorsic therapies are not brought sufficiently onto the agenda. In this context, attention was drawn to the importance of sectors working together and evaluating technology and medicine jointly. It was stated that this holistic approach would make an important contribution to both reducing costs and increasing effectiveness in next-generation therapies.

THE DESTRUCTIVE EFFECT OF THE EXCHANGE RATE DIFFERENCE ON ACCESS TO MEDICINES AND SUPPLY SECURITY

The deepening gap between the pharmaceutical exchange rate and the current exchange rate creates pressure most strongly on Access to Medicines and Supply Security, according to two-thirds of the participants (66%). This finding shows that the sector is seriously concerned not only about its own financial losses, which rank second at 22%, but also about the potential adverse effects on public health. The exchange rate difference brings with it the risk of medicine shortages by making imports more difficult and disrupting supply.

8. In your opinion, in which area does the steadily increasing gap between the pharmaceutical exchange rate applicable in Türkiye and the current exchange rate create the greatest pressure?

1. Financial sustainability
2. R&D and new product investments
3. Price competition and positioning in foreign markets
4. Access to medicines and supply security
5. It has no negative effect

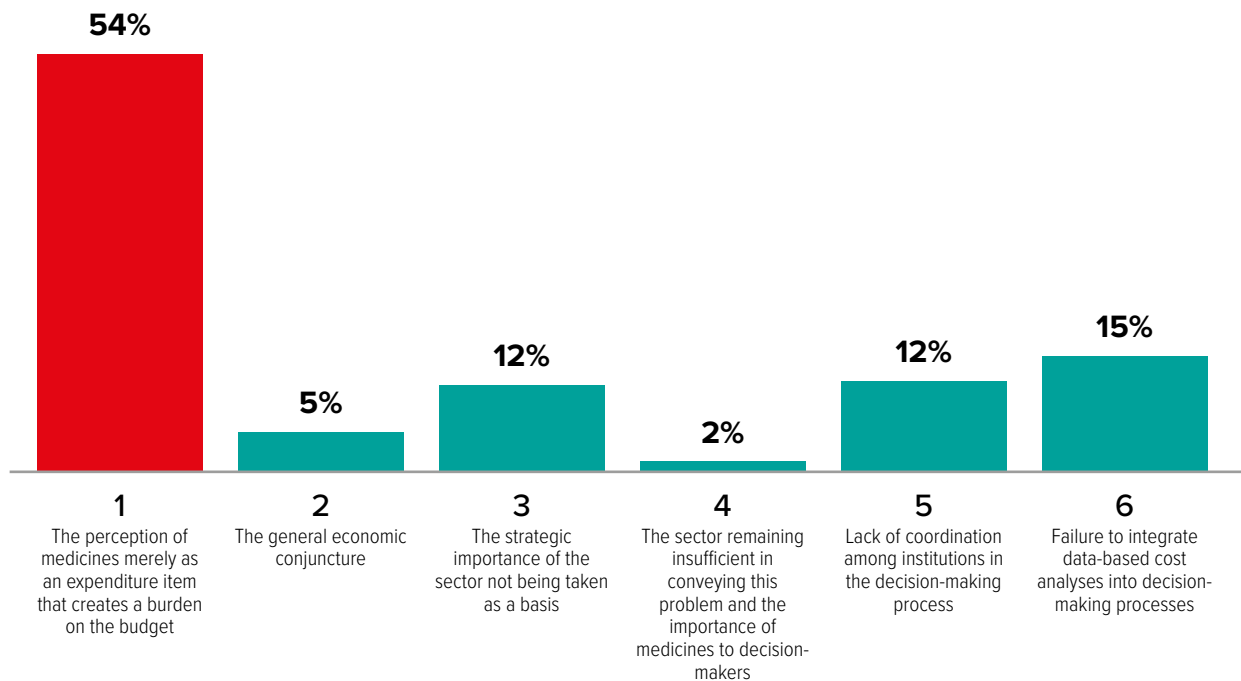


THE MAIN BARRIER IN THE PRICING PROBLEM: THE WAY MEDICINES ARE PERCEIVED

More than half of the participants (54%) see the perception of medicines merely as an expenditure item, that is, as a burden on the budget, as the biggest barrier to solving the medicine pricing problem. This result reveals that the root of the problem in the sector lies not in economic or technical details, but rather in the strategic and philosophical perspective toward medicines. The solution reinforces the expectation that the therapeutic and economic contribution of medicines should be seen as an investment.

