COMMITTEES, PHARMA DEUTSCHLAND E.V.

A number of representatives of Pharma Deutschland's member companies are involved in the numerous committees of Pharma Deutschland. Alongside their regular meetings, Pharma Deutschland also organises ad hoc meetings for political or strategic reasons.

Pharma Deutschland is thus able to react quickly, effectively and practically to upcoming changes and new political and scientific situations in the interests of its members.

In currently nineteen committees, employees of Pharma Deutschland's member companies support and advise Pharma Deutschland's Executive Board and management.

Furthermore, Pharma Deutschland offers its member companies the opportunity to participate in two working groups which focus on thinking "outside the box" and discuss topics that are outside of the defined articles of association.

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Communications and Public Relations Committee
Chair: Dr Traugott Ullrich, Dr. Willmar Schwabe GmbH & Co. KG

- The Communications and Public Relations Committee deals with all issues relating to press and public relations work for the pharmaceutical market. It also provides strategic and operational support to Pharma Deutschland's press and public relations department. The committee's tasks also include basic work on concepts and campaigns, the development of campaigns to position relevant association topics in the public eye (e.g. the pharmacy support campaign which is currently in place)
- Monitoring and support of ongoing association communication
- Knowledge-sharing on developments in online communication and social media topics.

Digital Health Committee
Chair: Dr Markus Mundhenke, Bayer Vital GmbH

The committee deals with both statutory and market-based digitalisation processes in the field of healthcare research and healthcare provision. The topics and current legislative procedures are analysed by the committee in close coordination with the other committees concerned, in particular the Market and Reimbursement Committee, and prepared with positions in such a way as to highlight the opportunities of digitalisation in the healthcare sector to stakeholders and politicians, and explain the measures required.

- E-prescription and electronic patient file, telematics infrastructure (TI), TI communication channels
- DiGA and DiPA as well as health apps
- Interoperability and information portals
- Research data, real-world data, implementation of GDNG and EHDS
- AI in healthcare.

Environmental Guidelines Committee
Chair: Dr Rainer Hartung, Puren Pharma GmbH & Co. KG

The new "Environmental Directives" committee focuses on discussing and monitoring legal requirements of European chemicals and environmental legislation and their implementation in Germany. These include, in particular, chemicals legislation with REACH and CLP requirements, ECHA restriction proposals, initiatives such as "One Substance One Assessment", the revision of the Environmental Risk Assessment and the Urban Wastewater Treatment Directive as well as implementation measures derived from the aforementioned regulations. The committee supports member companies in analysing and implementing relevant requirements and processes. The committee supports the association's positioning on the aforementioned points vis-à-vis policy

makers and external stakeholders. In addition, topics are also discussed in supporting expert groups such as the “Chemicals legislation for medicinal products and medical devices” working group.

- Discussion on European chemicals and environmental legislation and its implementation at national level (REACH, CLP)
- ECHA restriction proposals and initiatives such as “One Substance One Assessment”
- Environmental Risk Assessment (ERA)
- Urban Wastewater Treatment Directive, extended producer responsibility and its implementation measures in Germany
- Preparation of the association’s positioning on the aforementioned issues vis-à-vis policy makers and external stakeholders.

Herbal Medicinal Products Committee
Chair: Dr Bernd Roether, Bionorica SE

The committee deals with all topics relating to herbal medicinal products. These include, in particular, the authorisation and registration of plant-based pharmaceuticals as well as current quality issues such as purity tests. An important aim of the committee’s work is to raise the status of herbal medicinal products at national and international level.

- Regulatory developments in Germany and Europe with regard to herbal medicinal products
- Authorisation and registration issues and current safety assessments of ingredients
- Current quality issues such as purity tests or stability
- Support for pharmacopoeia work in the field of herbal medicinal products
- Strengthening herbal medicinal products at national and international level, also in differentiation from other product groups of herbal origin.

Homeopathic and Anthroposophic Medicinal Products Committee
Chair: Dr Gesine Klein, Deutsche Homöopathie-Union DHU-Arzneimittel GmbH & Co. KG

The committee deals with strategic and political issues relating to homeopathic and anthroposophic pharmaceuticals at national and international (EU) level. This work is particularly important in view of the criticism of homeopathic and anthroposophic medicines voiced by some politicians, the media and some professional associations.

- The committee observes and evaluates the political situation regarding homeopathic and anthroposophic medicines in Germany and Europe
- It develops strategies and positions to strengthen and safeguard homeopathic and anthroposophic medicines in the German and European healthcare system.

- The new Pharma Deutschland regional associations offer support in positioning homeopathic and anthroposophic medicines
- Networking with relevant stakeholders from the industry
- Commissioning of studies and surveys.

