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03/07/2022
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#SymposiumHAS

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An event organised as part of the French Presidency of the Council of the European Union.*

FRANCE22

HAUTE AUTORITÉ DE SANTÉ

Summary

**This event is not organised by the French government.
However, it isauthorised by the French Government to use the emblem of the French Presidency of the Council of the European Union.*

Editorial

Dominique Le Guludec,
President of the French National Authority for Health

The European regulation on health technology assessment has come into effect, marking the beginning of a new era. It establishes a necessary cooperation between European State authorities in charge of these assessments, with the aim of facilitating access to emerging technologies with clinical benefit, in the interest of patients all across Europe. How can this objective be met without departing from the quality, safety and transparency requirements inherent to any health technology assessment? What are the factors for success, both in times of crisis and in the long term?

This international, participative conference, organised as part of the French Presidency of the European Union, sets out to shed light on these key public health issues. It will call together stakeholders to whom this new framework for the governance and conduct of joint health technology assessments in Europe applies, including representatives of European bodies and assessment authorities, patients, academics and industry.

The symposium will first take a look back over European cooperation in health technology assessment, from earlier voluntary cooperation to the system set up by the new regulation today. It will attempt to bring the lessons learned from our shared experiences, along with the expectations of patients and industry, into focus.
It will then go on to look at the methodology aspect, cornerstone to the success of a joint, transparent, European assessment.
Our speakers will discuss deliberations that are ongoing among healthcare product assessment authorities and in academic areas.
Finally, in the recent context of the pandemic, the conference will address the involvement of authorities in the assessment of innovative health technologies during a health crisis.

I would like to extend my heartfelt thanks to all speakers, and to my European counterparts, who are making a point of coming to join us to discuss these matters. There is no doubt that they will raise numerous debates during this symposium.

Program

10:30

Opening

Dominique Le Guludec, President, *Haute Autorité de santé* (HAS), Co-Chair, Heads of Agencies Group (HAG)

Olivier Véran, French Minister of Health and Solidarity

Andrzej Rys, Director, Health Systems, Medical Products and Innovation, Directorate-Generalfor Health and Food Safety (DG SANTE), European Commission

11:00

Keynote: European HTA in a global context

Valérie Paris, Chair of the Economic and Public Health Committee, Board member, HAS

Health technology assessment has a long history and has established itself as a critical tool for clarifying price and reimbursement decisions in many countries. The decision of European countries to produce a joint clinical assessment answer to the needs of many stakeholders including governments, industry and patients. What impact will this reform have in Europe and beyond?

11:15

Cooperation of HTA agencies within Europe: From sharing experience to carrying out joint assessments

Focus on the challenges and issues of the new European HTA regulation

Tiemo Wölken, Member of the European Parliament

The Covid-19 crisis has highlighted that we were stronger together as a Union and that it was important to share our expertise and resources. Moreover, the pandemic has shown the need for a strong and inclusive European Health Union. With the adoption of the HTA Regulation, we are not only strengthening EU cooperation between Member States on HTA, but also taking a further step towards the Health Union. Ultimately, a European approach to joint clinical evaluations will not only combine national strengths, but also provide companies with a predictable and harmonized evaluation process at the EU level. At the same time, it is a milestone to ensure fair, affordable and transparent access to medicines for all EU citizens.

Implementation of the European HTA regulation

Flora Giorgio, Deputy Head of Unit B6 Medical Devices and HTA, Directorate-General for Health and Food Safety (DG SANTE), European Commission

This presentation will address the main elements of the recently adopted HTA Regulation, with a focus on the plans that will be put in place to prepare for its implementation.

Contribution of European cooperation in HTA

Marcus Guardian, Chief Operating Officer, European Network for Health Technology Assessment (EUnetHTA)

Patient and public involvement

François Houÿez, Treatment Information and Access Director, EURORDIS

The new European cooperation for health technology assessment is essential progress towards improving the transparency of assessment procedures. Thanks to this cooperation, patients and their doctors, wherever they may be living in Europe, will be able to refer to robust assessments and the EU is providing itself with the means to hone its expertise in that area. Working together in Europe has raised the level of expertise and the quality of scientific assessments in all areas. Some medical devices, in addition to medicinal products, can be submitted for joint European assessment and it is welcomed. In this field, information on their efficacy, safety, and their clinical added value is more difficult to assess. We therefore need to get organised, along with patients' associations, to comprehend the legal texts on medical devices and how the various procedures work.