9. What is the biggest barrier to solving the problem in medicine pricing in Türkiye?

1. The perception of medicines merely as an expenditure item that creates a burden on the budget
2. The general economic conjuncture
3. The strategic importance of the sector not being taken as a basis
4. The sector remaining insufficient in conveying this problem and the importance of medicines to decision-makers
5. Lack of coordination among institutions in the decision-making process
6. Failure to integrate data-based cost analyses into decision-making processes



ATTENTION WAS DRAWN TO THE LONG-STANDING PROBLEMS OF THE PHARMACEUTICAL SECTOR

It was stated that state officials also attended the meeting and that it was inevitable for the results shared to create discomfort. It was noted that the problems experienced in the pharmaceutical sector are not specific only to this year, but date back 6-7 years. It was expressed that the perspective toward medicines, rather than health, has gradually become more negative, and that this is clearly felt by the sector. Although it is hoped that the sector will transition to a trouble-free period in the near future, the impression was conveyed that current conditions make this transition difficult. It was emphasized that this meeting constituted an important opportunity to openly express the problems in question. In addition, it was stated that the sector has long been unable to obtain appointments from the competent authorities on this issue, that it only attracted attention for a while during the pandemic due to global medicine supply problems, but that, with the end of the pandemic, it was once again left to its own devices.

THE ESTABLISHMENT OF A HEALTH INDUSTRY PRESIDENCY WAS PROPOSED

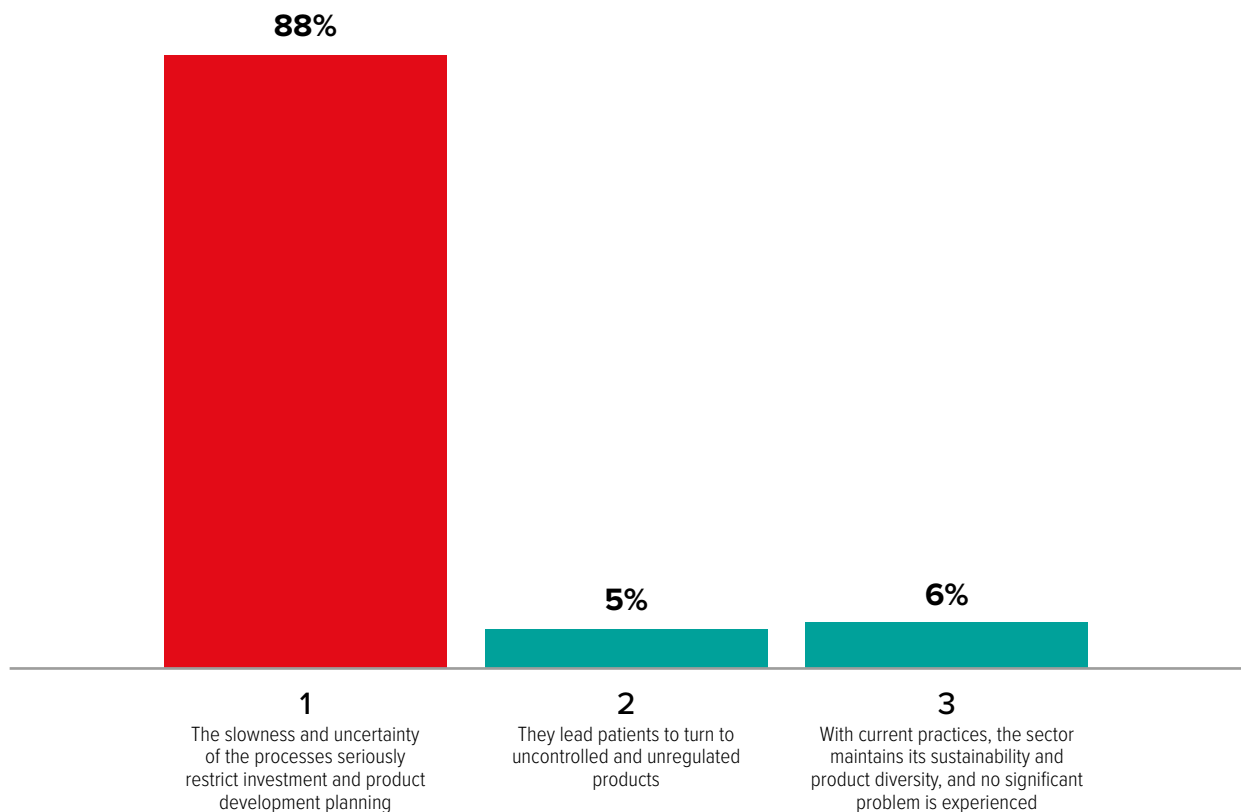
In response to the question of “how far this issue will go,” it was recalled that a similar process had been experienced in 1977. It was stated that, at that time, following prolonged negotiations between the Ministry of Finance and the Ministry of Health, medicine shortages began in the sector, and even aspirin became unavailable. It was emphasized that the necessary steps should be taken urgently in order not to reach the same point today. It was expressed that, for the problems to be solved permanently, the sector should be accepted as an interlocutor, it should be enabled to establish dialogue with its stakeholders, and a strategic structuring similar to that in the defense industry should be pursued. In this context, attention was drawn to the importance of establishing a structure under the name of the “Health Industry Presidency.” It was stated that this structure should include sector representatives, civil society organizations, the Ministries of Finance, Health, and Agriculture, and other relevant public institutions, and that the sector could regain strength by carrying out processes under this umbrella.

