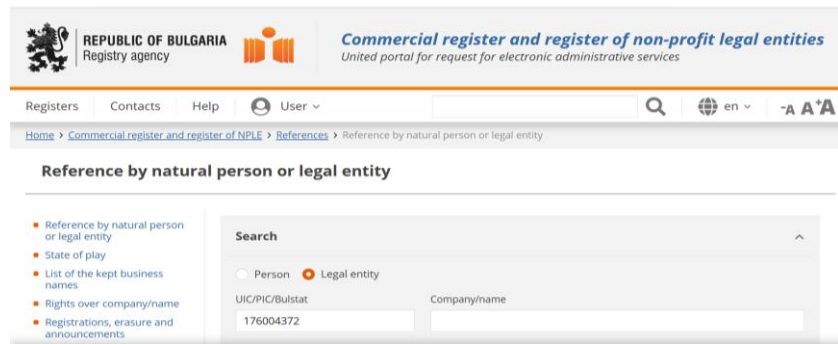


WHO WE ARE?

<p>Full name of the organisation: Bulgarian Association for Drug Information (BADI)</p>
<p>The registered address of the organisation (address of legal establishment): 16 Hubcha Str. , Office2, Sofia 1618, Bulgaria</p>
<p>Name and job title of the representative: Tatyana Velkova Benisheva – Dimitrova, President of Bulgarian Association for Drug Information (BADI)</p>
<p>Contact details: Name of contact person: Prof. Tatyana Velkova Benisheva – Dimitrova Email address: office@badibg.org Telephone number: +359887476909; +359889919655 Postal address: 16 Hubcha Str. , Office2, Sofia 1618, Bulgaria</p>

<p>Information about the organisation:</p>	<p><input checked="" type="checkbox"/> <u>Bulgarian Association for Drug Information is a non-profit legal entity in the public interest</u></p>  <p>Please enter the VAT Number 176004372 to enter the database and see the registration and all docs in the Bulgarian language.</p> <p>EPZEU (registry agency. bg)</p>
<p>EU Transparency Register number</p>	<p>VAT 176 0043 72</p>
<p>Affiliation of the organization:</p>	<p><input checked="" type="checkbox"/> <u>health professionals' organisation</u></p> <p><input checked="" type="checkbox"/> <u>clinical and learned society</u></p> <p><input checked="" type="checkbox"/> <u>other non-governmental organisations in the field of health</u></p>
<p>Description of the</p>	<p>Activities, based on our Statute /31.03.2017/, Art 5 https://www.badibg.org/2023/Statutes%20of%20BADI.pdf</p>

<p>organisation's current or planned Engagement in HTA development.</p>	<p><u>The Association has the following planned activities (2023 -2024)</u></p> <ol style="list-style-type: none"> 1. Improvement of the qualification and enhancement of the professional competence of its members, as well as activities related to Clinical trial regulation (EC) 536 and the EU HTA-Implementation rolling Plan in the field of medicines and medical devices. 2. Supporting HTA regulatory science, education and regulatory activities in the field of drugs and medical devices in the country. 3. Creating a platform for constructive dialogue between regulatory bodies, universities, the industry, and related organisations to the HTA - EU rolling plan 2023-2024 of medicines and medical devices in the country. 4. The HTA rolling plan, with a list of critical activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the "HTAR"), will be discussed among our members and stakeholders, after every update to follow different implementation steps due to BADI's work plan that is subject to regular review. The goal is to provide the interested stakeholders with the most updated information for a smooth transition of the EU- HTA regulation on local level. 4. Supporting the HTA - professional qualification for beginners and advanced experts and retraining of specialists in the HTA-legislative framework in Bulgaria and the EU. <p><u>Current objectives are a continuation of our past Workplan (Past Events 2011 – 2022):</u></p> <p>All programs of the past events are listed on our website (Section “Past events”), where is visible that HTA has been a primary objective in BADI's activity since its establishment in 2011.</p> <p>https://www.dropbox.com/s/i34odaauau9f0zn/BADI%20EVENTS.pdf?dl=0</p> <p>Information about the HTA Workplan (2019 – 2022) of the Bulgarian Association for Drug Information</p> <p>BADI membership and events provide many opportunities, benefits and access to healthcare policymakers, health technology assessment education and regulatory science.</p> <p>We have developed two years an EU funded -HTA - Project - which was one of the significant task of our Working plan (2019 -2020) - see <u>in EU-Funded Actions</u></p> <p>On June 5 2020, Bulgarian Association for Drug Information (BADI), held an online event on its 10th Anniversary titled "Meet the Regulators". Originally the event was planned as a face-to-face conference, but COVID-19 mandated a different approach. As a result, five directors from the EU Competent authorities, EMA, EMA -Management Board, Bulgarian Drug Agency - Bulgaria, Austria Medicines and Medical Device Agency (AGES) Austria, Paul Ehrlich Institute – (PEI) Germany) were involved.</p> <p><i>Prof Guido Rasi, Executive Director of EMA, addressed emerging business models concerning Health Technology Assessment and payers, the profound</i></p>
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transformation of the healthcare landscape, and the regulators' changing role to becoming enablers between science and healthcare systems. Prof Rasi presented the strategy of EMA for the next 5-year period where the innovation, digital tools and digital analytics, sustainability of the network and operational excellence are among them.

