Analysis of the Regulatory Conference of the Bulgarian Association for Drug Information, 04 June 2026, Sofia

Bulgarian Association for Drug Information
Regulatory Conference – The New EU Pharmaceutical Legislation
Sofia, Bulgaria, 4 June 2026

Lecturers and moderators of the conference on 4 June in Sofia, Bulgaria – The New EU Pharmaceutical Legislation

Sofia, Bulgaria, 4 June 2026

The conference brought together more than 95 specialists in the field of regulatory affairs, the pharmaceutical industry and healthcare to discuss the ongoing reform of the pharmaceutical legislation of the European Union. The main topics included the availability of medicines, innovation, the efficiency of regulatory processes, health technology assessment and precision medicine.

The event was organized by the Bulgarian Association for Drug Information (BADI) under the leadership of Prof. Tatyana Benisheva. The conference brought together leading European and Bulgarian experts who discussed the changing European regulatory environment and the future of the pharmaceutical sector.

The new EU pharmaceutical legislation aims to achieve a balance between innovation, patients' access to treatment, the sustainability of systems and the security of supply.

The most significant changes in the pharmaceutical sector were discussed:

✓ Preservation of the main incentives related to regulatory and market exclusivity
✓ New incentives for the repurposing of medicinal products and for the development of antibiotics, and the granting of vouchers worth millions of euros to the pharmaceutical industry,

which can be traded with other companies.
✓ Stricter environmental requirements (Environmental Risk Assessment – ERA)
✓ Simplified regulatory procedures
✓ Strengthened measures against antimicrobial resistance
✓ New tools for preventing shortages of medicinal products

Main highlights from the programme:

• Prof. Christa Wirthumer-Hoche, former Head of AGES, the Austrian Agency for Medicines and Medical Devices, and former Chair of the EMA Management Board, presented topics related to ensuring the supply of medicines in Europe, overcoming medicine shortages and strengthening the resilience of supply chains.

• Barbara Sickmüller, President of the German Association for Regulatory Affairs (DGRA) and expert at the Federal Association of the Pharmaceutical Industry (BPI), presented up-to-date information on the reform of EU pharmaceutical legislation and its impact on patients and industry.

• Dr. Birka Lehmann, former member of the EMA Paediatric Committee (PDCO), addressed the issues of regulatory data protection, market exclusivity and legislative changes affecting paediatric medicinal products and medicinal products for rare diseases.

• Mag. pharm. Lena Gebert, former expert at the Paul Ehrlich Institute (PEI), the main control authority in Germany and assessor of almost all biological products at EMA in the field of biological medicinal products and biosimilar medicines, presented aspects of regulatory decision-making and the assessment of comparability of monoclonal antibodies after changes in the manufacturing process.

• Prof. Ilko Getov, Chair of the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP), together with Boryana Ivanova, expert in health technology assessment (HTA) at the NCPRMP, presented the first joint clinical assessments under the new European HTA framework and their impact on access to innovative therapies.

• Prof. Harald Enzmann, former Chair of the EMA Committee for Medicinal Products for Human Use (CHMP), delivered a lecture on the role of biomarkers in precision medicine and the future of targeted therapies.

The conference, under the leadership and organization of Prof. T. Benisheva, DSc, provided valuable proactive knowledge and practical guidance regarding the development of the European regulatory environment and emphasized the importance of cooperation between regulatory authorities, the pharmaceutical industry, healthcare professionals and policymakers in ensuring patients' access to safe, effective and innovative medicinal products.

During their stay in Bulgaria, the lecturers also visited some of the emblematic tourist sites in the Gabrovo region, including Etara and Bozhentsi.

The programme covered the reform of European pharmaceutical legislation, the security of medicine supplies, regulatory data protection, market protection, changes concerning paediatric medicinal products and orphan medicines, HTA processes, biomarkers and regulatory requirements for biological medicinal products. The first two lectures outlined the main strategic framework of the conference and set the context for the other specialized topics.

Prof. Christa Wirthumer-Hoche

“Securing Europe’s Medicines – New Provisions”

The lecture by Prof. Christa Wirthumer-Hoche addressed one of the most important issues in contemporary European medicines policy: how Europe can ensure more reliable access to medicines in conditions of global manufacturing dependencies, supply chain crises and an increasing risk of shortages.

The main emphasis was that the security of medicine supply can no longer be viewed only as a logistical or commercial issue. It is becoming part of regulatory and public health responsibility. The presentation clearly showed that the new European framework is not based on a single act, but on several interconnected instruments:

• pharmaceutical legislation;
• the extended mandate of EMA;
• the Critical Medicines Act; and
• the European Health Data Space.

This structure aims to move the system from reaction after a shortage has occurred toward earlier forecasting, prevention and coordination.

A particularly important point was the discussion of the new obligations of marketing authorisation holders. These include earlier notification in cases of interruption or market withdrawal, 12 months, shortage prevention plans, shortage mitigation plans and greater responsibility for continuity of supply.