This cooperation also opens the way to multi-party discussions, possibly on a voluntary basis for some subjects, such as appropriate economic assessment methods. At all levels and in all the activities of this new cooperation, it will be crucial to include patients' representatives, at least as controls, for greater adherence from the public to this work, in order to more effectively contribute to the different scientific discussions.

Participation of pharmaceutical companies

Ansgar Hebborn, Chair, HTA Working Group, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Scientific advances, evolving medicine development paradigms, and sophisticated regulatory pathways have accelerated the development of innovative, safe and effective medicines that offer unique opportunities for patients in need. New innovation is only meaningful though, if patients are able to access it in the timeliest manner. EFPIA welcomes the unique opportunity provided by the EU HTA regulation to support the more timely and wider availability of innovative medicines for patients across the EU, to boost innovation and improve the competitiveness of the European healthcare sector. It is a shared responsibility of European Commission, Member States, HTA agencies and stakeholders to optimally implement and resource a European approach to clinical evidence assessments, so that it becomes a catalyst for improved patient access and not an additional bottleneck.

Questions & Answers

14:00

The challenge of methods for HTAs in Europe

Contribution of the EUnetHTA 21 consortium

Pierre Cochat, Chair of the Transparency Committee, Board member, HAS

The Transparency Committee's current approach is scientific and independent and, to this effect, it fits in fully with the European medicinal product assessment project. Beyond the conventional methodology based on randomised clinical trials, the specific features of the innovations in certain areas (cancer, rare diseases, paediatrics, antibiotic treatment, therapeutic stalemates, etc.) are an incentive to adapt assessment methodologies to enable more rapid access to medicinal products without necessarily affecting level of evidence (pragmatic trials, single-arm trials, cross-over, intermediate endpoint position, etc.).

Stefan Lange, Deputy Director, Institute for Quality and Efficiency in Health Care (IQWIG)

The recently adopted EU-HTA-regulation 2021/2282 provides the legal backbone for HTA-collaboration in Europe. In this context, it is now necessary to prepare the methodological bases and structural processes for joint clinical assessments (JCAs). However, even with the results of EUnetHTA Joint Action 3, many challenges remain. The EUnetHTA 21 consortium will address these issues to provide the basis for reliable, high-quality JCAs.

Stakes of HTA methods

Florian Naudet, Professor, University Hospital of Rennes

The data used by health authorities to assess new treatments are very precious in terms of treatment good practices. The value of the information contained in study reports or individual patient data are inestimable, through their exhaustiveness and their level of detail. For all that, these data are often difficult to access, even if the situation is gradually changing. Europe is undertaking to an open science dynamic and data from therapeutic research must not fail this revolution.

Rosanna Tarricone, Associate Dean, Bocconi School of Management

The new EU medical devices and HTA Regulations will substantially change the medtech ecosystem. Better quality of evidence will further improve patients' safety and health outcomes. Joint Clinical Assessments and Joint Scientific Consultations will dramatically reduce fragmentation and will help achieve common standards for market access of innovative technologies in EU. However, these promises will come true if all stakeholders will strive to change conventional approaches and take the challenge to experiment new methods and procedures. In this regard, strengthening collaborations with the academia is pivotal.

Focus - Artificial intelligence and health technologies: a challenge for assessment

Isabelle Adenot, Chair of the Medical Technology and Interventional Procedure Committee, Board member, HAS

Discussion

15:00

Innovation in the face of a world health crisis: the role of HTAs in the EU

The HTA agencies' perspective

Rui Santos Ivo, President, National Authority of Medicines and Health Products (INFARMED), Chair, HAG

The COVID-19 pandemic showed the importance of collaboration and building bridges between the different actors involved. Cooperation between regulators, HTA bodies, payers and the relevant stakeholders proved to be of utmost importance when facing a world health crisis. HTA is certainly key to the promotion of innovation for patients and society, particularly when responding to health emergencies. Priorities are working together in the field of HTA at EU level and reinforcing the system where timely access to innovative medicines is evidence-based.

