

BADI 15th Anniversary Conference – Analytical Overview

Theme: “*Meet the Regulators*”

Date: 9 October 2025

Venue: Grand Hotel Millennium Sofia, DaVinci Hall

This year marks the 15th Anniversary of BADI, celebrated with the international conference “Meet the Regulators” on 9 October 2025, in Sofia. It brought together over 240 participants from Bulgaria and abroad – distinguished experts from EMA, BDA, BADI, DGRA, national authorities, academia, and the pharmaceutical industry. Many distinguished guests were invited like Ms. Emer Cooke, director of European Medicines Agency and MPharm Bogdan Kirilov, director of Bulgarian Drug Agency . BDA- (www.bda.bg) guests at the event of 15 anniversary of the Bulgarian Association for Drug Information (www.badibg.org).



At the It was amazing event, Ms. Emer Cooke said. (Director of European Medicines Agency) All information will be on the website in a special section - 15 Anniversary. We have to thank to many organisations, like the MoH, BDA, NCPR, NHIF, Medical University- Sofia, Mu- Sofia - Faculty of Pharmacy, MU-Sofia - Faculty of Public Health, BG Pharma, ARPharm, Bulgarian Pharmaceutical Union. They presented welcome speech and we congratulated the whole audience of 240 experts who attended the event. The program also featured thought-provoking contributions by Christa Wirthumer-Hoche, former Head of the Austrian Medicines and Medical Devices Agency and former Chair of the EMA Management Board and by you (Harald Enzmann , Head of EU and International Affairs at BfArM (Germany) and former Chair of CHMP; Barbara Sickmueller, President of the German Society for Regulatory Affairs (DGRA); Lubina Todorova, CHMP Member at EMA and Director of Marketing Authorisation at BDA; and Dean Denev, Executive Director of ARPharm Bulgaria.

Our moderators - Birka Lehmann; Dr. Ekaterina Genova; Brigitte Franke-Bray; Lena Gebert and Anne Louise Kirkegaard and Prof. Benisheva guided the sessions with insight and depth, bridging perspectives from regulatory agencies, academia, and industry.

Ms. Cooke was awarded with a plaque for "Exceptional Contribution to the Drug Regulatory Society in Bulgaria" by Prof. Tatyana Benisheva - President, Dobriana Sidgimova - Vice President and the board members Prof. Valentina Petkova, Daniela Cherneva PhD, Margarita Strokova, PhD. (Fig 1)

Ms Cooke was awarded with a plaque for "Exceptional Contribution to the Drug Regulatory Society in Bulgaria"



Fig 1 Award with a plaque for "Exceptional Contribution to the Drug Regulatory Society in Bulgaria for Ms. Cooke.

Introduction

The 15th Anniversary Conference of the **Bulgarian Association for Drug Information (BADI)**

marked a milestone in Bulgaria’s integration within the European regulatory ecosystem. Under the motto “*Meet the Regulators,*” the event gathered 240 senior representatives from the **European Medicines Agency (EMA), national authorities, industry associations, and academic partners and patient organisations,** reflecting the full spectrum of the EU’s pharmaceutical governance network.

The sessions traced the evolution of Bulgarian and European regulatory practice - from early national frameworks to today’s complex system integrating digitalization, innovation, and crisis resilience. The overall narrative highlighted **Bulgaria’s transformation** from a regulatory observer to an **active contributor** to European pharmaceutical policy and decision-making as Member of the European Union.

1. “15 Years of BADI: From Vision to Reality”

Prof. Benisheva’s opening keynote set a reflective yet forward-looking tone. She revisited BADI’s founding vision in 2010 - “*to connect science, regulation, and practice*” — and emphasized how, over fifteen years, this idea evolved into a **trusted professional community** linking regulators, industry experts (generic and innovative), academics, and healthcare professionals.

Her address reviewed the growth of BADI's activities: over hundreds (115+) of seminars, EU-aligned workshops, and partnerships with local institutions such as, BDA, NCPR, Medical University - Sofia, Faculty of Pharmacy and Faculty of Public Health and international organizations like DGRA, BFArM, AGES and IFAPP

BADI's mission has always been dual - to **build professional competence** in the drug regulatory field and to **serve as a bridge between EU drug regulatory policy and Bulgarian drug legislation implementation**.

She also reflected on the explosion of new EU regulations and directives post-2007 to 2025 the emergence of the **Pharmaceutical Strategy for Europe (2020)**, and the ongoing digital transformation of regulatory science.