Dr Sophie Werkoe, Manager of International Relations & Patient Engagement at the Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU, and Chair of the Board of the International Network of Agencies for HTA, INAHTA, founded in 1993, explained this network and the global HTA bodies, the EU legislation proposed for HTA after 2020, the trust and capacity building between HTA bodies as well as their collaborative tools and joint works.

For more information, read IFAPP TODAY - The Global Newsletter on Pharmaceutical Medicine pages 2 – 5:

<https://ifapp.org/blog/ifapp-today-number-5-august-2020>

On June 2, 2022 (St. Ekaterina Hospital, Aula Prof. Dr. A. Chirkov) Medical University, Sofia, Bulgaria BADI realised the annual congress Drug Regulatory Affairs – update 2022, under the central theme - Revolution in Regulatory Affairs - How the pandemic is shaping the regulatory field and science. The international event gathered in one event one of the most experienced and professional experts in the field of drug regulatory affairs. Again among the lecturers from Austria, and Germany, Dr Alexander Natz, LL.M., Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), presented the Implications Of The New EU HTA Regulation for the stakeholders. Bulgarian Association, based on previous EC project with HTA activity, were involved with the published analysis and future challenges of Regulation 2012/2902 on the different stakeholder in the country. (see the program on the following link)

On December 2, 2022 – in Sofia, Bulgaria, the Bulgarian Drug Information Association held the third and final Module of this year's HTA and Regulatory Affairs Training Course 2022. The virtual event brought together over 100 regulatory experts from industry, academia and regulatory bodies. In the first session, Bulgarian experts from BDA and the industry participated. In the second session, besides the topic, Clinical trials - Regulation EU No 536/2014 (in force 01.02.2023), Mihai Rotaru - European Federation of Pharmaceutical Industries and Associations (EFPIA), presented the new HTA Regulation (EU) 2021/2282 | 15.12.21 with all future steps and challenges.



In addition, the ex-President of the HTA Competent Authority, Prof. Getov, was involved in the discussion about the EU- HTA methodology, timelines and comparators.

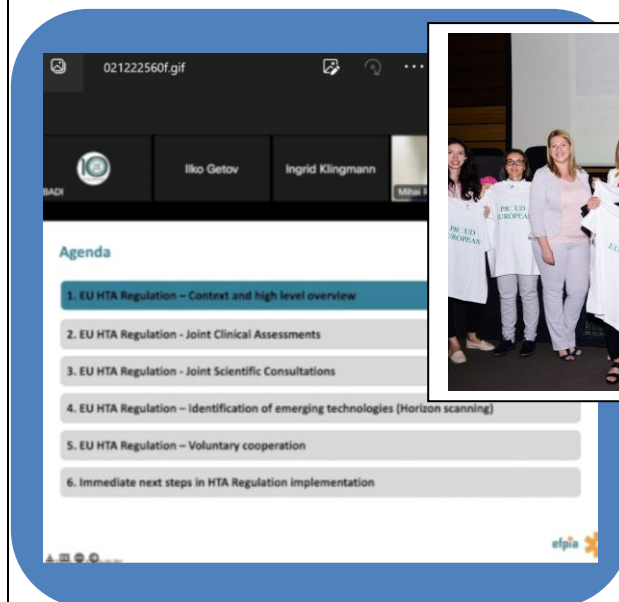
Mihai Rotaru -European Federation of Pharmaceutical Industries and Associations (EFPIA) 2 of December 2022

