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

Experts at the Paul-Ehrlich-Institut (PEI) dedicate themselves to Global Health through participation in all important international organisations.

1. European Medicines Agency

The European Medicines Agency (EMA) is an agency of the European Union (EU). It is responsible for scientific evaluation and monitoring of centrally authorised medicines. The agency is based on Council Regulation (EC) No. 2309/93 and is headquartered in Amsterdam. Various committees with different responsibilities have been founded within the agency. All EU Member States and the EU-associated countries of Iceland, Lichtenstein, and Norway are represented on the EMA committees:

- Committee for Medicinal Products for Human Use (CHMP)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Paediatric Committee (PDCO)
- Committee for Orphan Medicinal Products (COMP)
- Committee for Advanced Therapies (CAT)
- Pharmacovigilance Risk Assessment Committee (PRAC)

CHMP and CVMP are the highest scientific decision-making bodies at the EMA. They are responsible for the marketing authorisation and risk assessment of medicines used for humans and animals.

The Paul-Ehrlich-Institut is a co-opted member of the CHMP and was nominated to the Committee based on the Institute's expertise in advanced therapy medicinal products (ATMPs). The Paul-Ehrlich-Institut is the primary German representative on the CVMP.

The PDCO addresses issues connected to paediatric clinical trials, including Paediatric Investigation Plans (PIPs)

The COMP evaluates applications from pharmaceutical companies seeking orphan designation for a medicine. The German Federal Institute for Drugs and Medical Devices (BfArM) represents Germany on the committee. An exchange between the Paul-Ehrlich-Institut and the BfArM as higher federal authorities takes place whenever products that fall under the Paul-Ehrlich-Institut's responsibility are being discussed. An additional European committee, the CAT, was established at the EMA in January 2009 based on Council Regulation (EC) 1394/2007. This committee is composed of renowned experts in the areas of gene therapy, somatic cell therapy, and advanced therapy medicinal products (ATMPs). Two patient organisation representatives and two practicing doctors round out the committee.

The CAT is responsible for guidance on all procedures involving ATMPs (authorisation, certification, and classification). Its duties include preparing scientific opinions on the authorisation of ATMPs for the CHMP.

The PRAC was established at the EMA in 2012. This committee handles pharmacovigilance duties and measures for human medicines pre- and post-authorisation, provided that the medicines are authorised in more than one EU Member State. The Paul-Ehrlich-Institut is also represented as the alternate German member on this committee, due to the institute's expertise in the area of medicine safety.

As the highest decision-making bodies, the CHMP and the CVMP are supported by a number of working parties (WPs), which are composed of designated experts from the national medicines agencies. These working parties, operating within their field of expertise, are tasked with supporting the CHMP and the CVMP in their evaluations of marketing authorization applications and post-authorisation procedures (advice on amendments, authorization extensions). Additionally, they contribute to the drafting of scientific guidelines and are involved in the areas of scientific advice and protocol assistance prior to the marketing authorisation of a medicine.

CHMP Working Parties with Participation from the Paul-Ehrlich-Institut

Standing Working Parties

- Biologics Working Party (BWP)
- Safety Working Party (SWP)
- Scientific Advice Working Party (SAWP)

Temporary Working Parties

These working parties provide support in resolving temporary issues and in the drafting of scientific guidelines:

- Biosimilar Working Party (BMWP) (chaired by PEI)
- Biostatistics Working Party
- Blood Products Working Party (BPWP) (chaired by PEI)
- Vaccine Working Party (VWP)
- Oncology Working Party
- Pharmacogenomics Working Party (PGWP)
- Rheumatology/Immunology Working Party (chaired by PEI)
- Joint CVMP/CHMP Working Group on the application of the 3Rs.

CVMP Working Parties with Participation from the Paul-Ehrlich-Institut

- Immunologicals Working Party (IWP) (chaired by PEI)
- Pharmacoviligance Working Party - Veterinary (PhVWP)
- Scientific Advice Working Party - Veterinary (SAWP-V)

The CHMP, CVMP, and even working parties can convene ad hoc working groups that are assigned to a designated scientific topic. Experts from the Paul-Ehrlich-Institut participate in these groups as well, such as in the Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT).