THE SLOWNESS AND UNCERTAINTY IN LICENSING PROCESSES RESTRICT INVESTMENTS

The overwhelming majority of participants (88%) state that the slowness and unpredictability of licensing processes most seriously restrict investment and product development planning. This represents the clearest bureaucratic barrier faced by the sector and the one with the strongest consensus. Accelerating these processes and increasing their transparency are seen as a critical way to increase the interest of both local and international investors in the Turkish market.

10. How do the current speed and predictability of licensing processes in Türkiye affect product development and market entry in the sector?

1. The slowness and uncertainty of the processes seriously restrict investment and product development planning
2. They lead patients to turn to uncontrolled and unregulated products
3. With current practices, the sector maintains its sustainability and product diversity, and no significant problem is experienced



IT WAS STATED THAT SLOW PROCESSES RESTRICT INVESTMENTS AND PRODUCT DEVELOPMENT

A common view was expressed that the slow progress of processes and the continuation of uncertainties seriously restrict investment and product development planning. The reasoning behind marking the option “They lead patients to turn to uncontrolled and unregulated products” was also opened for discussion. In this context, it was stated that 90-95% of pharmacy faculty students provide consultancy services to patients as healthcare professionals by opening pharmacies in Türkiye after graduation. Drawing attention to the professional value of these students, it was emphasized that otherwise the rate of uncontrolled product use could be much higher. In addition, it was stated that universities, as public institutions, could also cooperate with the sector specifically in the field of the pharmacy profession.





CLOSING SPEECH

Prof. Dr. Nurullah OKUMUŞ
Deputy Minister of Health

WE MUST ESTABLISH REGULATIONS THAT WILL MEET THE MEDICINE NEEDS OF OUR OWN CITIZENS

I would like to extend my thanks to all sector representatives, academics, and my valuable bureaucrat colleagues who are interested in this field and who participated in the 43rd TÜSAP Vision Meeting.

Frankly, I had some reservations before the meeting. I was curious about who would speak in this meeting and in what way, how the issues would be addressed, how the problems would be expressed, and what the answers given would be like. Because this is truly a difficult field.

I particularly want to state this; as they say, “being caught between a rock and a hard place.” Until about four months ago, I was on the side where you are, as a rector. The field of pharmaceuticals is an area in which I personally have a special interest. When opening the Faculty of Pharmacy at Afyonkarahisar Health Sciences University, I had made a promise to our President of the Council of Higher Education. I made considerable efforts for the faculty to be opened. At first, I received a “No” response; they said, “We already have many faculties of pharmacy, there is no need for a new one.” I insisted by saying, “I will train pharmacists, and I will create a qualified workforce in this field.”

Everyone says similar things, but most of the time these do not find a response. Faculties are opened, but many of our pharmacists cannot find sufficient employment opportunities in the field. We made a promise, insisted, and eventually opened our faculty. My esteemed professor is also here; approval had been obtained during his term, but permission had not been given for it to be opened. I had said, “I will train pharmacists who can work in every field and take part in every stage of pharmaceutical production.”

When we looked at the field, we saw that people who had truly received pharmacy education were not sufficiently involved in this area, or that they did not have the necessary knowledge on the subject. For this reason, we acted with the understanding that “we must train pharmacists who know and can

implement the entire process, from R&D to production, from legislation to licensing, and even to patents.” It was a difficult process, but we managed to open the Faculty of Pharmacy. By the grace of Allah, we carried out truly valuable work at our university.