HTA in Europe and Germany Committee
Chair: Dr. Anne Meyer, Daiichi Sankyo Deutschland GmbH

The committee addresses all matters related to market access and the supply of patent-protected medicinal products, including ATMPs and orphan drugs. This includes the HTA (Health Technology Assessment) processes at both the European and national levels, as well as the corresponding methodological developments for evidence generation, e.g. for modified treatments for special treatment situations and for the stratification of the assessment processes. This forms the basis for the further development of benefit-oriented pricing and corresponding contract formats, which are a key focus area for the committee. Pricing is a critical factor in ensuring patient access to medicinal products, enabling solidarity-based financing, and ensuring market viability and return on investment (ROI) for pharmaceutical companies. In this context, legislative proposals at both the European and national level and the procedures of self-administration, as well as the positions of stakeholders, are evaluated, commented on and analysed in order to draw informed conclusions for the committee´s own political activities.

- EU-HTA, early benefit assessment and cost-benefit analyses
- Data and methodologies for generating evidence for highly innovative treatments
- Value-based pricing
- Protection and further development of the AMNOG framework
- Negotiations over of algorithm-driven decision-making.

Innovation & Research Committee
Chair: Dr Dirk Pamperin, APOGEPHA Arzneimittel GmbH

The committee focuses on the promotion of innovation and research, particularly in the field of highly innovative therapies such as ATMPs (advanced therapy medicinal products), biotechnologically produced medicinal products, and also in relation to well-known active ingredients or plant-based substances. This includes exploring the opportunities available to companies and identifying the best ways to support them during the relevant procedures. Other topics include personalised medicine and companion diagnostics, AI and real-world data in research and development. The committee provides constructive support for relevant legislative procedures, but also develops proposals for political and legislative initiatives. It liaises with the committee for HTA in Europe and Germany in

relevant fields such as method development and the handling of accelerated authorisation procedures.

- National strategy for gene and cell therapies
- Personalised medicine and companion diagnostics
- Germany as a biotechnology hub
- Drug - Repurposing and phytoengineering
- Innovation and research policy/promotion.

International Market and Distribution Committee
Chair: Norma Freise-Otto, DR. KADE Pharmazeutische Fabrik GmbH

The committee addresses developments and challenges in international pharmaceutical markets, with particular emphasis on economic, regulatory, cultural and political framework conditions. Its focus lies on analysing foreign markets, engaging in discussions with relevant stakeholders and experts in the field of global health and presenting specific projects, funding instruments and collaborations. In addition to concentrating on specific countries, the committee also explores cross-cutting issues of major relevance to companies, such as foreign and security policy assessments, sanctions and new EU legislation.

International Medical and Pharmaceutical Affairs Committee (IMPA)
Chair: Dr Erika Plenz, Boehringer Ingelheim Pharma GmbH & Co. KG

The committee's work focuses on centralised and decentralised registration procedures at European level. The committee additionally focuses on issues from the medical-pharmaceutical sector that are decided at European or international level and that are relevant to the pharmaceutical sector.

- Monitoring and commenting on changes to regulatory requirements at EU and international level (e.g. EU Pharma Package, variation regulation, ICH E and S guidelines, etc.)
- Regulatory topics relevant to DE/EU and CH
- Recent guidelines regarding medical and pharmaceutical aspects
- Recent information related to labelling and ePI
- Exchange on experience with regulatory requirements within and outside of Germany.

Legal Affairs Committee
Chair: Christoph Hofstetter, SALUS Haus Dr Otto Greither Nachf. GmbH & Co. KG

The Legal Affairs Committee deals with national and international legal policy. It supports the association's work by providing legal backing for association and health policy-related lines of

reasoning, and supplements legal aspects in statements for European and national draft directives, regulations and laws. The focus is on pharmaceutical legislation in all its facets: from authorisation, competition, health insurance and patient law to the legal provisions of adjacent fields of law, with a particular focus on borderline pharmaceutical/food products. Topics at a horizontal level such as data protection, compliance, environmental regulations and KRITIS are also covered.

- Information and evaluation of European and national legislative procedures
- Preparation of official statements issued by the association
- Pharmaceutical legislation, competition legislation
- Horizontal legal areas with relevance for pharmaceutical companies.

Market and Reimbursement Committee
Chair: Steffi Liebig, APOGEPHA Arzneimittel GmbH

The committee discusses all issues relating to market access and the supply of off-patent pharmaceuticals as well as the corresponding (social) legal and economic framework conditions. Legislative proposals are thereby evaluated and commented on, and self-administration procedures are monitored. Stakeholder positions are analysed and strategies are developed to improve social legislation and sub-legislation in the interests of manufacturers in the underlying market.