The Program of FOUNDATION SKILLS IN DRUG REGULATORY AFFAIRS MAY 12 - 13, 2022 | TRAINING COURSE, also include the HTA topic with basic frame and EU challenges click here:

https://www.badibg.org/2022/Program_FSinRA_Training%20Course_May%2012-13,%202022.final%20for%20printing.pdf

Activity report (2010-2020)

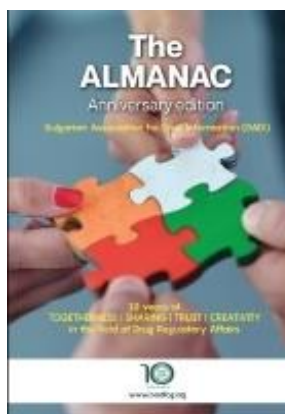
BADI has worked 13 years consistently to create a regulatory society in the pharmaceutical sector in our country by providing a platform for constructive dialogue and partnership



between interested parties in Bulgaria. Currently, we have organised over 100 events (meetings, training, sessions) in the field of drug regulations, HTA, REA,

EUnetHTA Guidelines and CORE-Model, pricing reimbursement and different clinical directions PASS, PAES in Bulgaria and the EU, life cycle management of medical products, clinical trials in the EU and pharmacovigilance. BADI's training has featured several experts, academia, and patient organisations.

The best illustration of our mission is in our Monography “Almanac” – please, see pages 8-11 where our mission is listed: Source: website link



https://www.badibg.org/index.php?option=com_content&view=article&id=230&Itemid=82

Our five basic principles of work are:

- efficiency,
 - innovation,
 - dynamics,
 - responsibility,
 - sharing, awareness
 - connectivity between members,
- especially when important information needs to be discussed

Please see the video dedicated to our 10th Anniversary, which is part of our activity report. (after 1.14min the video is in English language)

Prof. Barbara Sickmueller, President of German Association www.dgra.de



<https://www.youtube.com/watch?v=uz8C5PIUOpk>

Scientific publications and reports or initiatives

BADI members have many scientific publications in Bulgarian language, position papers – legislative statements – regarding the pricing, reimbursement and HTA policy in Bulgaria. (the list of these publications is upon request)

BADI members have HTA – articles published in the international database ISPOR (a leading source for scientific conference peer-reviewed and MEDLINE® indexed publications), most in the field of HTA. Many national publications are also available in Bulgarian language, which are not listed here.

Please, see the publication in English at the following link:

<https://www.dropbox.com/s/cnozaz22lc2ofI3/ISPOR%20Publications.pdf?dl=0>

Future Work Plan- 2023

1. Preparation and organisation of national and international forums for sharing experience, information, and qualification. (please, see the program 2023 on the website, In every event on March 31 2023, March 31st 2023, June 1st 2023, December See the Program 2023:

<https://www.badibg.org/2023/Draft%20program%202023%20BADI.pdf>

2. Development, examination, and preparation of opinions, scientific developments, and publications related to the HTA activities in the country and the EU.

3 Provide regular bulletin twice a week to all Association's members with EU information – EMA news, EDGM news, EU-HTA implementation rolling plan, flash reports of the EU-HTA Coordination Group -2023.

4. Maintenance of HTA-Regulation implementation and exchange of experience with the competent domestic and European authorities, universities, industry, professional and non-governmental organisations to fulfil the Association's objectives. Maintenance of EU and national HTA regulatory and publication activities on the Association's website Section “EU-HTA, HTA Organisations” (see the following link)

https://www.badibg.org/index.php?option=com_content&view=article&id=243&Itemid=85

5. Participation in the development, discussion, expert assessment, and Analysis of HTA draft legal acts, guidelines, and instructions relating to Bulgaria and the European Union. (Round table Discussion is foreseen on December 3 in our Draft program 2023)

The program 2023, click here:

<https://www.badibg.org/2023/Draft%20program%202023%20BADI.pdf>

6. Scientific clinical trial publication in 2023 PhD students group, members of Bulgarian Association for Drug Information.

The HTA-related working groups

Public health and real world data working group

HTA, artificial intelligence, machine learning working group.

Ad hoc working groups

EU-Funded Actions

We developed two years an EU -HTA - project - one of the significant topics in 2019 -2020 working plan



Project "**Development of proposals for improving civic participation in the processes of pricing and reimbursement of medicines, formation and reporting of public/budget funds for healthcare in the field of medicines**", No BG05SFOP001-2.009-0022-C01, implemented with the financial support of Operational Programme "Good Governance", co-financed by the European Union through the European Social Fund, launched on 15.01.2019.

