

# High level **conference** on the **future of medicines**

30 November & 1 December 2020 | **Digital**



The event is part of the associated programme of the German Federal Ministry of Health in the framework of the German Presidency of the Council of the EU 2020.

Organized in cooperation with the Heads of EU Medicines Agencies (HMA) and the Association of the European Self-Medication Industry (AESGP).

**The event will take place digitally.**

Simultaneous translation will be provided in English/German for all sessions. Participation is possible upon invitation free of charge; registration prior to the event is mandatory.

Further details can be found under [www.bah-bonn.de/en/topics/german-eu-council-presidency](http://www.bah-bonn.de/en/topics/german-eu-council-presidency).

# Background and **objective** of the meeting

The Corona-Pandemia brought unexpected challenges to the European health care systems. It changed everybody's life and has important implications on the agenda of the German EU Council Presidency in the second part of 2020.

The conference will address the learnings made during the course of this year and will discuss political conclusions for the pharmaceutical sector. It will also look into what is required to ensure access and availability of the prescription medicines and selfcare products we need in the future.

30 November 2020

17.30 – 19.00

## Opening session

### **Margaritis Schinas**

Vice-President of the European Commission  
for Promoting our European Way of Life

### **Prof Dr Klaus Cichutek**

President, Paul-Ehrlich Institute (PEI), Germany

### **Prof Dr Karl Broich**

President, Federal Institute for Medicines and  
Medical Devices (BfArM), Germany

### **Birgit Schuhbauer**

President, Association of the  
European Selfmedication Industry (AESGP)

### **Jörg Wieczorek**

Chairman of the Board of the German Medicines  
Manufacturers' Association (BAH)

1 December 2020

9.00 – 10.30

## Availability of medicines – How to cope with medicine shortages

The Corona-Pandemia has aggravated some challenges in the supply of medicines. By that the issue of medicine shortages has become one of the most discussed topics even in the general public. This session will identify ways to cope with the situation, at short term and at long term.

### Prof Dr Karl Broich

President, German Institute for Medicines and Medical Devices (BfArM)

### Dr Andrzej Rys

Director for health systems, medical products and innovation, European Commission

### Emer Cooke

Executive Director, European Medicines Agency

### Stephanie Stoff-Ahnis

Member of the Board, National Association of Statutory Health Insurance Funds

### Dr Thomas Müller

Director General, German Health Ministry

### Dr Hubertus Cranz

Director General, German Medicines Manufacturers' Association (BAH)

**Track I** on prescription medicines

11.00 – 12.30

## How to best evaluate new medicines / the contribution of real world evidence

Data generated after the issuing of a marketing authorization is nowadays recognized as an important source of information for the assessment of a medicinal product. But when to carry out such studies and how to judge the value of new data is not clarified yet. Equally the role of the pharmaceutical industry in the given context is still much debated.

**Prof Josef Hecken** | Chair, Federal Joint Committee, Germany

**Tino Sorge** | Member of the German Parliament

**Hugo Hurts** | Executive Director, Medicines Evaluation Board, the Netherlands

**Olga Solomon** | Health and Food Safety Directorate General, Head of Unit B5, Medicines: policy, authorisation and monitoring, European Commission

**Philipp Huwe** | Vice Chairman of the Board of the German Medicines Manufacturers' Association (BAH)

**Track II** on self-care products

11.00 – 12.30

## Switch to non-prescription status: Is more harmonization possible?

Switching medicines from prescription to non-prescription status is an important way to enlarge citizens' possibilities to treat themselves. Over the last years a wide range of safe medicines became available without a mandatory medical prescription. This had positive effects both on public health and the financing of the statutory health care systems. While this development is a European and even global phenomenon the procedures involved and the attitude of assessors differ. Consequently, the availability of nonprescription medicines is different even within the European Union. The session will discuss possible solutions.

**Christa Wirthumer-Hoche** | Head of the Austrian Medicines and Medical Devices Agency & Chair of the Management Board of the European Medicines Agency (EMA)

**Oliver Freichel** | Corporate Vice President BD and Strategy, Sanofi Consumer Health Care

**Iliaria Passarani** | Secretary General, Pharmaceutical Group of the European Union (PGEU)

**Martin Huber** | Chair, CMDh Non-Prescription Medicinal Product Task Force

**Track I** on prescription medicines

13.30 – 15.00

## Access and availability of vaccines

The Corona-Pandemia demonstrates the importance of vaccination. However the developments of vaccines is complex and the provision of sufficient quantities of vaccines a widely discussed challenge. The session will show ways of efficient cooperation between stakeholders and what can be improved in the future. Particular attention will be paid to the expectations of the patients.

**Prof Dr Klaus Cichutek** | President, Paul-Ehrlich Institute (PEI), Germany

**Dr Andreas Kiefer** | President, German Pharmacists' Chamber

**Marco Greco** | President European Patient Forum

**Dr Sibylle Steiner** | Head of Services Management, Federal Association for Statutory Health Insurance Physicians (KBV)

**Dr Elmar Kroth** | Managing Director Scientific Affairs, German Medicines Manufacturers' Association (BAH)

**Track II** on self-care products

13.30 – 15.00

## Finding a good balance for consumer health products between the status of medicines, food and medical devices

Selfcare products are primarily in the categories of non-prescription medicines, food supplements and self-care medical devices. This session will give an overview on the challenges for both regulators and industry in the given context. It will discuss ways for establishing a system which allows better predictability and planning.

**Dr Sabine Jülicher** | Director, Food and Feed Safety Innovation, European Commission

**Prof Werner Knöss** | Head of Division, Licensing, Complementary and Alternative Medicines and Traditional Medicines, Federal Institute for Drugs and Medical Devices, Germany

**Christine Eising** | Head Regulatory Affairs for Europe, Middle East and Africa, Bayer Consumer Care

**Maud Perrudin** | Deputy Director General, Association of the European Selfmedication Industry (AESGP)

**Track I** on prescription medicines

15.30 – 17.00

## How digitalisation improves the provision of innovative medicines

One of the priorities of the German EU Council Presidency is better use of digitalisation in health care. This has also implications on the development, authorisation and efficient use of medicines. The session will discuss the likely impact of important ongoing initiatives.

**Prof Jörg Debatin** | Chairman, innovation hub, German Ministry of Health

**Zaide Frias** | Chief Digital Officer - Digital Business Transformation Task Force, European Medicines Agency

**Thomas Senderovitz** | Director General, Danish Medicines Agency

**Dr Hermann Kortland** | Deputy Director General, German Medicines Manufacturers' Association (BAH)

**Track II** on self-care products

15.30 – 17.00

## How to build a positive self-care climate?

To fully realize the potential of selfcare for public health more political efforts are needed. This session will expose best practices and define policy expectations.

**Heiko Schipper** | Chair, Global Self-Care Federation

**Rui Santos Ivo** | President, Infarmed, Portugal

**Dr June Raine** | Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

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