There are also Scientific Advisory Groups that can be convened to address specific issues on a specific topic (ad hoc), usually regarding one particular case. These groups support the CHMP, CVMP, CAT, COMP, PDCO or PRAC committees in their evaluation of specific product groups or types of therapies. Members are mostly external experts that are university professors or practicing doctors with special expertise in a certain field and that don't belong to one of the national medicines agencies.

www.ema.europa.eu
www.pei.de/beratung

2. Heads of Medicines Agencies for Human and Veterinary Medicines

The heads of the national medicines agencies of the extended European economic area (EEA) have joined together in the Heads of Medicines Agencies (HMA). Their goal is to harmonise the actions taking place at a national level, especially those related to the authorisation and approval of clinical trials, through a European network.

The HMA is supported by the co-ordination groups listed below, as well as by temporary task forces and subgroups handling specific issues. While the HMA works on strategy issues, the work of the Co-ordination Groups for Mutual Recognition and Decentralised Procedure (CMD Human and CMD Veterinary) is focused on clarifying issues connected to mutual recognition procedures for national authorisations, decentralised authorisation procedures, and post-authorisation procedures (variations, renewals). Their work also includes the implementation of European legislation, drafting regulatory guidelines, and procedures in the case of divergent scientific opinions (referrals).

The Clinical Trial Facilitation Group (CTFG) is tasked with harmonising procedures and requirements for the approval of clinical trials that fall under national competence.

The Paul-Ehrlich-Institut is a member of the following HMS working groups:

- Benchmarking Steering Group (BEMA). (PEI is one of two co-chairs)
- Clinical Trial Facilitation Group (CTFG)
- CTS Working Group
- European Medicines Agencies Cooperation on Legal and Legislative Issues (EMACOLEX)
- EU Network Training Centre (EUNTC)
- HMA/EMA Task Force on Big Data
- Working Group of Communication Professionals (WGCP)
- Working Group of Quality Managers (WGCM).

Co-ordination Groups for Mutual Recognition and Decentralised Procedure

The Co-ordination Groups for Mutual Recognition and Decentralised Procedure for Human and Veterinary Medicines were established in 2005 to clarify issues regarding decentralised EU procedures. Their legal basis is in Article 27 of Directive 2001/83/EC (human) and Article 31 of Directive 2001/82/EC (veterinary).

- Co-ordination Group for Mutual Recognition and Decentralised Procedure – human (CMDh)

- Co-ordination Group for Mutual Recognition and Decentralised Procedure – veterinary (CMDv)

www.hma.eu

3. European Directorate for the Quality of Medicines

The EDQM (European Directorate for the Quality of Medicines) is a directorate of the Council of Europe. The EDQM's activities include maintaining and developing the European Pharmacopoeia and the coordination of a network of Official Medicinal Control Laboratories (OMCLs). These laboratories participate in the batch testing and market monitoring of nationally and centrally authorised medicines for humans and animals. The EDQM coordinates the drafting of product-specific guidelines for the testing of medicines, as well as overarching guidelines for quality management topics and procedures within the OCABR (Official Control Authority Batch Release) network. The implementation of the guidelines, which is checked during mutual joint audits in each of the OMCLs, is achieved by the mutual recognition of trials and batch releases within the OCABR network.

The EDQM also organises ring trials for the assurance of testing lab quality as well as to establish new methods (e.g., alternatives to animal testing). It also coordinates the establishment of European biological reference products (standards) and handles their storage and distribution.

Paul-Ehrlich-Institut experts participate in multiple EDQM working groups.

European Pharmacopoeia Expert Groups

- Group 1 (Biological Methods and Statistical Analysis)
- Group P4 (Biologicals)
- Group 6B (Human Blood and Blood Products) (chaired by PEI)
- Group 15 (Sera and Vaccines)
- Group 15V (Veterinary Sera and Vaccines)
- Group 16 (Plastic containers for pharmaceutical use)

Ad hoc Working Groups

- Allergens (chaired by PEI)
- Bacterial Endotoxin Test (chaired by PEI)
- Botulinum Toxin
- Bovine Serum
- Cell Therapy Products
- Electronic batch submission
- Gene Therapy Products

- Glycan mapping
- Host Cell Proteins
- Live Biotherapeutic Products
- Monoclonal Antibodies
- Mycoplasmas
- P4 Bio Biologicals
- Raw Materials for the Production of Cellular and Gene Transfer Products

Technical Advisory Boards

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

Standardisation Committees

- Biological Standardisation Programme - Steering Committee
- Biological Standardisation Programme – Project Leaders
- Biological Standardisation Programme – Participants in Collaborative Studies
- Elaboration of Common European Quality Standard Regarding Quality Systems for Blood Establishment (TS066)
- Plasma Supply Management (TS093)