Bulgarian Association for Drug Information (BADI) is a beneficiary of the project, as mentioned above. Based on the empirical data collected from the study of the legislative framework and the rules of the relevant authorities: Ministry of Health, National Health Insurance Fund and hospitals that are in contractual relations with the NHIF and the Ministry of Health on financing, control and accountability in spending. In addition, the report includes Analysis and preparation of recommendations for the Engagement of civic participation in health technology assessment processes, pricing, reimbursement and control of prescription drugs paid for with public/budget funds in the country, with 90 recommendations published in 2020 in the Bulgarian language. **Activity reports of EU-funded actions /period: 2019-2021/**

The result of the EU Funded project, which are *five scientific reports, are published here:*

https://www.badibg.org/index.php?option=com_content&view=article&id=219&Itemid=80

Activity 1

Conduct research, study and Analysis related to citizen participation in the process of health technology assessment, ***pricing, reimbursement and control of prescription drugs, payment with public/budgetary funds*** in the country:

Reports of that research in the Bulgarian language are on the website the organisation as follows: (*see the link above*)

Activity 2

Development of a mechanism and toolkit for feedback and evaluation by citizens and businesses for civic ***participation in tracking the processes of***

	<p><i>health technology assessments, pricing, reimbursement</i> and control of prescription drugs paid for with public/budgetary funds in the country.</p> <p>Activity 3 Exchange of good practices related to improving <i>citizen participation in the processes of health technology assessments, pricing, reimbursement</i> and control of prescription drugs paid for with public/budgetary funds in the country.</p> <p>Activity 4 Preparation of recommendations for engaging civil <i>participation in the processes of health technology assessments, pricing, reimbursement and control</i> of prescription drugs paid for with public/budgetary funds in the country.</p> <p>Activity 5 implementation of Activity 5, under the Project "Development of <i>proposals to improve citizen participation in the processes of drug pricing and reimbursement, formation and reporting</i> of public/budgetary funds for healthcare in the field of drugs", OP "Good Governance", co-financed by the EU: (Conference December 11, 2020)</p> <p>6. Results of the Analysis and Proposal to the competent authorities (Ministry Council, Ministry of Health, Ministry of Finance, HTA Body _NCPR, National Health Insurance Fund): on the link</p> <p>Доклад с препоръки по проект_ОП Добро управление.pdf (badibg.org)</p>
<p>Description of the organisation's expertise relevant to the Union's cooperation on HTA.</p>	<p>BADI organises and conducts several scientific and regulatory events, meetings, round table discussions and training with experts from HTA competent authorities, NGOs, and academia and industry with a regulatory HTA focus, comparing policies, pharmacoeconomic guidelines, HTA methodologies, REA, EUnetHTA Coremodel.</p> <p>Our members participated in different EUnetHTA events where the different Steps (I -III) were reported and analysed. In addition, experts from Bulgaria and the European Union, EUnetHTA attended to many events, training and activities as speakers and moderators, etc., as described in our website archive -Section"Past Events.</p>



28 of November .2014 (BADI' members and Finn Kristensen (EUnetHTA Project Chairman - in Sofia, Bulgaria.) Module 4 Clinical Assessment, Pricing and reimbursement of medicines for rare diseases) picture from archives

BADI is maintaining a delegated HTA section on its website, “EU-HTA and HTA-Organisations”, for the stakeholders and update their members weekly with all HTA activities on the EU and national level.

https://www.badibg.org/index.php?option=com_content&view=article&id=119&Itemid=56

These subsections in are in the website **“EU-HTA and HTA-Organisations”**:

- [HTA – Health Technology Assessment Bodies and Organisations in the EU](#)
- [European Commission -HTA Network](#)
- [International HTA Institutions](#)
- [Regulation on HTA Implementation](#)
- [NCPR – Bulgarian HTA Competent authority – HTA section \(legislation and HTA assessment of medicines\)](#)

The list of all HTA bodies and organisations is unique and is not listed by any other EU-HTA- Organisation

.The information in “EU-HTA - HTA Organisations“ is updated regularly and so the stakeholders could easy follow the assessment of the the HTA competent authorities in the EU- reference countries.