Key insight: BADI now functions as Bulgaria's main hub for pharmaceutical regulatory dialogue and education - a structure built on consistency, inclusiveness, and European solidarity. BADI has more than 60+ industry members and 70+ individual members. It has published 147 bulletins annually and also keeps unique database with 14 Bulgarian health laws and their relevant regulations almost every month 14 or 4 weekly with integrated information from 10 official Bulgarian drug regulatory sources and 6 EU and worldwide (EC, EMA, ECDC, ICH, WHO, EDQM). This unique regulatory intelligence work which provide our member timely managed regulatory information.

2. Bogdan Kirilov – “The Bulgarian Drug Agency: Integration and Future Priorities” (Fig2)

Fig. 2 MPharm. Bogdan Kirilov congratulates the audience on 9th of October at 15 Anniversary of BADI (Grand Hotel Millennium – DaVinci Hall)



Executive Director **Bogdan Kirilov** presented a comprehensive overview of the **Bulgarian Drug Agency's (BDA)** strategic evolution and international positioning. From its early roots (Decree No. 218/1999) to full EU integration, the BDA has matured into a **recognized European**

regulatory authority and the role of BDA in Network of European Agencies. (Fig 3)

He underscored Bulgaria's progress as a **Reference Member State** in decentralized procedures (over 20 in 2023–2024), active participation in **EMA assessment teams**, and membership in the **Pharmaceutical Inspection Co-operation Scheme (PIC/S)** since 2023.

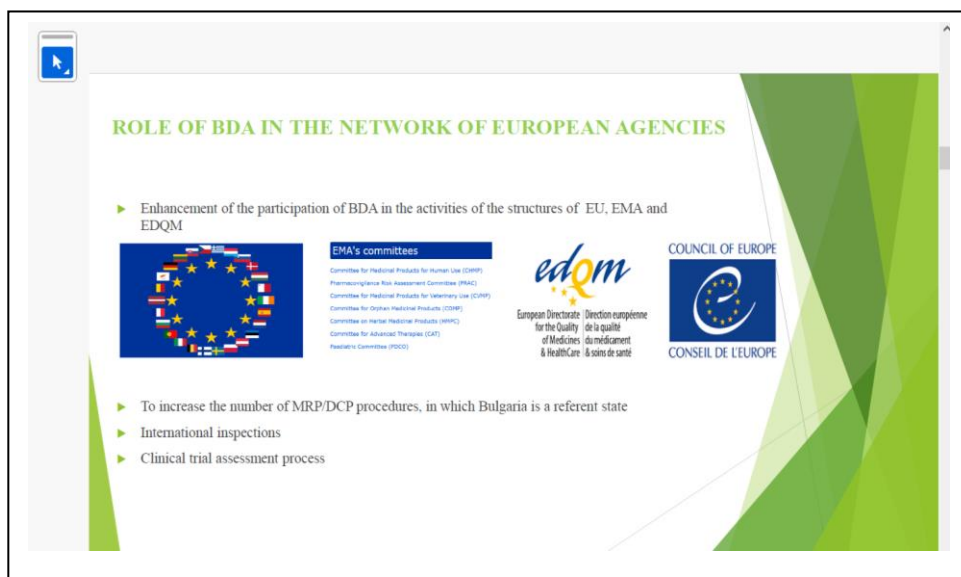


Fig. 3 BDA has matured into a recognized European regulatory authority and he role of BDA in Network of European Agencies.

The successful **BEMA V audit** reaffirmed the agency's quality management and contribution to the EU network of 79 authorities. Kirilov outlined six strategic priorities echoing the EMA's EMANS 2028 agenda:

1. Accessibility of medicines
2. Data, digitalization, and AI
3. Regulatory innovation
4. AMR preparedness
5. Security of supply
6. Network sustainability

Key insight: Bulgaria has moved from regulatory alignment to strategic participation, shaping regional and EU-level pharmaceutical governance.

The BDA's capacity is constrained, handling several international reference procedures annually. The director stressed out that many well-trained specialists eventually move to the pharmaceutical industry for higher remuneration. Retaining expertise in the public sector is now a strategic priority for sustaining Bulgaria's growing regulatory role.

The BDA's activities align with Europe's broader priorities:

- **Accessibility** through the **Specialized Electronic System (SESPA)**

for Monitoring and Analysis of Medicinal Products included in the Positive Drug List, which try ensures transparency, traceability and evidence-based market management.