This demonstrates a serious change in the logic of European medicines policy: companies are no longer viewed only as applicants and marketing authorisation holders, but as active participants in the resilience of the healthcare system.

The lecture was particularly valuable because it did not present the reform as a guarantee that problems with shortages will disappear.

On the contrary, the message was realistic: the new instruments can make shortages rarer, more predictable and more manageable, but success will depend on implementation, coordination between Member States and the willingness of industry to work in a more transparent and responsible environment.

Prof. Dr. Barbara Sickmüller

“Current Changes in the EU Pharmaceutical Legislation – Update 2026”

The lecture by Prof. Dr. Barbara Sickmüller was one of the main highlights of the conference and provided a systematic analysis of the ongoing changes in European pharmaceutical legislation. She presented the reform not as a formal legislative change, but as a new balance between innovation, access to medicines, data protection, market protection, environmental requirements and regulatory efficiency.

Prof. Sickmüller examined the structure of the new legal framework, in which the dual system of a directive and a regulation is preserved, in total nearly 1,000 pages, as well as the dual system for marketing authorisation. She managed to systematize this information within almost one hour, which is an incredible advantage for the Bulgarian audience working in these areas of medicines, considering where they need to focus.

At the same time, the new regulation consolidates key existing regulations, including those on the centralized procedure, orphan medicines and paediatric medicinal products. This is an important element of the reform because it shows the aim of achieving greater coherence and a clearer regulatory architecture.

A substantial part of the analysis was devoted to regulatory data protection and market protection. The new approach was presented, under which the basic period of regulatory data protection remains 8 years, while market protection is modulated according to certain conditions. It is particularly important that an extension of protection may be linked to a new significant indication in an unmet medical need or to the conduct of clinical trials in the EU, with the total duration of the protection periods limited to 11 years.

Prof. Sickmüller paid special attention to the concept of unmet medical need, which has direct relevance to future incentives and market protection. The emphasis was on clinically significant improvement in efficacy or safety compared with existing products or methods. This is a key change because it directs incentives not only toward formal innovation, but toward demonstrable therapeutic value.

The lecture also addressed the topics of repurposing, orphan medicines, paediatric products, antimicrobial resistance, the transferable exclusivity voucher and Environmental Risk Assessment.

Incentives for priority antibiotics: Transferable Exclusivity Vouchers (TEV)

According to Chapter III, Articles 40–43a of the draft EU regulation, a new mechanism is introduced to encourage the development of priority antibiotics.

What is TEV? The Transferable Exclusivity Voucher (TEV), issued by the European Commission, provides:

• An additional 1 year of regulatory data protection.
• This additional year is not included in the maximum limit of 11 years of regulatory protection provided for in the legislation.

Who can use the voucher?

The Marketing Authorisation Holder (MAH) who has received the voucher may:

1. Use it for its own medicinal product; or
2. Sell or transfer it to another marketing authorisation holder in exchange for financial compensation.

Restrictions ("Blockbuster Clause")

TEV cannot be applied to a medicinal product that has achieved total sales of more than EUR 490 million. This restriction aims to prevent the use of the mechanism for the best-selling "blockbuster" medicines and to direct incentives toward products with higher public health value.

Purpose of the measure

The TEV mechanism aims to:

• stimulate investment in the development of new antibiotics;
• support the fight against antimicrobial resistance;
• provide an economic incentive for pharmaceutical companies in an area where return on investment is traditionally low.

Committees at EMA are being closed and only the Committee for Medicinal Products for Human Use (CHMP) and the Safety Committee PRAG remain. The other committees for paediatric medicines, herbal products and advanced therapies will be transformed into working groups and will meet depending on the relevant expertise of the working groups.

The analysis of the new Environmental Risk Assessment requirements had particular practical importance, including the possibility that an incomplete or insufficiently justified ERA may be grounds for refusal of a marketing authorisation.

The advantages of generics were also addressed, although indirectly.

This lecture had high value for the participants because it provided a working framework for understanding the reform: how developments will be planned, how incentives will be assessed, how added therapeutic value will be demonstrated and how the new rules will change market access strategies.

Dr. Birka Lehmann

“Regulatory Data Protection, Paediatric Medicinal Products and Orphan Medicinal Products – Changes in the New EU Legislation”

The lecture by Dr. Birka Lehmann continued the topic of the new European legislation, but with a more specific focus on regulatory data protection, paediatric medicinal products and orphan medicines. She examined the division between the regulation, which governs the scientific and administrative aspects, and the directive, which covers marketing authorisation, data protection, market protection and market exclusivity. The orphan status is reduced to 4 years in .

Particularly important was the analysis of the changing role of CHMP. Instead of sequential and fragmented procedures, the new framework is moving toward more integrated interaction, in which the paediatric and orphan aspects of medicines are considered earlier and more systematically in the product lifecycle. The practical value of the lecture was that it showed the need for companies to plan paediatric obligations and orphan strategies as early as the initial stages of development.