Our members are regularly informed about the EU HTA -Implementation Rolling Plan, the initiatives of the Coordination Group, meetings and flash reports.

The HTA national regulatory requirements (in Bulgaria) and assessment reports are part of that page as well.

	<p>The Bulgarian Association of Pharmacoeconomics is a distinguished member of BADI, where the best-qualified HTA experts in Bulgaria are members who could be involved in future EC-subgroups of HTA assessment.</p> <p>BADI members have, published different scientific HTA – articles in the international database which proves their expertise and qualification to work with regulatory science and scientific data.</p>
<p>Geographical coverage of several Member States/EEA countries. (List of organisation's works within its HTA-related activities and description of the nature of these activities.)</p>	<p><u>Geographical coverage:</u></p> <p>Bulgarian Association for Drug Information (BADI) is the only drug regulatory-non-governmental organisation in Bulgaria,</p> <p>BADI's training has featured significant number of experts, academia, patient organisations and individual speakers with HTA-focused expertise from the UK, Finland, Denmark, the Netherlands, Germany, Belgium, Croatia, Italy, Poland and others.</p> <p>Several initiatives of the Organisation-BADI have been organised with representatives from EUnetHTA, Joint ActionII. The focus was different regulatory HTA approaches, HTA comparators, methodologies, guidelines among the Member States regarding pharmacoeconomic guidelines and HTA methodology.</p> <div data-bbox="448 1003 687 1151"> <p>DEUTSCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS</p> </div> <p>We work closely with experts from German association of regulatory affairs DGRA (www.dgra.de) (more than 1100 members in the pharmaceutical field)</p> <div data-bbox="448 1263 707 1431"> <p>IFAPP Pharmaceutical Medicine</p> </div> <p>We work also with IFAPP organisation (https://ifapp.org/) and the membership there provide the BADI organisation to develop different HTA initiatives, which is an excellent example for future work and initiatives. IFAPP is global but cover 15 EC countries Austria, Belgium, Czech Republic, Finland, Germany, Greece, Hungary, Italy, The Netherlands, Portugal, Romania, Spain and Sweden. Bulgaria</p> <div data-bbox="448 1637 756 1720"> <p>BAPEMED</p> </div> <p>Bulgarian Association for Personalized Medicine work with BADI in different joint project.: https://bapemed.org/en/about-bapemed/membership/</p> <p>(Bulgarian Association for Personalized Medicine has 13 members, among them the Patient organisation and membership in 6 additional organisation. Following of them are in the EC.</p> <ul style="list-style-type: none"> • European Society of Pharmacogenomics and Personalised Therapy • European Alliance for Personalized Medicine (EAPM)

