Committee for Orphan Medicinal Products (COMP)
Draft agenda for the meeting on 18-20 June 2024

Chair: Violeta Stoyanova-Beninska
18 June 2024, 09:00-19:30, room 2A
19 June 2024, 08:30-19:30, room 2A
20 June 2024, 08:30-17:00, room 2A

Health and safety information
In accordance with the Agency’s health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers
Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the COMP meeting reports once the procedures are finalised.

Of note, this agenda is a working document primarily designed for COMP members and the work the Committee undertakes.

Note on access to documents
Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to ongoing procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).
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- Vote by proxy
- Strategic Review & Learning meetings
- Protocol Assistance Working Group (PAWG)
- COMP Decisions Database
- Election of COMP Chairperson

#### 7.2. Coordination with EMA Scientific Committees or CMDh-v

- Recommendation on eligibility to PRIME – report
- Joint resolution on the principles of conduct within EMA Scientific Committees, WPs and CMDx

#### 7.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

- Working Party with Patients’ and Consumers’ Organisations (PCWP) and Working Party with Healthcare Professionals’ Organisations (HCPWP)
- Innovation Task Force (ITF) meetings
- Scientific Advice Working Party (SAWP): nomination of COMP member to SAWP

#### 7.4. Cooperation within the EU regulatory network

- European Commission

#### 7.5. Cooperation with International Regulators

- Food and Drug Administration (FDA)
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#### 7.6. Contacts of the COMP with external parties and interaction with the Interested Parties to the Committee

#### 7.7. COMP work plan

#### 7.8. Planning and reporting

- List of all applications submitted/expected and the COMP rapporteurship distribution of valid applications submitted in 2024
- Overview of orphan marketing authorisations/applications

### 8. Any other business

#### 8.1. Spinal muscular atrophy (SMA) registry report

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1. Introduction

1.1. Welcome and declarations of interest of members and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the COMP plenary session to be held 18-20 June 2024. See June 2024 COMP minutes (to be published post July 2024 COMP meeting).

1.2. Adoption of agenda

COMP agenda for 18-20 June 2024.

1.3. Adoption of the minutes

COMP minutes for 21-23 May 2024.

2. Applications for orphan medicinal product designation

2.1. For opinion

2.1.1. - EMA/OD/0000164215

Treatment of myasthenia gravis

Action: For information

Note: Withdrawal request received on 5 June 2024.

2.1.2. - EMA/OD/0000139776

Prevention of T-cell engaging immunotherapy induced cytokine release syndrome

Action: For adoption, Oral explanation to be held on 18 June 2024 at 11:30

2.1.3. - EMA/OD/0000164923

Treatment of Duchenne muscular dystrophy

Action: For information

Note: Withdrawal request received on 3 June 2024.

2.1.4. - EMA/OD/0000169022

Treatment of symptomatic obstructive hypertrophic cardiomyopathy

Action: For information

Note: Withdrawal request received on 6 June 2024.
2.1.5. - EMA/OD/0000164949

Treatment of retinitis pigmentosa

**Action:** For adoption, Oral explanation to be held on 18 June 2024 at 14:00

2.1.6. - EMA/OD/0000163852

Treatment of hepatocellular carcinoma

**Action:** For adoption, Oral explanation to be held on 19 June 2024 at 11:30

2.1.7. - EMA/OD/0000169732

Treatment of hepatocellular carcinoma

**Action:** For adoption, Oral explanation to be held on 19 June 2024 at 11:30

2.1.8. - EMA/OD/0000167882

Treatment of variegate porphyria

**Action:** For adoption, Oral explanation to be held on 20 June 2024 at 08:45

2.1.9. - EMA/OD/0000169065

Treatment of eosinophilic esophagitis

**Action:** For information

Note: Withdrawal request received on 3 June 2024.

2.1.10. - EMA/OD/0000162927

Treatment of small cell lung cancer

**Action:** For information

Note: Withdrawal request received on 29 May 2024.

