
## Drug development in EU: regulatory standards, support and new approaches

**Sunday, 22 September**
**8:00 am – 4:00 pm**
***Content accurate as of 15 August***

**Facilitators:**

- **Matthias Dormeyer,** MDC RegAffairs GmbH, Managing Director
- **Sabine Haubenreisser,** European Medicines Agency, Stakeholders and Communication Division, Principal Scientific Administrator
- **Karl-Heinz Huemer,** Austrian Medicines and Medical Devices Agency, Member of PDCO
- **Andrea Laslop,** Austrian Medicines and Medical Devices Agency, Member of CHMP
- **Jan Mueller-Berghaus,** Paul-Ehrlich-Institut, Member of CHMP and CAT
- **Maria Concepcion Prieto Yerro,** Agencia Espanola de Medicamentos y Productos Sanitarios, Member of CHMP
- **Bjørn Oddvar Strøm**, Norwegian Medicines Agency, Senior Scientific Adviser

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| **7:00 am** | **Registration and Continental Breakfast** |
| **8:00 am** | **Welcome and introduction to the Workshop and to the legislative background of EU regulation of drugs**<br>• **Matthias Dormeyer**, MDC RegAffairs GmbH, Managing Director |
| **8:20 am** | **Regulatory interactions in Scientific Advice, joint advice EMA-HTA and PRIME**<br>• **Andrea Laslop**, Austrian Medicines and Medical Devices Agency, Member of CHMP |
| **9:00 am** | **Challenges in Paediatric development**<br>• **Karl-Heinz Huemer**, Austrian Medicines and Medical Devices Agency, Member of PDCO |
| **9:40 am** | **Refreshment Break** |
| **10:10 am** | **How to get and keep the Orphan Designation**<br>• **Matthias Dormeyer**, MDC RegAffairs GmbH, Managing Director |


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| **10:50pm** | **Different pathways to Marketing Authorisation including early access**<br>• **Maria Concepcion Prieto Yerro**, Agencia Espanola de Medicamentos y Productos Sanitarios, Member of CHMP |
| **11:30 am** | **Requirements and importance of Post-marketing activities, registries and real-world data**<br>• **Sabine Haubenreisser**, European Medicines Agency, Stakeholders and Communication Division, Principal Scientific Administrator |
| **12:10 pm** | **Lunch** |
| **1:10pm** | **Specific aspects and support of Advanced Therapies**<br>• **Jan Mueller-Berghaus**, Paul-Ehrlich-Institut, Member of CHMP and CAT |
| **1:50pm** | **Taking the fourth hurdle: challenges with reimbursement and pricing**<br>• **Bjørn Oddvar Strøm**, Norwegian Medicines Agency, Senior Scientific Adviser |
| **2:30 pm** | **Refreshment Break** |
| **3:00 pm** | **Interactive discussion of practical examples in groups**<br>• format to be agreed among speakers |
| **3:45 pm** | **Review of the day: Tying it all together** |
| **4:00 pm** | **Workshop closure** |