<p>Description of the organisation's communication and dissemination capabilities.</p>	<p>Communication and dissemination capabilities: Bulgarian Association for Drug Information is continuously communicating with its members (mailing list of 1000+) through email – bulletin (at least twice weekly). Therefore, BADI members can learn the latest national and EU developments, updates and publications in the HTA field.</p> <p>Additional information is provided to the following organisations when necessary where the Bulgarian Association for Drug Information is a member/or has signed an agreement for collaboration, or the organisation is a member of BADI</p> <p><u>National association memberships and collaborations:</u></p> <p>1. Bulgarian Association for Personalized Medicine: https://bapemed.org/en/about-bapemed/membership/ <i>(Bulgarian Association for Personalized Medicine has 13 members, among them the Patient organisation)</i></p> <p>2. Union of Bulgarian Medical Specialists; (all Bulgarian clinical medical Association are a member) http://www.medunion-bg.org/companies.aspx <i>(88 medical societies are members of the Union of Bulgarian Medical Specialists)</i></p> <p>3. Bulgarian Association for Patients' Defence; https://patient.bg/en/members/ <i>40 members</i></p> <p>4. Clinical Research (BACR) signed an Agreement for cooperation and joint activity in conducting training seminars and communication capabilities. https://bacr-bg.com/en/info/about</p> <p>5. The Bulgarian Association of Pharmacoeconomics is a member of BADI, where the best-qualified HTA experts from academia and industry in Bulgaria are included. https://ispor-bulgaria.org/</p> <p><u>International association memberships and collaborations could be used in our dissemination capabilities.</u></p> <p>1 IFAPP- International Federation of Association of Pharmaceutical Physicians : https://ifapp.org/members-and-individual-affiliates <i>(organisations from EUROPE, USA, ASIA, AFRICA, Latin America and many individual members Prof. Tatyana Benisheva, President of BADI, is a member of the House of Delegates of IFFAP:: https://ifapp.org/about/governance/the-house-of-delegates</i></p> <p>We work closely with each other. and exchange HTA expertise with experts from IFAPP, as well as about New HTA Regulations because the EU is well represented with 15 Organisations from 15 EC countries.</p> <p>2. HTAi – Health Technology Assessment International</p>
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	<p>The organisation work on a global international level and we could use that international HTA- like a communication platform as well.</p> <p>3. German Association for Regulatory Affairs (DGRA) - www.dgra.de</p> <p><i>Prof. Tatyana Benisheva, President of BADI, is a DGRA member on behalf of BADI and the organisation has more than 1000 professional members.</i></p>
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<p>Motivation letter</p>  <p>Българска Асоциация за Лекарствена Информация (БА.ИИ) Bulgarian Association for Drug Information (BADI)</p> <p>10 February 2023</p> <p>Dear Colleagues,</p> <p>Bulgarian Association for Drug Information (BADI) was founded with the German Association of Regulatory Affairs (DGRA) support in 2010. Our mission is to foster constructive dialogue between the pharmaceutical society, competitive authorities, scientific organisations, pharma industry, healthcare professionals, and patient organisations in Bulgaria in order to permanently improve their knowledge, qualification, and professional competency. As a public interest Association, our financial resources come from membership and workshop fees. The BADI brings together 90 individuals and more than 70 corporate members who are representatives of competent authorities, industry, academia, healthcare professionals, patient organisations, etc. Since 2010, we have organised more than 100 events in regulatory affairs training, with over 6320 participants.</p> <p>Our guest speakers are scientists, experts from competent authorities, pharma industry representatives, healthcare professionals, patient organisations, academia and consultants from Bulgaria and the EU. The BADI events have been attended by over 460 renowned experts, from Bulgaria, Germany (DGRA), UK, Norway, France, Austria, Hungary, Portugal, Denmark, Switzerland, Poland, and Finland.</p> <p>Over the years, BADI has built a functional network of experts who partner, exchange work practices, and brainstorm good ideas. As a result, the Association has grown to be a community of regulatory stakeholders and HTA as well who recognise and communicate with each other.</p> <p>We provide for our members opportunities to develop and enhance their expertise by organising training events, professional discussions and discussion studios, regulatory e-newsletters with news from Bulgaria and the EU, forming working groups on specific drug-related problems and cases, developing opinions. Our members have the space and audience to report on professional topics. A key domain focusing our hard and exclusive work is Marketing Access; HTA REA, Pricing and Reimbursement; followed by Good Regulatory Practices; Clinical Trials; Pharmacovigilance; and many others important drug topics. The Association is a member of several national and international organisations.</p> <p>BADI discloses any new information in the field of HTA and offers independent HTA expertise, where necessary. The expertise is provided by BADI members habilitated in teaching at various medical universities in Bulgaria. Furthermore, our members are regularly updated with HTA knowledge through our training sessions, events and daily e-newsletters.</p> <p>By becoming part of the HTA network, we hope to further our proactivity for development in this direction, taking advantage of numerous Bulgarian experts in this field.</p>  <p>Prof. Tatyana Benisheva MD, PhD, MDRA President of Bulgarian Association for Drug Information</p> <p>16 Hubscha Str., Office 2, Krasno Selo, 1618 Sofia, Bulgaria Tel.: +359 2 955 85 86; Mobile: +359 889 919 655; e-mail: office@badibe.org; http://badibe.org/</p>	<p><input checked="" type="checkbox"/> yes</p> <p><input type="checkbox"/> no</p>
<p>Declaration of membership in other organisations/networks</p>	<p><input checked="" type="checkbox"/> yes</p> <p><input type="checkbox"/> no</p>



Българска Асоциация за Лекарствена Информация (БА.ЛИ)
Bulgarian Association for Drug Information (BADI)

Dear Sirs,

The Association is a member of the following Bulgarian and international organisations:

National association memberships and collaborations:

1. Bulgarian Association for Personalized Medicine:

<https://bapemed.org/en/about-bapemed/membership/>

2. Union of Bulgarian Medical Specialists:

<http://www.medunion-bg.org/companies.aspx>

3. Bulgarian Association for Patients' Defence:

<https://patient.bg/en/members/>

4. The Bulgarian Association of Clinical Research (BACR) and BADI have joint activity in conducting training seminars and attracting speakers, for the benefit of their members and for the purpose of exchanging experience.