Currently, at Afyonkarahisar Health Sciences University, a research complex consisting of approximately 16 separate laboratories, including cell culture laboratories where academics can actively conduct research, has been completed in a way that will serve preliminary pharmaceutical research and has become ready for opening. Interior furnishing works were ongoing. I believe it is currently one of Türkiye’s most comprehensive and most advanced technology facilities, established in cooperation with the Ministry of Industry and Technology with 50% grant support, including Bioequivalence / Bioavailability and Bioanalysis Phase 1 Clinics and laboratories.

The TİTCK team completed its inspections this week and gave the necessary approvals. If Allah permits, the license will also be obtained next week and the facility will begin service. We also established a pharmaceutical production facility within the university campus. At the very least, we wanted our students to be able to see the production processes of some simple medicines. Thus, a student entering the faculty of pharmacy will be able to participate in laboratory and R&D processes, observe Bioequivalence / Bioavailability analyses, and experience the production process.

Our aim was to train individuals who, when they graduate and enter the field, would be knowledgeable in this area and able to contribute to the sector. Because the sector is open to equipped and experienced people in this field. In this direction, we worked to create an education model that would contribute to the field. I would like to state once again that what I have described belongs to the period before I became Deputy Minister.

For this purpose, we submitted three pharmaceutical license applications. They were simple medicines; our only aim was for our students to be able to see the production process. However, due to legislation and bureaucratic processes, after three written and two verbal meetings, our right to obtain the license expired and we had to restart the process. In the first correspondence, four questions were asked; we answered them. In the second correspondence, five new questions came; we answered those as well. In the third correspondence, between 34 and 39 new questions came, and we had to stop the process. Frankly, I was surprised by this situation. Our aim was only for our students to be able to experience this process in a university environment. We had even included licensing, patents, and international licensing processes in our courses. Therefore, I know the difficulties experienced very closely. When I took office, I also conveyed to our President that these processes needed to be reviewed and improved.

Of course, this field is mainly under the responsibility of our TİTCK President, Mr. Şuayip Birinci, but I am also trying to contribute as much as I can. Most importantly, our Minister attaches great importance to this issue. Including the meeting held recently with the Ministry of Treasury and Finance, he gave a clear instruction in the direction of, “Citizens should not experience a shortage of medicines; they should be able to access medicines. I do not want to see a news story in the press saying ‘medicines cannot be found.’ Whatever the obstacles are regarding this, we will take every facilitating step in light of scientific data and in accordance with the law.”

Our Minister is ready to provide every kind of support to the sector, and therefore to the health of citizens. In this context, improvement efforts have been initiated and will continue.

For this reason, I would like to emphasize once again: We are in the same boat; when it takes on water, we all sink together. We will do our best for improvements in all processes such as pricing, sustainability, R&D, production, and licensing. We may have mistakes, shortcomings, or things we know incorrectly; however, when they are stated and when we are warned, we are always ready to correct them and do what is right. Do not forget that we are together with you and that we stand by you.



I truly love this sector; the fields of pharmaceuticals and biotechnology have always been special areas of interest for me. During my time at the university, I supported all work in this field, including medicinal aromatic plants. We carried out important projects on transforming traditional and complementary herbal products and medicinal aromatic plants used in the field into medicines. We were one of the universities in Türkiye providing the highest funding per research project. Our greatest advantage was that we were focused only on the field of health. Therefore, we directed all the income we obtained and our Scientific Research Projects resources largely to this field.

In this context, very valuable studies were carried out. During the pandemic, we were the only university conducting a Phase 3 clinical trial on ivermectin. As the only university conducting pharmaceutical research in Türkiye, this study attracted great interest worldwide and has now received more than 150 citations. This field is truly a passion for me, and I will continue to provide every contribution I can.

However, I would especially like to emphasize that there is very strong interest and support on this issue not only from me, but also from my Minister Şuayıp, our institution president, and especially our Minister. TİTCK is carrying out important work in this direction, and the necessary instructions have also been given. We, too, will continue to provide all the support we can in this process.

We also expect support from you. These processes are not always easy; changing legislation or established habits can take time. However, I believe that we can overcome these difficulties by working together.

I would also like to share a few thoughts that are in my heart here.

I believe we completed the European Union acquis on pharmaceuticals in 2017-2018. However, in the period after this, instead of following the regulations of EMA, FDA, Saudi Arabia, Japan, or China, we must now establish our own regulations. We should have a set of standards prepared together with our own scientists, pharmacists, and academics, in accordance with the needs and conditions of our country. Whether there are 10 rules or 100 rules does not matter; what matters is that these rules are determined within a framework that is specific to us and national. We must leave behind the approach of “I did not like it, let me look at the FDA; if that does not work, let me look at the EMA.”