- SGB V and pharmaceutical guidelines
- Fixed amounts, discount agreements and manufacturer discounts
- Pharmaceutical agreements and supply contracts as well as framework agreements
- Protecting the underlying market and securing supply
- Rethinking price singularity.

Market and Self-Medication Committee
Chair: Thomas Stadler, Hermes Arzneimittel GmbH

The committee's work focuses on self-medication with over-the-counter medicines and healthcare products, as well as the further development of self-care. Core topics are market developments, the political and legal framework and health economic issues. Concepts for strengthening self-medication and in particular further developments in content and communication options will also be discussed and implemented. Cooperation with the healthcare professions, especially local pharmacies, is of great importance.

- Preservation of the in-pharmacy sale obligation for pharmaceuticals
- Support for pharmacies as an important customer-product contact location
- Expansion of medical recommendation for over-the-counter preparations

- Improved access to services, products and innovations, including OTC-switches
- Sharpening the health-economic line of reasoning in favour of more self-medication.

Pharmaceutical Development Committee

Chair: Jessica Schönborn, STADA Arzneimittel AG

The committee deals with issues relating to the pharmaceutical development process and the relevant regulatory requirements. Topics such as the definition of a target Product profile for the commercial product (TPP = Target Product Profile) and the development of specifications for the active substance and medicinal product with regard to physico-chemical properties, impurities, degradation and the release profile as well as analytical methods for characterisation, structural elucidation & quality control, and technology transfer will be discussed. The committee also deals with issues relating to formulation development and active substance/excipient interaction, taking quality by design (QbD) aspects into account. The dosage form, stress and stability tests and in-vitro release tests must be defined, considering the dose strength and BCS classification. At this stage, primary packaging and storage conditions are also optimised and coordinated in accordance with the current ICH guidelines. The manufacturing process of the optimised formulation is being further developed regarding its scalability to produce commercial batch sizes. The CMC package is finally consolidated for the submission of the marketing authorisation.

- Supporting member companies in implementing the regulatory requirements for CMC documentation
- Characterisation of chemically defined active ingredients
- Formulation and process development: Quality by Design (QbD)
- Analytical method development & validation
- Biopharmacy and/or bioequivalence concepts for generic active ingredients.

Pharmaceutical Technology Committee

Chair: Dr Rolf Breßer, Bayer AG

The Pharmaceutical Technology Committee addresses key regulatory and practical issues relating to the manufacture, testing, placing on the market and transport of medicinal products. One of its main areas of focus is the interpretation, further development and implementation of GMP and GDP requirements, as well as contributing to the development of the regulatory framework. The Committee also serves as a specialist forum for exchanging views on current developments, regulatory expectations and practical challenges, for example in connection with audits and inspections, active substances and excipients, impurities, proposed restrictions, and new technological and legal requirements. In addition, the Committee addresses cross-cutting topics such as crisis resilience, geopolitical impacts on supply and manufacturing processes, EU pharmaceutical legislation, packaging law, protection against counterfeiting, artificial intelligence in

the GxP environment and pharmaceutical residues in the environment and assesses their significance for pharmaceutical practice.

- GMP and GDP requirements and their implementation
- Questions relating to active substances and excipients
- Exchange of experience on audits and inspections
- Impurities and restrictions
- AI in the GxP area

Pharmacovigilance Committee

Chair: Imke Simmchen-Wittekopf, Engelhard Arzneimittel GmbH & Co. KG

The committee deals with various topics related to drug safety (pharmacovigilance). The discussion of important current issues also includes the analysis and commentary on new legal regulations at European and national level in this area. In addition, the committee also plans and directs working groups on various pharmacovigilance projects.

- Current exchange of experiences on pharmacovigilance inspection topics
- AI in pharmacovigilance (PV)
- General exchange of information and experience on the interpretation of PV provisions
- Legal changes in PV (pharmaceutical package, EAMIV etc.)
- Implementation of text amendments (e.g. due to PSUSA procedures etc.).

Politics Committee

Chair: Dr Ralf Mayr-Stein, Mylan Germany GmbH

The Politics Committee identifies, monitors and analyses topics and trends relevant to pharmaceutical policy at both European and national level. Its main focus lies on legislative initiatives from the Federal Ministry of Health, economic policy and projects of the European Commission. Statements, initiatives and position papers from other Pharma Deutschland's committees are consolidated, prioritised, and strategic approaches are developed to feed them into political decision-making processes and to highlight them appropriately. In collaboration with the Communications Committee and Pharma Deutschland's national associations, the Policy Committee develops campaigns for relevant topics, with the aim of publishing them through specialist media and the press.