5. Bulgarian Association of Pharmacoeconomics is a distinguished member of BADI, from where we use the bank and the expertise for HTA in Bulgaria.

<https://ispor-bulgaria.org/>

International association memberships and collaborations:

1. IFAPP - INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS:

<https://ifapp.org/members-and-individual-affiliates> Prof. Tatyana Benisheva, President of BADI is a member of House of Delegate of IFAPP: <https://ifapp.org/about/governance/the-house-of-delegates>

2. HTAI – HEALTH TECHNOLOGY ASSESSMENT INTERNATIONAL: <https://htai.org/membership-page-main/>

Sincerely Yours,

Prof. Tatyana Benisheva MD, PhD, MDRA

President of BADI

16 Hubcha Str., Office 2, Krasno Selo, 1618 Sofia, Bulgaria
Tel.: +359 2 955 85 86; Mobile: +359 889 919 655;
e-mail: office@badi.bg; <http://badi.bg>

Information of the representative:

yes

no



Information concerning the nominated representatives

- Name: Tatyana Velkova Benisheva – Dimitrova
- Function/title in the organisation – Chairperson/President of BADI
- E-mail address: - office@badibz.org; benisheva@yahoo.com
- Telephone number: +359 887476909; +359 889919655
- Address: 16 Hubcha Str., Office2, Sofia 1618
- Country: Bulgaria
- Description of the specific expertise and experience relevant to the Union cooperation on HTA (maximum one page per representative).

Specific expertise of Prof. Tatyana Benisheva-Dimitrova, DSc., President/Chairperson of Bulgarian Association for Drug Information (BADI) is a medical doctor, and currently is a professor at the Faculty of Public Health - Medical University, Sofia, Bulgaria in Drug Regulatory Affairs, HTA and Pharmacoeconomics. Her drug cycle management experience is based on 10 years of work at Bulgarian Drug Agency (BDA www.bda.bg) and on a master's degree in Drug Regulatory Affairs (MDRA) at the University of Bonn-Germany – where cost benefit of new innovative medicinal products was part of the study. Her outcome research, pricing and reimbursement knowledge is gathered as Director of the "Drug Policy" Directorate at the Ministry of Health (2000-2004) where she was vice chairman of the Pricing Committee and Reimbursement Committee and clinical assessor as well. As first president of the National Council on Prices and Reimbursement (NCPDR) - first HTA competent authority in Bulgaria set up in 2013) of medicinal products (2013-2014), she was responsible for the quality of HTA appraisals and assessments of new innovative medicines and decisions for adding new medications to the Bulgarian reimbursement (Drug Positive List – paid buy the National Health Insurance Fund). Her HTA knowledge has been enhanced with experience as an assessor on behalf of the HTA Committee at the Ministry of Health. (2015-2019).

Experience relevant to the Union cooperation on HTA Like director at the Drug Policy Department, she was responsible for harmonization of the Transparency Directive 89/105 (for pricing and reimbursement) in the national law before Bulgaria's EU accession in 2007. Based on her support, she apply the Bulgarian HTA competent authority (NCPDR) to be a partner of EUnetHTA in Step II (2014) and many Bulgarian experts were involved in various EUnetHTA initiatives, working groups and events. As Chairperson of the Bulgarian Drug Information Association, she has organized multiple events and meetings on HTA - reimbursement procedure for beginners and advanced experts. As leader of an EU funded-Projects-Administrative capacity (BG 0510PO002/13/3.1-8) for establishing of official database of HTA procedures and pricing and reimbursement at the Bulgarian HTA competent authority, she has added value for better drug regulatory environment in the country. Additionally, she was consultant of HTA pricing and reimbursement Chapter of EU funded Project PLAC II in Serbia and EU and Chair of Project - Project "Development of proposals for improving civic participation in the processes of pricing and reimbursement of medicines, formation and reporting of public/budget funds for healthcare in the field of medicines", No BG05SFOP001-2.009-0022-C01, implemented with the financial support of Operational Programme "Good Governance", co-financed by the European Union through the European Social Fund, launched on 15 January 2019.

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Tel.: +359 85 86; Mobile: +359 889 919 655;
e-mail: office@badibz.org; <http://badibz.org/>

Signature

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