We must establish regulations that will meet the medicine needs of our own citizens. Of course, manufacturers who want to sell medicines to countries such as Germany, China, Saudi Arabia, or Belgium must prepare files in compliance with the regulations of those countries. However, for our own domestic market, we must absolutely determine our own standards.

We need to nationalize in this regard. America has its own rules; we respect that. European Union countries are subject to EMA; we have no objection to that either. A manufacturer who wants to sell medicines there must of course comply with those rules. However, we are obliged to establish our own regulations in order to meet the medicine needs of our own citizens.

As I conclude my remarks, I would like to express once again my intention, request, and wish on this matter; I thank each and every one of you for your participation, and I also extend my special thanks to the organization team for their invitation.



TÜSAP EXECUTIVE BOARD

Prof. Dr. Kemal MEMİŞOĞLU, Minister of Health of the Republic of Türkiye

Assoc. Prof. Dr. Şuayip BİRİNCİ, Deputy Minister of the Ministry of Health of the Republic of Türkiye

Prof. Dr. Sabahattin AYDIN, Former Deputy Minister of the Ministry of Health of the Republic of Türkiye (Chair)

Op. Dr. Reşat BAHAT, President of OHSAD

Prof. Dr. Haluk ÖZSARI, Secretary General of the Association of University Hospitals

Assoc. Prof. Dr. Abdullah Emre GÜNER, Istanbul Provincial Health Director

Feyzullah AKBEN, Chairman of the Board of Satur

Savaş MALKOÇ, Secretary General of İEİS

T. Ufuk EREN, CEO of Volitan Global

PARTICIPANT PROFILE

At the 43rd TÜSAP Vision Meeting, held under the theme of “**Strategic Issues in Biotechnology, Pharmaceuticals, and Next-Generation Therapies,**” opinion leaders representing the healthcare sector were asked questions related to the agenda. In a panel setting with two speakers representing the private and public sectors, the result graphs prepared based on the responses of more than 235 senior executives representing the public sector, NGOs, the private sector, and universities were again interpreted by the participants. NGO representatives constituted 17% of the participants, while public executives accounted for 32%. Private sector executives represented 21%, and universities focused on the field of health took their place with a share of 30%.

TÜSAP Vision Meetings are held every year under 4 main headings: “Health Technologies,” “Healthcare Service Delivery,” “Pharmaceuticals and Pharmacy,” and “Health Financing.” Following these meetings, the meeting reports are generally evaluated through the TÜSAP Health Summit, and future projections in health are determined. The meetings are held only with the participation of invitees, and invitations are sent to relevant persons before the meeting. Corporate information about the TÜSAP Vision Meetings and the TÜSAP Summit, which are planned to be held simultaneously 4 times a year, can be accessed at www.tusap.org.

ABOUT TÜSAP

In rapidly changing conditions, sector stakeholders need to act with common wisdom in order to use limited resources efficiently and produce permanent solutions to problems for a sustainable and high-quality healthcare system.

Founded by the leading opinion leaders of the sector who came together with this idea, the TÜSAP Health Platform aims to hold vision discussions based on the current state of the sector and to produce qualified information that will affect the future of the sector.

Ensuring sustainability in healthcare service delivery, the value-based health system, increasing quality, the transition of the domestic medical and pharmaceutical industry to high value-added production, the steadily developing healthcare service delivery in our country, public health practices, and health financing are listed as important agenda items of the events that TÜSAP will regularly organize.

In these events, held under the name TÜSAP Vision Meetings in Health, mid- and senior-level executives from the public sector, civil society, and the private sector have the opportunity to directly share their views on the agenda with other participants. These views are shared with the participants themselves, the media, and the public through special reports prepared after each event.

The work carried out in these meetings, which are held four times a year, is re-evaluated with broader participation at the special event titled “Health Platform Summit” held at the end of each year, and is presented directly to representatives of the sector and other relevant institutions.

For more detailed information and participation in events, you can visit www.tusap.org.

HEALTH SECTOR LEADERS
OF TURKEY COME TOGETHER
FOR SUSTAINABLE HEALTH

VISION MEETINGS

2024 EVENTS



HEALTH PLATFORM SUMMIT

CONTACT

Executive Committee Secretariat

Satur®

Kore Şehitleri Cad. Yonca Apt. A Blok No:1/5

Zincirlikuyu / Şişli / İstanbul - TURKEY

Phone: +90212 272 61 06 Fax: +90212 272 61 07

bilgi@tusap.org

www.tusap.org

ISBN: 978-605-4123-88-9