Antimicrobial resistance (AMR) where progress includes electronic prescriptions, tighter pharmacy control, vaccination campaigns and public awareness initiatives

Kirilov also commented on the growing role of artificial intelligence in the drug regulation area. Although personally cautious about its widespread adoption, he acknowledged that AI represents the future of efficient, data-driven regulatory processes, pharmacovigilance and quality oversight

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- **Verification** where Bulgaria rdemonstrating strong compliance with European safety measures
 - **Digitalization** accelerated by the COVID-19 pandemic, enabling more efficient workflows, data exchange and automation

3. Emer Cooke – “Seizing Opportunities in a Changing Medicines Landscape”

Emer Cooke, Executive Director of the **EMA**, offered a panoramic view of the Agency’s **30-year evolution** and its upcoming transformation. (Fig 4)



Fig. 4 Panoramic view of the Agency’s 30-year evolution and its upcoming transformation.

Her presentation outlined EMA’s shift toward a **data-driven, digitally empowered authority**, structured around six priorities: (Fig. 5)

- **accessibility,**
- **AI and digitalization,**
- **regulatory science and competitiveness,**
- **antimicrobial resistance,**
- **availability and supply, and**

- **network sustainability. (Fig 5)**

Ms. Cooke also discussed **EMA’s engagement with EU Biotech Hubs**, a pilot initiative, aimed at supporting early-stage biotechnology companies that often lack awareness of regulatory requirements. By fostering this dialogue, EMA helps innovators integrate regulatory science early in product development, reducing delays and market access barriers.

The concept of **Regulatory Sandbox**, a controlled testing environment where novel technologies can be evaluated safely before formal implementation of every drug.

Ms. Cooke commented the European regulatory practice and ensure that the system remains adaptive and felexible to digital innovation.

She discussed ongoing revision of **the EU pharmaceutical legislation** which presents a unique opportunity to make Europe more attractive to innovation, Simplifying procedures, reducing administrative burdens and reinforcing trust in science will remain as key points.

She demonstrated how new tools - such as **Scientific Explorer (AI for regulatory data)** and **Collabor RARE (rare diseases platform)** - are streamlining decision-making and evidence review. Cooke also showcased the EMA’s new role in **fostering innovation ecosystems** through biotech clusters in Leiden, Berlin, and Flanders.



Fig. 5 Priorities of EMA

Key insight: The EMA’s modernization aims to shorten the innovation-to-patient timeline and make Europe globally competitive again by merging regulatory excellence with digital intelligence.

4. Dr. Christa Wirthumer-Hoche – “Will the New Pharma Legislation Solve Europe’s Challenges?”

Dr. Wirthumer-Hoche provided a detailed and highly structured analysis of the **EU Pharmaceutical Package (2023–2025)** and the **Critical Medicines Act (CMA)**.

She identified the EU's persistent challenges: shortages, supply dependency on Asia, low competitiveness, and the need for AI and data-based regulation.

The new framework introduces:

- Mandatory **shortage prevention plans** and **early notification** systems.
- A **Critical Medicines List** tied to coordinated EU-level procurement.
- The **European Health Data Space (EHDS)**, which will enable real-time data sharing for forecasting and research.

Her presentation emphasized the complementarity between the **Pharma Review (regulatory structure)** and **CMA (policy execution)** — one providing monitoring and obligations, the other mobilizing investment and manufacturing resilience. •

Dr. Wirthumer-Hoche discussed the broader **worksharing mechanisms** such as joint assessments of Active Substance Master Files (ASMF) to support smaller national agencies like Bulgaria's A new **ASMF certification system**, valid across the EU and managed by the EMA, is expected to simplify quality assessment procedures and reduce duplication of work.

Wirthumer-Hoche also discussed AI's emerging role in regulation, highlighting its potential to automate product information preparation, forecast supply disruptions, optimize stock management and enable risk-based inspections. However, she emphasized the importance of ethical frameworks

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Use of artificial intelligence (AI) in the medicinal product lifecycle

- **Artificial intelligence (AI)** - key to leveraging large volumes of regulatory and health data.
 - In the lifecycle of medicinal products, including medicinal products development, authorisation, and post-authorisation
 - Encourage research and innovation
 - Support **regulatory decision-making** for safe, effective and high-quality medicines that reach patients faster.

[The use of Artificial Intelligence \(AI\) in the medicinal product lifecycle | European Medicines Agency \(EMA\)](#)

- Guiding principles
- Covers the following principles and recommendations on the use of large language models:
 - Ensuring safe input of data
 - Applying critical thinking and cross-checking outputs

9 September 2024
EMA/COMPARISON/REG/1812/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Fig 6. Use of AI in the medical product lifecycle

and guiding principles for responsible AI use in the regulatory environment. (Fig 6)

Key insight: The new legislation is Europe’s first serious attempt to achieve “pharmaceutical sovereignty” — by merging regulatory robustness, industrial policy, and digital capacity.