The industry's perspective

Alexander Natz, Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

The role of HTA decisions has always been a major issue for pharmaceutical manufacturers in Europe. However, the pandemic has exacerbated this issue considerably. While patient access is crucial, especially during health crises, HTAs require careful consideration and decision-making to guarantee quality for the end-user. There is a therefore a need for a clear methodology to generate and gather real world evidence (RWE) to help HTAs make decisions that benefit patients and manufacturers.

Round Table

Francis Arickx, Head of the Directorate Reimbursement of Medicines and Pharmaceutical Policy, RIZIV-INAMI

Michael Berntgen, Head of Scientific Evidence Generation Department - Human medicines division, European Medicines Agency (EMA)

Alexander Natz, Secretary General, EUCOPE

Andrzej Rys, Director for Health Systems, Medical Products and Innovation, Directorate-General for Health and Food Safety (DG SANTE), European Commission

Rui Santos Ivo, President, INFARMED, Chair, HAG

Valentina Strammiello, Head of Programmes, European Patient Forum (EPF)

16:00

Closing

Rui Santos Ivo, President, INFARMED, Chair, HAG

Agneta Karlsson, Director General, TLV, Co-Chair, HAG

Dominique Le Guludec, President, HAS, Co-Chair, HAG

Speakers

Valérie Paris,

Chair of the Economic and Public Health Committee, Board member, HAS

Valérie Paris, an economist and with a specialist studies diploma in economy and statistics from Paris 1 University, began her career at the Institute for Research and Information in Health Economics (IRDES) as a researcher in 1990. As author of a number of articles, reports and scientific studies, she was member of the health accounts committee (research, studies, assessment and statistics division (*Direction de la recherche, des études, de l'évaluation et des statistiques* - DREES), of the French high council for the future of national health insurance (*Haut conseil pour l'avenir de l'assurance maladie* - HCAAM) and even of the Advisory Expert Group for the organisation Medicines Patent Pool. She worked as a health systems analyst at the OECD from 2005 where she was also head of the medicinal products and medical devices expert group. Appointed member of the HAS college on 1st June 2020, she chairs the Economic and Public Health Evaluation Committee (*Commission évaluation économique et de santé publique* - CEESP).

Tiemo Wölken,

Member of the European Parliament

Tiemo Wölken is a young politician from northern Germany. He has been active in local politics since 2003 in his home region and holds a LL.M. in International Law from the University of Hull, England. Since 2016, he is a lawyer in addition to being a Member of the European Parliament. Mr Wölken is the S&D Coordinator in the Committee on Environment, Public Health and Food Safety and a Member in the Committee on Legal Affairs. In addition, he is the health spokesperson of the German S&D Delegation, the Vice Chair of the MEP AMR Interest Group and Co-Chair of the MEP working group on innovation, access to medicines and poverty-related diseases. His areas of expertise are healthcare, environmental issues, legal affairs, and all things digital - from eHealth to tackling geoblocking.

Flora Giorgio,

Deputy Head of Unit B6 Medical Devices and HTA, Directorate-General for Health and Food Safety (DG SANTE), European Commission

Flora Giorgio is a trained pharmacist and joined the European Commission in 2006 to work in DG Information Society and Media (now DG CNECT) as policy and project officer in the ICT for Health Unit. She joined DG SANTE in 2012 and since 2015 she has been heading the Health Technology Assessment team responsible for the drafting and the successful negotiating for the Regulation on Health technology Assessment. Since July 2021, Flora is deputy Head of Unit of Unit B6 «Medical Devices and Health Technology Assessment". Before joining the European Commission, Flora has been working in community pharmacy and she has been Secretary General of the Pharmaceutical Group of the European Union representing community pharmacists.

Marcus Guardian,

Chief Operating Officer, European Network for Health Technology Assessment (EUnetHTA)

Based on an educational background in international law (Technische Universität Dresden), business administration (Qingdao University), and diplomatic studies (University of Leicester) Marcus has forged a career in network development, strategic guidance, and policy management. In 2016, he accepted the challenge of steering EUnetHTA Joint Action 3 as its Chief Operating Officer (COO). In tandem with this, Marcus recently launched the International Horizon Scanning Initiative (IHSI) as General Manager, building a global stakeholder pool to adopt innovative data-driven tools that will significantly impact national healthcare product negotiation potential.