2.1.11. - EMA/OD/0000169553

Treatment of thrombotic thrombocytopenic purpura

**Action:** For adoption, Oral explanation to be held on 20 June 2024 at 11:00

2.2. **For discussion / preparation for an opinion**

2.2.1. - EMA/OD/0000159992

Treatment of acute lymphoblastic leukaemia

**Action:** For discussion/adoption
2.2.2. - EMA/OD/0000164952
  Treatment of complex regional pain syndrome
  **Action:** For discussion/adoption

2.2.3. - EMA/OD/0000165577
  Treatment of Fabry disease
  **Action:** For discussion/adoption

2.2.4. - EMA/OD/0000166679
  Treatment of primary central nervous system lymphoma (PCNSL)
  **Action:** For discussion/adoption

2.2.5. - EMA/OD/0000166750
  Treatment of epidermolysis bullosa
  **Action:** For discussion/adoption

2.2.6. - EMA/OD/0000167609
  Treatment of thrombotic thrombocytopenic purpura
  **Action:** For discussion/adoption

2.2.7. - EMA/OD/0000168590
  Treatment of mitochondrial neurogastrointestinal encephalomyopathy
  **Action:** For discussion/adoption

2.2.8. - EMA/OD/0000169543
  Treatment of chronic pancreatitis
  **Action:** For discussion/adoption

2.2.9. - EMA/OD/0000169884
  Treatment of spinocerebellar ataxia
  **Action:** For discussion/adoption

2.2.10. - EMA/OD/0000171666
  Treatment of alpha-1 antitrypsin deficiency
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2.3. **Revision of the COMP opinions**

None

2.4. **Amendment of existing orphan designations**

None

2.5. **Appeal**

None

2.6. **Nominations**

2.6.1. **New applications for orphan medicinal product designation - Appointment of COMP rapporteurs**

*Action*: For adoption

OMPDR applications - appointment of rapporteurs at the 18-20 June 2024 COMP meeting

2.7. **Evaluation on-going**

None

2.8. **Ongoing procedures**

2.8.1. **Treatment of narcolepsy**

*Action*: For adoption

2.8.2. **Treatment of glioma**

*Action*: For adoption

2.8.3. **Treatment of acute myeloid leukaemia**

*Action*: For adoption
3. Review of orphan designation for orphan medicinal products at time of initial marketing authorisation

3.1. Orphan designated products for which CHMP opinions have been adopted

3.1.1. Adzynma - apadamtase alfa - EMEA/H/C/006198, EU/3/08/588, EMA/OD/0000150694

Takeda Manufacturing Austria AG; Treatment of thrombotic thrombocytopenic purpura

Action: For adoption, Oral explanation to be held on 19 June 2024 at 15:00

3.2. Orphan designated products for discussion prior to adoption of CHMP opinion

3.2.1. - masitinib - EMEA/H/C/005897, EMA/OD/081/16, EMA/OD/0000125972

AB Science.; In combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis

Action: For information

3.2.2. Tepkinly - epcoritamab - EMEA/H/C/005985/II/0001, EU/3/22/2634, EMA/OD/0000157895

Abbvie Deutschland GmbH & Co. KG; Treatment of follicular lymphoma

Action: For discussion/adoption

3.2.3. - sotatercept - EMEA/H/C/005647, EU/3/20/2369, EMA/OD/0000157014

Merck Sharp & Dohme B.V.; Treatment of pulmonary arterial hypertension

Action: For discussion/adoption

3.2.4. - chimeric monoclonal antibody against claudin-18 splice variant 2 - EMEA/H/C/005868, EU/3/10/803, EMA/OD/0000166702

Astellas Pharma Europe B.V.; Treatment of gastric cancer

Action: For discussion/adoption

3.2.5. - odronextamab - EMEA/H/C/006215

Regeneron Ireland Designated Activity Company

a) Treatment of follicular lymphoma, EU/3/22/2649, EMA/OD/0000168564 Action: For discussion/adoption

b) Treatment of diffuse large B-cell lymphoma, EU/3/22/2656, EMA/OD/0000168574

Action: For discussion/adoption
3.2.6.  - elafibranor - EMEA/H/C/006231, EU/3/19/2182, EMA/OD/0000173044

Ipsen Pharma; Treatment of primary biliary cholangitis

**Action:** For discussion/adoption

3.3.  **Appeal**

None

3.4.  **On-going procedures**

**Action:** For information

Review of orphan designation for OMP for MA - On-going procedures

3.5.  **Orphan Maintenance Reports**

**Action:** For information

4.  **Review of orphan designation for authorised orphan medicinal products at time marketing authorisation extension**