EDQM/OMCL Network Advisory Groups

- Advisory Group OCABR: Batch release for human biologicals: Vaccines, blood and plasma derivatives
- Advisory Group VBRN: OCABR/OBPR for Immunological Veterinary Medicinal Products (IVMPs)

www.edqm.eu

4. European Commission

The European Commission (EC) is the executive body of the European Union (EU). Its duties include both the development and implementation of pharmaceutical legislation valid throughout Europe as well as the monitoring of European treaties and laws. The commission also manages the EU budget and is responsible for the allocation of financial assistance. The EC is therefore one of the most significant bodies within the EU, whose interests it upholds and represents.

The EC is divided into various divisions called Directorates-General (DGs). The Directorate General for Health and Food Safety (DG SANTE) is actively supported by the Paul-Ehrlich-Institut. Institute colleagues contribute to the coordination and harmonisation of the authorisation of human and veterinary medicines through their participation in various working groups in the DG.

www.ec.europa.eu

5. World Health Organisation

The World Health Organisation (WHO) is the 194-member United Nations' specialised agency for health issues. The goal of the WHO is to make the best possible healthcare a reality for all.

In order to reach this goal, the WHO has formed a number of committees and working groups, whose duties include drafting detailed requirements and guidelines. These are published in the WHO's Technical Report Series (TRS) and can establish rules for areas such as the manufacture, authorisation, and testing of blood products and vaccines. Members of these committees come from organisations such as the national medicines agencies.

WHO Committees with Participation from the Paul-Ehrlich-Institut

- Expert Committee on Biological Standardisation (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 Immunisation (SAGE)

International Conference of Drug Regulatory Authorities

The International Conference of Drug Regulatory Authorities (ICDRA) is a WHO forum in which representatives of WHO member states discuss internationally-relevant topics and drive global regulatory harmonisation forward. Common goals are formulated in the form of recommendations. The Paul-Ehrlich-Institut has regularly participated in these conferences since 1999, in some years acting as a working group chair.

WHO Collaborating Centres

There are two WHO collaborating centres currently located at the Paul-Ehrlich-Institut:

The Major Policy Issues, Coordination Division coordinates the WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices. The centre supports the WHO at relevant meetings. The collaborating centre actively organises and carries out laboratory and ring trials for the purpose of standardising international reference products. It also participates in the drafting of WHO guidelines and recommendations.

Experts from the Virology and Microbiology Divisions, which focus on the authorisation and testing of vaccines, work in the WHO Collaborating Centre for Standardisation and Evaluation of Vaccines. In addition, the International Coordination, Regulatory Service Unit supports the WHO in its activities aimed at strengthening regulatory systems, especially in Africa. The WHO Collaborating Centre helps the WHO to develop written standards and guidelines for the international scientific and regulatory evaluation of vaccines.

www.who.int
www.pei.de/who-cc

6. Bilateral international cooperation

The first written agreement was made in 2006 with the Food and Drug Administration (FDA), a US public health agency. The institute concluded additional agreements (memorandum of understanding) in the second half of 2010 with its Chinese agency counterpart, the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP, since renamed as the National Institute for Food and Drug Control, NIFDC), and the Health Sciences Authority (HSA) in Singapore. The enhanced cooperation with Asian authorities reflects the significance of the increasing international interdependence of the medicines market.

An agreement on the exchange of information with the Health Products and Food Branch of Health Canada followed in 2011. Further agreements were made with Swissmedic (Switzerland, 2012), the National Institute of Food and Drug Safety (NIFDS, South Korea, 2013), the Scientific Centre on Expertise of Medical Application Products (SCEMP, Russia, 2013), the Therapeutic Goods Administration (TGA, Australia, 2015), the Food and Drugs Authority Ghana (Ghana FDA), and the Federal Commission for the Protection against Sanitary Risk (COFEPRIS, Mexico, 2016).

Cooperation Partners

COFEPRIS (Mexico)
Food and Drug Administration (USA)
Food and Drugs Authority Ghana (Ghana FDA)
Health Canada (Canada)
Health Sciences Authority (Singapore)
National Institute of Food and Drug Safety (South Korea)
NIFDC (China)
Scientific Centre on Expertise of Medical Application Products (Russia)
Swissmedic (Switzerland)
Therapeutic Goods Administration (Australia)