5. Deyan Denev – “Europe’s Competitiveness and the Innovation Gap”

Speaking on behalf of ARPharM, Mr. Denev delivered a dynamic industry viewpoint focused on the **erosion of Europe’s innovation leadership**.

He presented compelling statistics:

- Europe now accounts for only **22% of global new treatments**, compared to **48% in the U.S. (Fig. 7)**
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- Average approval times in the EU reach **426 days** — nearly double those in the U.S.
- The **R&D investment gap** between the EU and U.S. exceeds **€25 billion annually**.

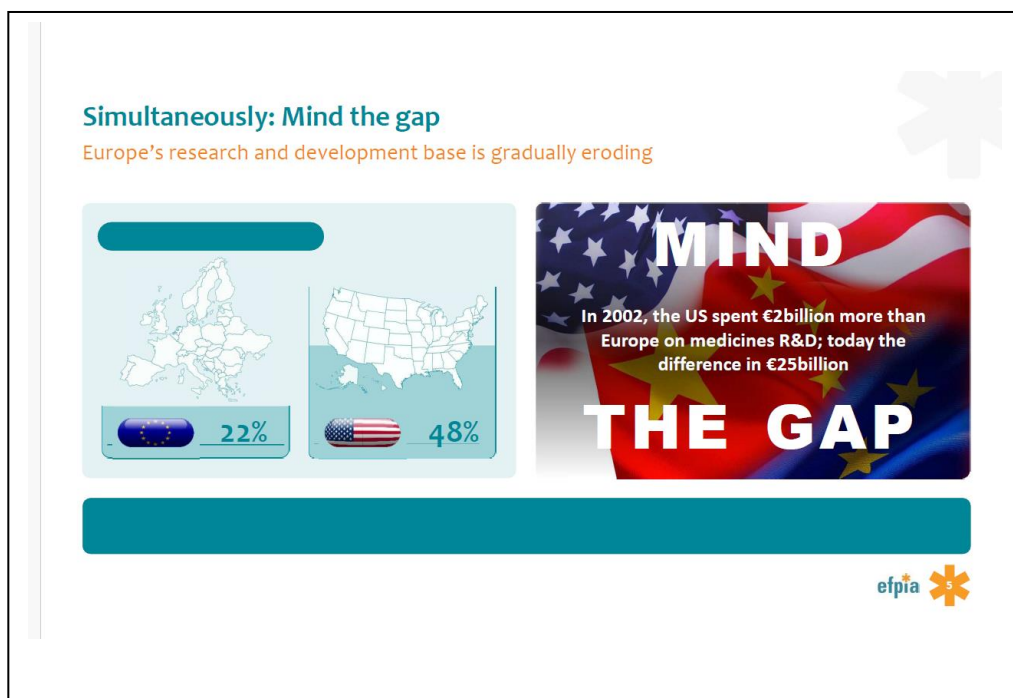


Fig 7. Europe now accounts for only 22% of global new treatments, compared to 48% in the U.S. (Fig. 7)

Denev argued that reducing **Regulatory Data Protection (RDP)** would

further weaken Europe’s competitiveness and disincentivize R&D. He urged policymakers to preserve robust intellectual property protections and a predictable regulatory climate.

Key insight: Europe’s innovation ecosystem hinges on maintaining strong incentives and faster access pathways — otherwise, it risks falling irreversibly behind.

6. Prof. Dr. Barbara Sickmüller – “DGRA and BADI: A Shared Academic Legacy”

Representing Germany’s **DGRA**, Prof. Sickmüller delivered a personal and institutional tribute to the long partnership between DGRA and BADI.

She recalled how **Prof. Tatiana Benisheva’s MDRA studies in Bonn (2004–2005)** inspired the founding of DGRA. The DGRA, established in 1999, now counts over 1,100 members and continues to champion education in regulatory affairs through its **Master’s Program in Drug Regulatory Affairs (University of Bonn)**. (Fig 8)



Fig 8. Master’s Program in Drug Regulatory Affairs (Benisheva with her classmates at the University of Bonn).

Both organizations, she noted, share a mission to **advance regulatory science through education, research, and professional networking**.