François Houÿez,

Treatment Information and Access Director, EURORDIS

François has always represented patients, on a voluntary basis to begin with then in a professional capacity. He began with the fight against AIDS as member of Act Up-Paris from 1989. He then joined the rare diseases cause in 2003. Today he represents the European rare diseases organisation, EURORDIS, at the European Medicines Agency, at the joint venture EUnetHTA for the European assessment of health technologies, and European projects on methods used in health technology assessment, the HTX - Next Generation HTA project especially. He organises and educates patients and their representatives, among other functions, to set up working relations with industrialists and health authorities at national and European level. François is also a patient.

Ansgar Hebborn,

Chair, HTA Working Group, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Ansgar Hebborn is Roche Pharma's Head of Access Policy Affairs Europe. As part of this role, he represents Roche in EFPIA and is the current Chair of the EFPIA HTA Working Group with specific focus on the implementation of the upcoming EU HTA regulation. During many years at the interface of pharmaceutical industry and health systems, he has actively participated in a wide range of initiatives with focus on patient access e. g. as stakeholder representative of EU HTA Network, EUnetHTA and the HTAi Policy Forum Committee. He has been the co-founder of a number of other initiatives in this field e.g. the Green Park Collaborative, the HTAi Asia Policy Forum, SwissHTA, and RWE4Decisions. He has been a member of the ISPOR Board of Directors in the past, has co-led the development of ISPOR's Vision 2020 Research agenda. In earlier industry roles, Ansgar led global pricing and outcomes research functions, based in Europe and the US.

Pierre Cochat,

Chair of the Transparency Committee,
Board member, HAS

Pierre Cochat is a paediatrician, university professor and hospital physician at the *Hospices Civils* in Lyon, and was Dean of the Laennec research unit between 2006 and 2009 in which he headed the medical studies courses from the 7th year. He is also chairman of the medical studies coordination committee (*Comité de coordination des études médicales* - CCEM) at Claude-Bernard Lyon 1 University. He was also chairman to the French transplant establishment's ethics committee between 2002 and 2005, member of the paediatrics national universities' council (*Conseil national des universités* - CNU), member of the Biomedicine Agency's medical and scientific committee from 2005 to 2008. He chaired the scientific committee for the French paediatrics society and the nephrology society, and also chaired the paediatric nephrology society, the European Society for Paediatric Nephrology and the International Pediatric Nephrology Association. He was corresponding member of the National Academy of Medicine.

He headed the rare renal diseases reference centre at *Hospices Civils* in Lyon and founded the paediatric CIC in 2008. He was investigator/coordinator for numerous clinical trials, especially in the field of rare diseases, and his research mainly covers hereditary renal diseases, organ transplantation, exploration of renal function and drug-induced nephrotoxicity. He was director of the Pédia (Elsevier) book collection before joining the HAS College, and chairman of the scientific council of the association for information and research on renal genetic diseases (AIRG - *association pour l'information et la recherche sur les maladies rénales génétiques*). Appointed member of the HAS College on 17 July 2020, he chairs the Transparency Committee (CT).

Stefan Lange,

Deputy Director, Institute for Quality and Efficiency in Health Care (IQWIG)

Stefan Lange completed his medical studies at the Heinrich-Heine-University in Düsseldorf in 1989 and received his Dr. med. in 1994. From 1989-1993 he was initially in practical training at the Ferdinand-Sauerbruch-Clinic in Wuppertal, then assumed the position of intern/resident physician. In 1993 he joined the department of medical biometry at the Ruhr-University in Bochum and was appointed to the position of research assistant in 1995. In 2003 he received his Habilitation (qualification for a professorship) and venia legendi (award of title of Privatdozent) in Medical Biometry and Clinical Epidemiology. He joined the Institute for Quality and Efficiency in Health Care in 2004, and has held the position of Deputy Director of the institute since 2005.

Florian Naudet,

Professor, University Hospital of Rennes

Florian is a psychiatrist, meta-research expert and former post-doc at Stanford's Meta-Research Innovation Center (METRICS). He is currently Professor of Therapeutics at the University of Rennes, in France. His research work consists of evaluating and developing methodological solutions for treatments administered to patients, mainly, but not exclusively, in psychiatric research. He specialises in the study of data sharing and collection of research waste practices.

Rosanna Tarricone,

Associate Dean, Bocconi School of Management

Rosanna Tarricone is Associate Dean at SDA Bocconi School of Management and Associate Professor in Public Administration at Bocconi University, Department of Social and Political Science, Milan. She graduated in Business Administration at Bocconi University and holds an MSc in Health Services Management and PhD in Public Health and Policy, both from the London School of Hygiene and Tropical Medicine, University of London, UK. She has over 100 publications in the areas of health policy, healthcare management, economic analysis of health care services and health technology assessment (HTA).

In the last 10 years Rosanna has been awarded over 10 multi-annual competitive research grants from international institutions such as the European Union, the Swiss Bridge Award and InHealth (USA). She has been the leader of MedtecHTA, a large, three-year EU-funded research project that has made recommendations on how to improve methods for assessing the effectiveness and cost-effectiveness of medical devices and she currently serves as scientific supervisor of COMED, a three-year EU-funded research project on improving assessment methods of costs and outcomes analysis of medical technologies, including mhealth.

Rosanna served as an expert for the DG Research and DG Health of the European Commission. She facilitated the continuous exchange of experiences and harmonisation of methods and procedures between the HTA Agencies of the EU Member States within EUnetHTA. Rosanna has been an advisor for the Ministry of Health (MoH) of Italy and has contributed to the design and development of the National Programme of HTA for Medical Devices.

Isabelle Adenot,

Chair of the Medical Technology and Interventional Procedure Committee, Board member, HAS

Doctor of pharmacy, she worked as a private practice pharmacist from 1984 to March 2017. She was elected on the national pharmacists' board in 1987, a position in which she worked closely on interdepartmental dossiers such as private practice-hospital relations and the ethical use of communication technologies. She also played a major role in the creation and implementation of the pharmacy record. She chaired the National Council of Pharmacists from 2009 to March 2017 to promote the primacy of human beings and ethics. She was also a member of the French national agency for medicines and health products safety (*Agence nationale de sécurité du médicament* - ANSM) board of directors from 2012 to March 2017. On the international scene, she chaired the international French-speaking pharmacists conference (*Conférence Internationale des Ordres de pharmaciens francophones* - CIOPF) from 2009 to March 2017, the European Industrial Pharmacists Group (EIPG) in 2012 and she was vice-chairwoman of the International Pharmaceutical Federation (FIP) from 2014 to March 2017. Isabelle Adenot is a full member of the French national Academy of Pharmacy. Appointed member of the HAS college on 10 April 2017, she chairs the national committee for the evaluation of medical devices and health technologies (CNEDiMTS).

Rui Santos Ivo,

President, National Authority of Medicines and Health Products (INFARMED), Chair, HAG

Products, I.P. (since June 2019) and an invited Associate Professor of Medicines Regulation, at the University of Lisbon Faculty of Pharmacy since 2009. He is member of the Management Board of the European Medicines Agency (EMA) since March 2016, Vice-chair of the Valletta Permanent Technical Committee/Valletta Declaration, since July 2017, Chair of the Heads of HTA Agencies Group (HAG), since September 2021. Along the years, at the Ministry of Health in Portugal, he held various functions, namely: Vice-president of INFARMED (2016/2019), President (2014/2016) and Vice-President (2011/2014) of the Central Administration of the Health System (ACSS, IP) and he served as President (2002-2005) and vice-president (1994-2000) of INFARMED.

In 2000-2002 he was Rui Santos Ivo is currently President of INFARMED – National Authority of Medicines and Health Administrator at the Directorate of the EMA, in London, and in 2006-2008 in the European Commission, Pharmaceuticals Unit of the Directorate General for Enterprise and Industry, in Brussels. He was the first Chairman of the European Union Heads of Medicines Agencies Management Group (2004/2005) and, between the years 2008 and 2011, he was Executive Director of the Portuguese Association of the Pharmaceutical Industry (APIFARMA). Rui Santos Ivo initiated his professional career as a hospital pharmacist at Lisbon Egas Moniz Hospital and in 1993 he joined INFARMED, where he initiated functions at the Licensing and Inspectorate Department.