- Monitoring current political developments
- Developing lists of demands for party manifestos and elections at both European and national level
- Strategically preparing for hearings on current legislative procedures

- Planning and implementing campaigns and events to promote the association's key demands for better supply of pharmaceuticals and improved regulatory framework conditions for the pharmaceutical industry.
- Building networks and maintaining regular dialogue with stakeholders and interest groups within the healthcare sector to pursue shared political objectives.

Regulatory Affairs Committee
Chair: Yvonne Karmann-Proppert, Pharma-Labor Yvonne Proppert GmbH

The Regulatory Affairs Committee deals with all regulatory topics related to the authorisation of medicinal products at national and European level. Main focus is on the many procedural issues, however, the committee also discusses aspects such as effectiveness and quality.

- Monitoring and commenting on updates to regulatory requirements (e.g. EU Pharma Package, variation regulation, changes of German Drug Law, etc.)
- Reflection and discussion on general regulatory procedural issues (specific focus on BfArM (Federal Institute for Drugs and Medical Devices**)**, PEI (Federal Institute for Vaccines and Biomedicines)
- Discussion of current experiences in dealing with supervisory authorities from a regulatory point of view, e.g. in relation to text amendments
- Updates in terms of national labelling requirements
- Sharing of information and knowledge on relevant authorisation issues.

Substance-based Medical Devices Committee
Chair: Bettina Funke, Merz Consumer Care GmbH

The committee's work focuses on regulatory issues relating to medical device law with a focus on substance-based medical devices. Regulation (EU) 2017/745 on medical devices (MDR) including the delegated and implementing acts detailing the requirements for medical devices, plays a key role here. Other relevant topics include borderline issues and market access in other countries (with a focus on Europe).

- Implementation of the requirements of Regulation (EU) 2017/745 on medical devices (MDR) and the associated legal acts
- Borderline and classification issues relating to substance-based medical devices
- Discussion and evaluation of national and international legislations and implementation of requirements relating to substance-based medical devices
- Strategic orientation of the association in the field of medical devices
- Exchange of information and experience on current decisions by notified bodies, authorities and other bodies.

Sustainability and Climate Protection Committee
Chair: Dr Stefan Müller, AbbVie Deutschland GmbH & Co. KG

The committee focuses on political developments and legal requirements in the climate, energy and circular economy sectors at German and European level. The committee also deals with relevant societal, scientific and economic framework conditions. The committee supports the member companies by analysing relevant processes, developing a position vis-à-vis politicians and external stakeholders and answering questions on improving operational sustainability.

- Sustainability reporting (CSRD) & greenhouse gas (GHG) balancing (especially Scope 3)
- German and European Supply Chain Due Diligence Act (LkSG & CSDDD): Data gathering in accordance with the CSRD
- Discussion of the EU taxonomy
- Implementation of the EU Urban Wastewater Treatment Directive (UWWTD)
- Switch to more environmentally friendly/recyclable packaging.

PHARMA DEUTSCHLAND E.V. WORKING GROUPS

“Dental” Working Group
Chair: Vanessa Kuhne, Reckitt Benckiser GmbH

Dental medical devices such as filling resins, artificial teeth, orthodontic products, crowns and bridges constitute a special feature within the medical device sector. These products were once subject to marketing authorisation. With the Medical Devices Act (MPG), they became medical devices in 1995. This working group focuses in particular on regulatory issues and their implementation in operational practice. The latter also is also expressed in the corresponding Standard Operating Procedures (SOP), which are drawn up by the members of the working group and which can serve as suggestions and assistance for the company’s own SOPs.

“Pharmaceuticals and Borderline Products” Working Group
Chair: Heiko Hünemeyer, A.Moras & Comp. GmbH & Co. KG – Haus Schaeben

Pharmaceutical-related “health products” with food status are becoming increasingly interesting for companies that want to supplement their portfolio of pharmaceuticals and distribute attractive products quickly and cost-effectively without complex licensing procedures. Pharma Deutschland has observed that the boundary between pharmaceuticals and foodstuffs similar to medicinal

products – primarily food supplements, but also certain dietary foods – is becoming increasingly difficult to recognise. The European debate on “botanicals”, i.e. plant-based food supplements, continued to occupy the working group last year. The expertise of the working group members in the borderline area is becoming increasingly valuable for the defence of the medicinal status of established active substances and plants - and thus for the entire association. This specialised knowledge enables the Pharma Deutschland association to take a well-founded and balanced position.