Key insight: Education and mentorship remain the backbone of European regulatory excellence - and BADI’s origins are deeply rooted in this cross-border academic cooperation.

7. Prof. Dr. Barbara Sickmüller – “Technical Aspects of the EU Pharma Reform”

In a more technical session, Prof. Sickmüller examined key provisions of the new **EU Regulation and Directive (2023–2025)**:

- **Regulatory Data Protection (RDP):** 8 years baseline, +1 via transferable exclusivity vouchers.
- **Market Protection:** base 1 year, extendable for innovation or EU-first submission.

- **Orphan Market Exclusivity:** up to 12 years for multiple orphan indications.
- **Paediatric development:** simplified PIPs and continued SPC extensions.
- **AMR incentives:** tighter use of transferable vouchers.

Repurposing: 4 years of new protection for established substances. She also emphasized **regulatory sandboxes** for novel therapies and **parallel trade controls** to prevent shortages. Sickmueller also emphasized the importance of **drug repurposing**, developing new therapeutic uses for known substances as a strategic opportunity to improve patient access and reduce costs. (Fig 9)

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Repurposing Art. 84 Draft Dir.

- **New indications** for medicines based on established active Substances: **Repurposing**
- **EU-Commission:** Proposal of RDP of 4 years, instead of actual 1 year (Art. 10 (5) Dir. 2001/83/EC), provided
 - appropriate non-clinical or clinical studies have been carried out with regard to the therapeutic indication and demonstrate that
 - the indication is of significant clinical benefit.
 - should be granted once for a specific product, provided
 - there was previously no RDP for the medicinal product or
 - 25 years have passed since the first approval of the drug in question was granted!
- **Council and EU-Parliament** adopted EU Commission proposals largely unchanged

10

She supported maintaining the existing structure of regulatory protection with eight years of data protection, two years of market protection and one year for a new indication. According to her, this model provides the stability required for sustainable innovation in the pharmaceutical industry.

Fig. 9 Repurposing for medicines based on established active substances

Key insight: The legislative reform balances innovation and public health, but medium-sized enterprises require clearer, more accessible incentives to remain competitive.

8. Dr. Harald Enzmann – “Benefit-Risk Assessment and HTA Convergence”

Dr. Enzmann, from the **Federal Institute for Drugs and Medical Devices (Germany)**, presented a rigorous methodological overview of **benefit-risk assessment (BRB)** and its interface with **Health Technology Assessment (HTA)**.

Using real case studies (Ibrutinib, Trodelvy®), he demonstrated how regulators quantify benefit and risk profiles and how such analyses feed into subsequent HTA evaluations.

He called for deeper integration between **regulatory and HTA frameworks**, arguing that fragmented evidence interpretation leads to access delays and inconsistent national decisions. The conclusion was as Regulators' benefit-risk assessment as contribution to subsequent HTA. (Fig 10)

Fig. 10 Regulators' benefit-risk assessment as contribution to subsequent HTA

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Wrap-up

Regulators' benefit-risk assessment as contribution to subsequent Health Technology Assessment

1. Unbiased conclusion of a positive benefit-risk balance
Usually based on clinical trials, not RWD
2. Description of benefits and risks
Usually based on clinical trials, not RWD
3. Different shades of "positive BRB" for subgroups
Allowing nuanced downstream decision
4. Contextualization of a new medicine
Better? As good as? We don't know yet?

Key insight: The future of medicine evaluation lies in early alignment between regulators and HTA bodies to ensure coherent, patient-centred outcomes.

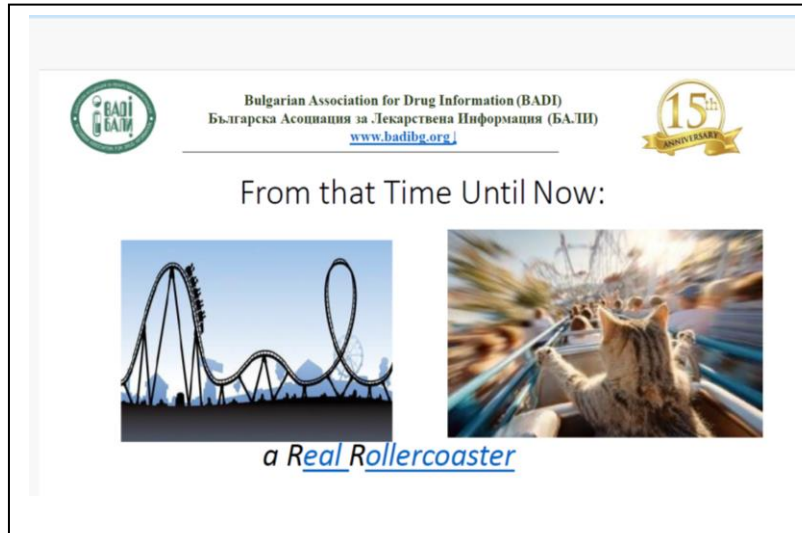
9. Assoc. Prof. Lyubina Todorova – “Regulatory Challenges After EU Accession”

Prof. Todorova provided an engaging historical retrospective, tracing Bulgaria's pharmaceutical oversight from **1904** to its EU integration.