4.1.  **After adoption of CHMP opinion**

None

4.2.  **Prior to adoption of CHMP opinion**

4.2.1.  Darzalex – daratumumab – EMEA/H/C/004077/II/0072, EU/3/13/1153, EMA/OD/0000171125

Janssen Cilag International; Treatment of plasma cell myeloma

**Action:** For discussion/adoption

4.3.  **Appeal**

None

4.4.  **On-going procedures**

**Action:** For information

Review of orphan designation for OMP for MA extension - On-going procedures

5.  **Application of Article 8(2) of the Orphan Regulation**

None
6. Organisational, regulatory and methodological matters

6.1. Mandate and organisation of the COMP

6.1.1. COMP membership

**Action:** For information

6.1.2. Vote by proxy

**Action:** For information

6.1.3. Strategic Review & Learning meetings

None

6.1.4. Protocol Assistance Working Group (PAWG)

Proposed meeting time on 18 June 2024 at lunch time

PAWG draft agenda for 18 June 2024 meeting

6.1.5. COMP Decisions Database

**Action:** For discussion

6.1.6. Election of COMP Chairperson

**Action:** For adoption

6.2. Coordination with EMA Scientific Committees or CMDh-v

6.2.1. Recommendation on eligibility to PRIME – report

PRIME eligibility requests - list of adopted outcomes May 2024

6.2.2. Joint resolution on the principles of conduct within EMA Scientific Committees, WPs and CMDx

**Action:** For information

6.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

6.3.1. Working Party with Patients’ and Consumers’ Organisations (PCWP) and Working Party with Healthcare Professionals’ Organisations (HCPWP)

None
6.3.2. Innovation Task Force (ITF) meetings

**Action:** For discussion

Upcoming ITF meetings

6.3.3. Scientific Advice Working Party (SAWP): nomination of COMP member to SAWP

**Action:** For adoption

Election of Joint COMP-SAWP alternate member - call for nomination – Extended deadline 12 June 2024

6.4. Cooperation within the EU regulatory network

6.4.1. European Commission

None

6.5. Cooperation with International Regulators

6.5.1. Food and Drug Administration (FDA)

None

6.5.2. Japanese Pharmaceuticals and Medical Devices Agency (PMDA)

None

6.5.3. Therapeutic Goods Administration (TGA), Australia

None

6.5.4. Health Canada

None

6.6. Contacts of the COMP with external parties and interaction with the Interested Parties to the Committee

None

6.7. COMP work plan

None

6.8. Planning and reporting

6.8.1. List of all applications submitted/expected and the COMP rapporteurship distribution of valid applications submitted in 2024

**Action:** For information
6.8.2. Overview of orphan marketing authorisations/applications

**Action:** For information

7. Any other business

7.1. Spinal muscular atrophy (SMA) registry report

**Action:** For discussion

8. Explanatory notes

The notes below give a brief explanation of the main sections and headings in the COMP agenda and should be read in conjunction with the agenda or the minutes.

**Abbreviations / Acronyms**

- CHMP: Committee for Medicinal Product for Human Use
- COMP: Committee for Orphan Medicinal Products
- EC: European Commission
- OD: Orphan Designation
- PA: Protocol Assistance
- PDCO: Paediatric Committee
- PRAC: Pharmacovigilance and Risk Assessment Committee
- SA: Scientific Advice
- SAWP: Scientific Advice Working Party

**Orphan Designation (section 2 Applications for orphan medicinal product designation)**

The orphan designation is the appellation given to certain medicinal products under development that are intended to diagnose, prevent or treat rare conditions when they meet a pre-defined set of criteria foreseen in the legislation. Medicinal products which get the orphan status benefit from several incentives (fee reductions for regulatory procedures (including protocol assistance), national incentives for research and development, 10-year market exclusivity) aiming at stimulating the development and availability of treatments for patients suffering from rare diseases.

Orphan Designations are granted by Decisions of the European Commission based on opinions from the COMP. Orphan designated medicinal products are entered in the Community Register of Orphan Medicinal Products.

**Protocol Assistance (section 3 Requests for protocol assistance with significant benefit question)**

The protocol assistance is the help provided by the Agency to the sponsor of an orphan medicinal product, on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of the medicinal product in view of the submission of an application for marketing authorisation.
Sponsor

Any legal or physical person, established in the Community, seeking to obtain or having obtained the designation of a medicinal product as an orphan medicinal product.

**Maintenance of Orphan Designation** (*section 4 Review of orphan designation for orphan medicinal products for marketing authorisation*).

At the time of marketing authorisation, the COMP will check if all criteria for orphan designation are still met. The designated orphan medicinal product should be removed from the Community Register of Orphan Medicinal Products if it is established that the criteria laid down in the legislation are no longer met.

For a list of acronyms and abbreviations, see:

*Abbreviations used in EMA scientific committees & CMD documents and in relation to EMA’s regulatory activities*

More detailed information on the above terms can be found on the EMA website: