Paul-Ehrlich-Institut – Regulatory and Scientific Engagement in International Organisations

Guidelines and laws for shaping the pharmaceutical market are developed in close European and global cooperation. The authorisation and monitoring of the quality, efficacy, and safety of medicinal products have international relevance.

Experts from the Paul-Ehrlich-Institut (PEI) are involved in various committees and working groups of international organisations within the framework of global health and thus contribute to the coordination and harmonisation of medicinal product authorisation in the human and veterinary sector.

European Commission

The European Commission (EC) is the executive body of the European Union (EU). It consists of 27 members, with each Member State providing one member. Its tasks are to ensure the development, implementation, enforcement, and advancement of pharmaceutical legislation valid throughout Europe, as well as the monitoring and compliance with European treaties and legislation. It also manages the EU budget and is responsible for the allocation of financial resources. The EC is thus one of the most important institutions within the European Union, whose interests it safeguards and represents.

Directorates-General of the European Commission

The EC is divided into various departments, known as Directorates-General (DGs). The Directorate-General for Health and Food Safety (DG SANTE) is responsible for protecting the health of residents, monitoring food safety, and ensuring the implementation of relevant legislation.

Experts from the Paul-Ehrlich-Institut are represented in various working groups of DG SANTE and thus contribute to the coordination and harmonisation of medicinal product authorisation for humans and animals in Europe.

Further information

- European Commission

EMA – European Medicines Agency

The European Medicines Agency (EMA) is an Amsterdam-based agency of the European Union (EU) responsible for coordinating the scientific evaluation and

monitoring of medicinal products that are or will be authorised throughout Europe. Decisions are drawn up in seven scientific committees, numerous working parties, and sub-working groups. The committees and working groups include scientists from all European Member States as well as the EU-associated countries Iceland, Liechtenstein and Norway. The Paul-Ehrlich-Institut is also represented by experts in the committees and working groups.

CHMP – Committee for Medicinal Products for Human Use

Within the framework of the central authorisation procedure, the Committee for Medicinal Products for Human Use (CHMP) undertakes the scientific assessment of application documents with regard to the quality, safety, and efficacy of a new medicinal product for human use and its environmental compatibility. The CHMP's scientific assessment report forms the basis for the European Commission's decision to grant or refuse a central authorisation for a medicinal product for human use in all EU Member States. A member and an alternate are represented on the CHMP from each EU Member State as well as Iceland and Norway. An additional five members are co-opted based on their particular expertise. The Federal Institute for Drugs (BfArM) provides Germany's CHMP member and their alternate. The Paul-Ehrlich-Institut is represented on the CHMP as a co-opted member.

CVMP – Committee for Veterinary Medicinal Products

Within the framework of the central authorisation procedure, the scientific assessment of application documents for veterinary medicinal products with regard to their quality, safety and efficacy is the responsibility of the Committee for Veterinary Medicinal Products (CVMP). The CVMP's scientific assessment report forms the basis for the European Commission's decision to grant or refuse a central authorisation for the veterinary medicinal product in all EU Member States.

The CVMP is composed of one member and one alternate member from all Member States of the European Economic Area as well as up to five additional co-opted members with a specific scientific competence. The Federal Office of Consumer Protection and Food Safety (BVL) currently provides the member and the Paul-Ehrlich-Institut the alternate member for Germany. This arrangement alternates every three years between the BVL and the Paul-Ehrlich-Institut.

PRAC – Pharmacovigilance Risk Assessment Committee

The Pharmacovigilance Risk Assessment Committee (PRAC) was established in 2012 under the pharmacovigilance legislation that came into force. The aim was to improve the safety monitoring of human medicines before and after authorisa-

tion, once the medicine is or is about to be authorised in more than one EU Member State. The tasks of the PRAC thus include the evaluation and monitoring of the safety of medicinal products for human use.

This committee is composed of

- a chair (elected by PRAC members)
- one expert plus one alternate member from the medicines authority of each EU Member State as well as of the EEA Member States Iceland and Norway,
- six independent scientific experts (nominated by the European Commission) and
- one member plus one alternate member to represent healthcare professionals and
- patient organisations (nominated by the European Commission)

The BfArM provides the PRAC member and the Paul-Ehrlich-Institut provides the alternate member for Germany.

PDCO – Paediatric Committee

The Paediatric Committee (PDCO) was established by the Paediatric Regulation, which came into force in 2007, and has since been responsible for the review and approval of paediatric investigation plans (PIPs). A PIP defines the paediatric studies that pharmaceutical companies must carry out if a new medicine is to be developed and placed on the market in a national or central marketing authorisation procedure. The plans are intended to facilitate the development and availability of paediatric medicines. The PDCO is not responsible for the marketing authorisation of medicinal products for paediatric use. This activity falls within the scope of the CHMP.

The PDCO consists of five members from the CHMP and one member plus one alternate from all Member States of the European Economic Area. Three independent scientific experts from patient organisations and three from the health professions complete the PDCO. The BfArM provides the member for Germany, while the alternate comes from the Paul-Ehrlich-Institut.

CAT – Committee for Advanced Therapies

The Committee for Advanced Therapies (CAT) was established in January 2009 as a multidisciplinary committee based on Regulation (EC) 1394/2007. Advanced Therapy Medicinal Products (ATMPs) include gene therapeutics, somatic cell therapeutics and tissue engineered products. ATMPs must undergo a centralised marketing authorisation procedure. The CAT is responsible for all ATMP-related procedures (authorisation, certification, and classification) and prepares a draft

opinion on each ATMP application before the CHMP issues a final opinion on the marketing authorisation for the medicinal product concerned.

The CAT is composed of one member and one alternate member from each EU Member State as well as an additional five (co-opted) members from the CHMP. The committee is completed by two independent members and their alternates from patient organisations as well as clinic representatives (practising doctors), who are designated by the European Commission. The Paul-Ehrlich-Institut provides both the member and the alternate member for Germany.

COMP – Committee for Orphan Medicinal Products

In accordance with Regulation (EC) No 141/2000, the Committee for Orphan Medicinal Products (COMP) is responsible for the scientific evaluation of applications by pharmaceutical companies for designation of medicinal products for the treatment of orphan diseases. If the COMP issues a recommendation, the medicinal product receives what is known as orphan drug status.

The BfArM provides the COMP member for Germany, whereby an exchange between the two German higher federal authorities – Paul-Ehrlich-Institut and BfArM – takes place if any products are discussed that fall under the responsibility of the Paul-Ehrlich-Institut.

EMA Working Groups Involving the Paul-Ehrlich-Institut

Quality

- Biological Working Party (BWP)
- Biosimilar Medicinal Products Working Party (BMWP)
- Quality Innovation Group (QIG)

Non-clinical

- Non-clinical WP (NcWP)
- 3Rs Working Party (3RsWP)

Methodology

- Methodology Working Party (MWP)
- Biostatistics Operational Expert Group (BSOEG)
- Modelling and Simulation Operational Expert Group (MSOEG)
- Leadership Team for Biostatistics Special Interest Area (SIA) of the MWP
- Leadership Team for Pharmacogenomics Special Interest Area (SIA) of the MWP

Clinical

- Haematology Working Party (HAEMWP)
- Oncology Working Party (ONCWP)

- Rheumatology/Immunology Working Party (RIWP)
- Vaccines Working Party (VWP)

Veterinary

- Pharmacovigilance Working Party (PhVWP-Vet)
- Scientific Advice Working Party (SAWP-Vet)
- Immunological Working Party (IWP)
- Working Group on Quality Review of Documents
- VeDDRA (Veterinary Dictionary for Drug Regulatory Activities) subgroup

Further working groups

- Scientific Advice Working Party (SAWP)
- Working Group on Quality Review of Documents (QRD)
- Emergency Task Force (ETF)
- EU Innovation Network (EU-IN)
- Medicine Shortages Singe Point of Contact (SPOC)
- (Invented) Name Review Group (NRG)
- GMP/GDP Inspectors Working Group (GMDP IWG)
- Good Clinical Practice Inspectors Working Group (GCP IWG)
- Pharmacovigilance Inspectors Working Group (PhV IWG)
- Signal Management Review Technical (SMART) Working Group
- Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)
- Immunisation and Vaccine Monitoring Advisory Board (IVMAB)
- Plasma Master File (PMF) Group (associated to BWP)
- Summary of Product Characteristics Advisory Group (SmPC AG)
- CHMP/CAT CDx Expert Group
- CHMP/BWP Ad hoc Influenza Working Group
- CHMP/BWP Vaccine Core Group
- Change Management Board eSubmission (CMB eSubmission)
- Change Management Board Human (CMB Human)
- Maintanance Group Common Repository (CR)
- eApplication Form & Single Submission Portal Management Group (eAF&SSP MG)
- PSUR Repository Advisory Group
- EudraVigilance Telematics Implementation Group (EV-TIG)
- EudraVigilance Expert Working Group (EV-EWG)
- Costing Group
- ICH-Expert Working Group (EWG) ICH Q5A

- SPOR Key User Group
- UPD PO/SME Group
- PMS PO/SME Group
- Pilot Signal Management Expert Group (P-SMEG)
- CTS Working Group

Further information

- PEI International: Our Involvement in the CHMP
- PEI International: Our Involvement in the PRAC
- EMA: Committees, working parties and other groups

HMA – Heads of the national regulatory authorities for human and veterinary medicinal products

The heads of the national regulatory authorities for human and veterinary medicinal products of the European Economic Area (EEA) have joined forces to form the Heads of Medicines Agencies (HMA). The HMA focuses on key strategic issues (e.g. exchange of information, IT development and experience, implementation of EU legal requirements) as well as on the development, coordination and harmonisation of the European medicinal product authorisation system. The members aim to harmonise their national activities through a European network, in particular in the context of the authorisation and licensing of clinical trials. In addition, the HMA organises the CMDh and CMDv committees (more information below). HMA members also develop and monitor the structure of the network's division of labour for the effective and efficient use of resources.

The HMA works closely with the EMA and the European Commission to maintain and continue to develop this EU medicines regulation network.

The HMA is supported in its work on strategic issues by numerous working groups and co-ordination groups, as well as temporary task forces and subgroups working on specific issues. The Paul-Ehrlich-Institut is represented in some of these HMA working and co-ordination groups.

CMD – Co-ordination Groups for Mutual Recognition Procedures and Decentralised Procedures

The HMA operates two co-ordination groups that are responsible for examining and coordinating issues relating to the decentralised marketing authorisation of medicinal products for human or veterinary use in two or more EU Member States in accordance with the Mutual Recognition Procedure (MRP) or the Decentralised

Procedure (DCP) and for post-authorisation procedures (e.g. changes to and renewals of the authorisation). Their area of focus also includes the implementation of European legislation, the preparation of regulatory guidelines and procedures for divergent scientific views (referrals).

There are two co-ordination groups for Mutual Recognition and Decentralised Procedures: one for human medicinal products (Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human, CMDh) and one for veterinary medicinal products (Co-ordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products, CMDv). Both groups were established in 2005.

The CMDh is composed of one member and one alternate member from the European Economic Area as well as representatives (observers) of the European Commission and EU acceding countries. The BfArM provides the member and the Paul-Ehrlich-Institut the alternate for Germany.

The structure of the CMDv is similar. Each member country of the European Economic Area (EEA) provides one member and one alternate. The Federal Office of Consumer Protection and Food Safety (BVL) currently provides the member and the Paul-Ehrlich-Institut the alternate for Germany.

CTCG – Clinical Trial Coordination Group

The Clinical Trial Coordination Group (CTCG) is a working group of the HMA and is responsible for the classification, evaluation, and supervision of clinical trials. The aim is to harmonise procedures and requirements for the approval of clinical trials that are a national competence in the European Economic Area. Furthermore, the CTCG monitors developments in the field of clinical trials and develops guidelines.

The CTCG is composed of members from the national authorities, the European Commission, and the EMA. Germany is represented by both the BfArM and the Paul-Ehrlich-Institut.

HMA Working Groups Involving the Paul-Ehrlich-Institut

- Heads of Medicines Agencies – Human & Veterinary – HMA
- CMDh and CMDv
- CMDh Working Party on Variation Regulation
- CMDh Working Party on Pharmacovigilance Procedures Work Sharing
- CMDh CTS Working Group
- CMDh Subgroup on Allergen Products
- CMDh GCP Inspectors Working Group
- Clinical Trials Facilitation and Co-ordination Group (CTCG)

- Working Group of Communication Professionals (WGCP)
- Working Group of Enforcement Officers (WGEO)
- Working Group of Quality Managers (WGQM)
- Benchmarking (BEMA) Steering Group
- European Medicines Agencies Cooperation on Legal and Legislative Issues (EMACOLEX)
- EU Network Training Centre (EU NTC)
- HMA Veterinary Strategy Focus Group (VSFG)
- European Medicines Network International Cooperation Platform (IntCoP)
- HMA Substance Validation Group (SVG) Working Group (VET)
- IT Directors Group
- HMA Working Group for better use of medicines
- HMA Working Group of Biosimilars (BSWG)
- HMA/EMA Task Force on Availability of Authorised Medicines for human and veterinary use (TF AAM)

Further information

- Heads of Medicines Agencies

EDQM – European Directorate for the Quality of Medicines and HealthCare

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is an institution of the Council of Europe responsible for the maintenance and development of the European Pharmacopoeia & European Pharmacopoeia Online and the coordination of the European network of Official Medicines Control Laboratories (OMCLs). OMCLs are involved in batch testing and market surveillance of nationally, centrally and decentrally authorised medicinal products for humans and animals.

The EDQM coordinates the preparation of product-specific guidelines for the testing of medicinal products as well as higher-level guidelines on quality management topics and processes in the Official Control Authority Batch Release Network (OCABR). The implementation of the guidelines is checked in mutual audits in the individual OMCLs. This ensures the mutual recognition of tests and batch releases within the OCABR network.

The EDQM organises collaborative tests to ensure quality in the testing laboratories and to establish new methods (e.g. alternatives to animal testing). Furthermore, it coordinates the establishment of European chemical and biological reference preparations (standards) and takes over their storage and distribution.

EDQM Expert Groups Involving the Paul-Ehrlich-Institut

European Pharmacopoeia

- European Pharmacopoeia Commission
- Group 1 (Microbiology)
- Group 6B (Human plasma and plasma products)
- Group 15 (Human vaccines and sera)
- Group 15V (Veterinary vaccines and sera)
- European Committee on Blood Transfusion (CD-P-TS)
- European Committee on Organ Transplantation (CD-P-TO), Tissues & Cells

Ad hoc working groups

- Steering Committee Certification of the suitability to the Monographs of the European Pharmacopoeia
- Allergens (ALG) Working Party
- Aluminium in Parenteral Nutrition Solutions (ALU) Working Party
- Bacteriophages (BACT) Working Party
- Bacterial Endotoxin Test (BET) Working Party
- Cell Therapy Products (CTP) Working Party
- Gene Therapy Products (GTP) Working Party
- High Throughput Sequencing (HTS) Working Party
- Monoclonal Antibodies (MAB) Working Party
- mRNA Vaccines for human use (mRNAVAC) Working Party
- Mycoplasmas (MYC) Working Party
- P4 Biologicals (P4Bio) Working Party
- Spectroscopy and Data Analysis (SDA) Working Party
- Host Cell Proteins (HCP) Working Party
- Live Biotherapeutic Products (LBP) Working Party
- Raw Materials for the production of cellular and gene transfer therapy products (RCG) Working Party

Technical Advisory Committee

- Certification of Suitability of Monographs of the European Pharmacopoeia, TSE Transmissible Spongiform Encephalopathy Risk Products

Standardisation bodies

- Biological Standardisation Programme (BSP)
- Elaboration of Common European Quality Standard Regarding Quality Systems for Blood Establishment (TS066)
- Plasma Supply Management (TS093)
- EDQM (European Pharmacopoeia) Drafting Group for Vaccine Guidelines

EDQM/OMCL Network Advisory Groups

- Advisory Group OCABR: Batch Release for Human Biologicals: vaccines, blood and plasma derivatives
- Advisory Group Veterinary Batch Release Network (VBRN)
- OCABR/OBPR for Immunological Veterinary Medicinal Products (IVMPs)
- AdGEON: Advisory Group of the general European OMCL Network
- OMCL Gene Therapy Group

Further information

- European Directorate for the Quality of Medicines and HealthCare (EDQM)
- European Pharmacopoeia (Ph. Eur.)

WHO – World Health Organization

The World Health Organization (WHO) is a United Nations agency that specialises in health issues. The goal of WHO is to provide all people with the best possible health care by focusing on improving local health systems and coordinating the global response to health threats.

To achieve this goal, WHO has set up a variety of committees and working groups that carry out tasks such as creating detailed requirements and guidelines. These are published in documents such as the WHO Technical Report Series (TRS) and can establish procedures for specific areas, for example, the manufacture, authorisation and control of blood products and vaccines. Members of these committees come from bodies such as the national regulatory authorities.

WHO Committees Involving the Paul-Ehrlich-Institut

- Expert Committee on Biological Standardization (ECBs)
- Global Advisory Committee on Vaccine Safety (GACVS)
- International Nonproprietary Names Expert Group (INN)
- Product Development for Vaccines Advisory Committee (PDVAC)
- Strategic Advisory Group of Experts for Vaccines and Immunization (SAGE)

WHO Collaborating Centres

Since its founding in 1948 as a specialized agency of the United Nations (UN), the World Health Organization (WHO) has worked closely with a worldwide network of WHO Collaborating Centres. The Paul-Ehrlich-Institut supports this commitment to world health in multiple capacities, including by establishing two WHO Collaborating Centres at the Institute.

ICDRA – International Conference of Drug Regulatory Authorities

The International Conference of Drug Regulatory Authorities (ICDRA) is a WHO forum for representatives from WHO Member States to discuss issues of global interest and to advance global regulatory harmonisation and cooperation. Quality issues are also among ICDRA's topics, as are regulatory reforms, drug safety, counterfeiting, access, regulation of clinical trials, harmonisation, new technologies and e-commerce. Recommendations for measures to be taken by the agencies, WHO, and related institutions are proposed and common goals are formulated as recommendations. The conferences have been held since 1980. The Paul-Ehrlich-Institut has regularly participated in the conferences since 1999 and has taken on additional tasks such as chairing individual working groups.

Further information

- World Health Organization (WHO)
- WHO Collaborating Centres at the Paul-Ehrlich-Institut for Quality Assurance of Blood Products and in vitro Diagnostic Medical Devices and for Standardization and Evaluation of Vaccines