Rui Santos Ivo graduated in Pharmaceutical Sciences by the University of Lisbon in 1987. Specialist in Hospital Pharmacy by the Ministry of Health (1992) and the Pharmaceutical Society (2006) and in Pharmaceutical Regulation by the Portuguese Pharmaceutical Society (1997). Post graduate education on Health Law and Pharmaceutical Legislation (by the University of Lisbon Faculty of Law and National School of Public Health), Pharmaceutical Medicine (by the University of Basel), Regulation (by the London School of Economics and Political Science) and on Health Management (by the Portuguese Catholic University, in 2000, and by AESE Business School, in 2015). He was granted with the Almofariz Prize - Personality of the Year in the Pharmaceutical Sector (2004), recognized, in France, as European Correspondent Member of the Académie de Pharmacie (2014) and, for distinguished Services, he was awarded with Gold Medal of the Ministry of Health (2015).

Alexander Natz,

Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

Alexander Natz is the Secretary General of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) in Brussels and advises innovative pharmaceutical and biotech companies, including start-ups, in regulatory and pricing & reimbursement matters from the EU law and German law perspective. From 2008 to 2013, he was Head of the Brussels Office of *Bundesverband der Pharmazeutischen Industrie e.V.* (BPI). Before, he worked as a lawyer at Sträter Law Firm in Germany with a special focus on managed entry agreements and licensing of pharmaceuticals. Dr. Natz has also worked in the field of competition law with the European Commission and in the pharmaceutical industry. As a research assistant at Duke University (USA) he has dealt with international pharmaceutical law. His doctorate was supervised by the former judge at the European Court of Justice, Prof. Dr. Dr. Ulrich Everling.

Francis Arickx,

Head of the Directorate Reimbursement of Medicines and Pharmaceutical Policy, RIZIV-INAMI

Francis Arickx is the head of the directorate Reimbursement of Medicines and Pharmaceutical Policy within the Health Care Department at the National Institute for Health and Disability Insurance (NIHDI RIZIV/INAMI) in Belgium where he manages the departments responsible for administrative and scientific assessment and appraisal of reimbursement claims for medicines, orphan drugs, medical nutrition… Francis Arickx is the former secretary general for the Commission for Reimbursement of Medicines and acts as representative/expert for the Institute and Belgium on a number of national and European platforms (NM CAPR, MEDEV, EUnetHTA…). He is one of the country coordinators for the BeNeLuxA Initiative, and today the overall coordinator of the Initiative. Francis graduated in pharmaceutical sciences from the University of Ghent, Belgium and teaches 'Health Policy' in the Pharmaceutical Sciences Department at the University of Antwerp.

Agneta Karlsson,

Director General, TLV, Co-Chair, HAG

Mrs Agneta Karlsson is the Director General for the Swedish Dental and Pharmaceutical Benefits Agency. Mrs Karlsson has a long and rich experience from different parts of the life science and pharmaceutical sector which includes both a pharmaceutical industry background as well as work for the Swedish Government. For five years between 2014 and 2019 Mrs Karlsson was the secretary of state for health care and social affairs and she served under two ministers of health. Previous experiences include being deputy party secretary for the Swedish Social Democratic Party, employment at the Swedish Trade Union Confederation (LO) and CEO for Arena Media.

Michael Berntgen,

Head of Scientific Evidence Generation Department - Human medicines division, European Medicines Agency (EMA)

Michael Berntgen is Head of the Scientific Evidence Generation Department at the European Medicines Agency (EMA), Amsterdam. This department aims to support the development of medicines to ensure generation of robust and relevant scientific evidence, also in collaboration with other stakeholders (e.g. patients, HTAs). Activities include the provision of scientific advice and methodology qualification, support to medicines for the paediatric population and for orphan diseases, as well as provision of expertise and support in translational sciences. Furthermore, the department monitors the portfolio related to human medicines, manages the PRIME scheme and facilitates collaboration with downstream decision-makers (HTA bodies and payers), to foster timely access to medicines.