Data were also presented showing that nearly 25% of those that received orphan status for medicines for rare diseases reach marketing authorisation. Thus, according to the figures shown, less than 50% reach the Bulgarian market, given the low prices and the NHIF mechanism for reimbursement of new medicines. This concerns quite significant ethical aspects, since our patients cannot afford such therapies and finance them themselves, while on the other hand they simply do not reach our market, raising the question of the extent to which the ethical aspect concerning patients is observed.

Lena Gebert

Regulatory Decision-Making in
“Regulatory Decision-Making Process in the Assessment of Comparability of Monoclonal Antibodies after Changes in the Manufacturing Process”

Presented by Lena Gebert, who is a long-standing expert in medicines with extensive regulatory experience both in industry and at the regulatory authority, the Paul Ehrlich Institute.

The lecture by Lena Gebert examined regulatory decision-making in comparability assessments of monoclonal antibodies after changes in the manufacturing process. The topic is particularly important for biological products, where the manufacturing process is an inseparable part of the characteristics of the product.

The presentation showed that, when analytical and functional comparability is properly conducted, the regulatory decision can be scientifically justified without automatically requiring new clinical trials. The analysis reviewed 39 manufacturing changes, with no quality differences identified in 24 cases, while differences were found in 15 cases and were assessed individually according to their regulatory requirements.

The main value of the lecture was the practical distinction between the different types of evidence: analytical data, in vitro functional tests, mechanistic studies, historical clinical data and pharmacological traceability of medicines of biological origin. This gave participants a clear view of how "quality drift" is assessed in a real regulatory environment.

Prof. Ilko Getov and Boryana Ivanova

"First Joint Clinical Assessment under HTAR – The Role of NCPRMP in the EU Joint HTA Work"

The joint lecture by Prof. Ilko Getov and Boryana Ivanova placed the topic of HTAR in a direct national and practical context. It examined the first joint clinical assessment under Regulation 2021/2282 and the role of the NCPRMP in European HTA work.

The presentation emphasized the main principles of joint clinical assessments: common scientific and clinical aspects, quality and timeliness of reports, transparency, stakeholder involvement and a phased approach. Particularly important was the link between the European assessment and the national HTA process, including the preparation of PICO, the use of the IT platform and the subsequent application of JCA reports in national decisions.

The practical value of the lecture was that it showed how the European HTA framework will influence the work of companies and institutions in Bulgaria. HTAR was not presented as a distant administrative change, but as a real process that will change dossier preparation, interaction with institutions and market access planning. However, in reality reimbursement is a national procedure and each country will decide for itself what it will pay for, regardless of a positive HTA assessment.

Harald Enzmann

"Biomarkers as Prerequisite for Accurately Targeted Precision Medicines"

The lecture by Harald Enzmann examined the role of biomarkers as a basis for precision medicine and for the proper definition of the targeted patient population. The topic was presented not only as a scientific issue, but also as a regulatory and practical factor in the authorisation and use of medicinal products.

The presentation showed that biomarkers are increasingly becoming part of the regulatory definition itself of the indication of a medicinal product. This has direct relevance to clinical practice, companion diagnostics, reimbursement and the potential risk of off-label use. Particularly useful was the analysis of oncology therapies, in which biomarkers may determine both the inclusion and the exclusion of certain patient groups.

The lecture also raised future regulatory questions related to increasingly smaller target populations, tumor-agnostic indications, real-world clinical data and the need for marketing authorisations to adapt to new evidence.

Moderation and discussion

The moderators Prof. Tatyana Benisheva, Ekaterina Genova, Daniela Cherneva, Margarita Strokova and Radoslava Naydenova contributed to the clear structure of the event and to the professional conduct of the discussions. Their role was important because the programme included complex topics requiring a link between the European legislative perspective and the specific practical issues facing the Bulgarian pharmaceutical environment, and how they will actually work here, which was also the purpose of this event.

Overall assessment of the event on 4 June

BADI Regulatory Conference 2026 on 4 June was an event of high expert value and clear practical significance. The lectures by Prof. Christa Wirthumer-Hoche and Prof. Dr. Barbara Sickmüller had a strong regulatory focus in the programme, outlining the strategic and legislative framework of the European pharmaceutical reform for the coming years. The remaining lectures built upon this framework with specific regulatory and scientific analyses on paediatric and orphan products, biological medicinal products, HTA and biomarkers.

With the participation of around 95 professionals from regulatory institutions, the BDA, the NCPRMP, academic circles and industry, the conference confirmed the role of BADI as a platform for expert dialogue, professional training and exchange of knowledge in the field of medicines regulation. This is a unique platform in the Republic of Bulgaria.

The event provided current and applicable information on the changes that will shape the European pharmaceutical environment in the coming years.