She paid tribute to the pioneers of Bulgarian regulatory science — particularly **Prof. Radi Ovcharov**, founder of the **Drug Safety Centre (1974)** - and described the challenges faced by small teams harmonizing dossiers, adopting new procedures, and transitioning into the EU system after 2007.

Her narrative blended technical history with personal reflection, symbolizing the human dimension of Bulgaria's regulatory evolution.

She discussed the limited number of available reference procedure slots, issues with inconsistent applicant behavior and the workload challenges arising from new variation regulations.



While work-sharing mechanisms can reduce the burden on assessors, administrative teams face increasing responsibilities for validation and coordination.

Todorova's intervention reinforced a broader theme of the event that regulatory modernization must be realistic, inclusive and adequately resourced. She emphasized how

difficult was after the Bulgarian EU Entry, where there were more 800 marketing authorization procedures annually. She had done a metaphoric comparison with real Rollercoaster the period after BG joined the EU.

Key insight: Bulgaria's path from isolated national oversight to full EU integration was built on professional dedication and perseverance — an inspiring foundation for its future role in the European network.

Overall Conclusions

The BADI 15th Anniversary Conference was more than a commemoration — it served as a **strategic reflection point for the future of pharmaceutical regulation** in Europe.

Four key trends emerged across all presentations:

1. **Regulatory Evolution and Resilience:**

The EU's new legislative cycle emphasizes preparedness, diversification, and sovereignty in medicine supply chains.

2. **Innovation and Competitiveness:**

Maintaining Europe's scientific edge requires not only incentives but also faster regulatory processes and harmonized data use.

3. **Digital and Data-Driven Regulation:**

The European Health Data Space (EHDS) and AI-supported tools will reshape how evidence is generated, shared, and assessed.

4. **Education and Collaboration:**

BADI's partnership with DGRA and other European institutions illustrates that regulatory progress is ultimately built on continuous learning and trust.

Final Reflection of Prof. Benisheva

BADI's 15th Anniversary was not just a celebration of institutional success, but a **symbol of Bulgaria's full maturity within the European regulatory family.**

The event demonstrated how a national organization can evolve into a respected European partner — bridging academia, industry, and governance in pursuit of the same goal: **safe, effective, and accessible medicines for all European citizens.**

BADI's President **Prof. Tatyana Benisheva** closed the anniversary forum by underlining the association's enduring mission to act as a bridge between regulators, academia, pharmaceutical industry and patient organisations. For 15 years, BADI has been a key organisation in cultivating regulatory expertise, ensuring that Bulgaria remains a respected contributor to the European regulatory community.

Artificial intelligence, data transparency and digital workflows are redefining not only efficiency but also trust among all stakeholders. The real challenge is to use these tools wisely to serve both innovation

and public health.

The 15th anniversary of BADI was not just a look back in the drug regulatory field but a bold vision forward, what will be next.

As EU redefines its pharmaceutical legislation and regulatory strategies, Bulgaria stands ready to contribute in the drug regulatory field.

The country's has growing role in the drug regulatory affairs, like pharmacovigilance and digital transformation of better, more equitable healthcare for all. Many challenges still remain but that will one of the mission of the BADI like an organization to gather all stakeholders in order to solve them step by step.

Appreciation to Our Sponsors and Partners



Looking to the Future 

- The challenges ahead are many:
- rapid scientific **innovation, (AI)**
- evolving regulations,
- growing expectations from patients and society.
- to continue shaping the conversation
- inspiring progress
- and our Motto is **Building capacity for the next generation of professionals.**

The Organizing Committee extends its heartfelt appreciation to all sponsors and partners for their invaluable support and contribution to the success of this event.

Your trust, engagement, and commitment have made it possible for the 15th Anniversary of the Bulgarian Association for Medicinal Information to be celebrated with excellence, professionalism, and shared vision for the future of pharmaceutical regulation and innovation.

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