Michael is a pharmacist by training and holds a PhD as well as a Master of Regulatory Affairs. From 1999 to 2006, Michael worked in various positions in regulatory affairs in the pharmaceutical industry in Germany and in the UK. In 2006 he joined the German national competent authority BfArM as Scientific Administrator in the Scientific Advice unit. Following this assignment he moved to the European Medicines Agency in 2007 where he initially took up a position as Scientific Administrator in the Therapeutic Group «Anti-infectives» of the Safety and Efficacy sector, followed in September 2009 by the assignment as Head of Rheumatology, Respiratory, Gastroenterology and Immunology in this sector. From September 2013 he was heading the Scientific and Regulatory Management Department and from September 2016 the Product Development Scientific Support Department. In March 2020 he took over the current position as Head of the Scientific Evidence Generation Department.

Andrzej Rys,

Director for Health Systems, Medical Products and Innovation, Directorate-General for Health and Food Safety (DG SANTE), European Commission

Dr. Andrzej Ryś is a medical doctor specialised in radiology and public health, graduated from Jagiellonian University, Krakow, Poland. He founded in 1991 and ran as Director until 1997 the School of Public Health at the Jagiellonian University. Thereafter, from 1997-1999, he served as Director of the Krakow's City Health Department. Between 1999-2002, he continued his career as Deputy Minister of Health in Poland where he developed a new system of emergency medical service, a reform of the education system for the health professionals and he was a member of the Polish EU accession negotiators team for the harmonisation of the Polish Health Care Law with the EU's Acquis Communautaire. After becoming Senior Consultant of "Health and Management Ltd" for the World Bank (WHO) and EAR in Serbia (in 2002), he founded in 2003 the "Center for Innovation, Technology Transfer and University Development" (CITTRU) at the Jagiellonian University in 2003, where he assumed the role of Director until 2006 . From 2004-2005 he was also Director of Development at "Diagnostyka Ltd". In 2006, he became Director for Public Health and Risk Assessment at the Directorate-General for Health and Consumers (DG SANCO), in the European Commission, and from 2011 -2014 he assumed the position of Director for Health Systems and Products in DG SANCO. Since 2014, Dr. Andrzej Rys is the Director responsible for Health Systems, Medical Products and Innovation at DG SANTE, in the European Commission in Brussels, Belgium.

Valentina Strammiello,

Head of Programmes, European Patient Forum (EPF)

Valentina Strammiello is Head of Programmes at the European Patient Forum, where she oversees the Project Portfolio. Experienced in managing a wide range of EU funded projects in the health sector, she also represents EPF in HTA-related debates and fora at European and global level. She is member of the HTAi Patient and Citizen Involvement Interest Group and member of the Scientific Advisory Board at Vall d'Hebron Institute of Research.

Dominique Le Guludec ,

President, *Haute Autorité de santé* (HAS),
Co-Chair, Heads of Agencies Group (HAG)

Dominique Le Guludec, former intern in hospitals in Paris, is a cardiologist and professor of biophysics and nuclear medicine. Head of the nuclear medicine department at Bichat hospital since 1993, she directed the medical imaging unit from 2006 to 2011. As university professor and hospital physician (PU-PH) she was head of teaching in biophysics at the Paris Diderot medical faculty from 1994 to 2011, in the heart-lung imaging module at the national institute for nuclear sciences and techniques (*Institut national des sciences et techniques nucléaires* - INSTN) and co-head of the biomedical imaging master's course at Sorbonne Paris Cité University. Her clinical and fundamental research works cover nuclear medicine applications in cardiology, in particular the development of new molecular imaging tracers. In parallel to her clinical activity, she has several roles within *assistance publique - hôpitaux de Paris* (AP-HP) as member of the committee for the assessment and distribution of technological innovation (*Comité d'évaluation et de diffusion de l'innovation technologique* - CEDIT), and chairwoman of the Paris Nord Val de Seine university hospital group hospital committee since 2016. She was chairwoman of the board for the radiation protection and nuclear safety institute (*Institut de radioprotection et de sureté nucléaire* - IRSN) from 2013 to 2017. She was appointed chairwoman of HAS on 4 December 2017 to replace Prof. Agnès Buzyn appointed Minister of Solidarity and Health. She continues to hold nuclear medicine consultations at Bichat hospital.

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