



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA perspectives

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**How can we develop new treatments in ultra-rare sarcomas, as a model for ultra-rare tumours?  
12<sup>th</sup> January 2024**

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**The views expressed are personal views and not necessarily the views of ANSM or EMA**





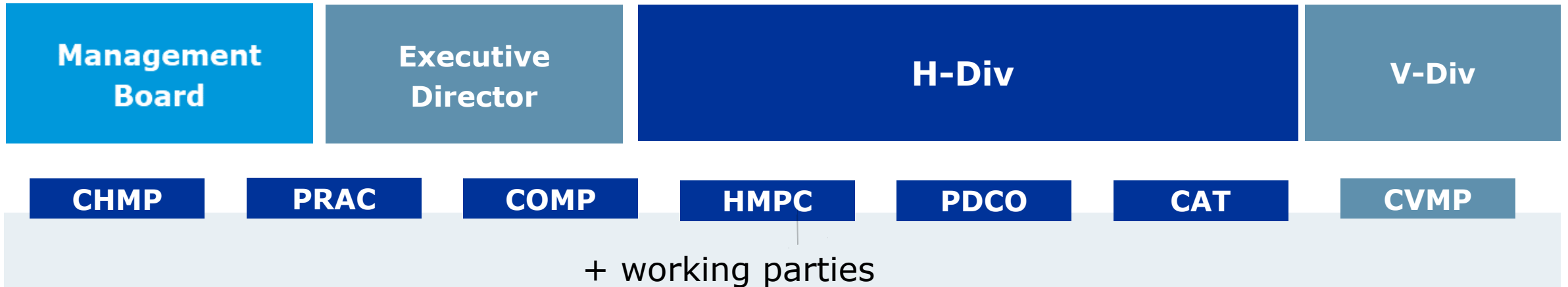
# EU regulatory strategies and review of Regulations – a time of change



- **Reform of the EU pharmaceutical legislation**: review of the pharma legislation: “ build a holistic, patient-centred, forward-looking EU Pharmaceutical Strategy”
- **European Health Data Space**
- **New Health Technology Assessment** (HTA) regulation
- **EMA regulatory science strategy** (further collaboration with HTAs/payers for their decision making on pricing and reimbursement)
- **EC beating cancer plan** (e.g. focusing on prevention)



# EMA – organisation and network



**EU National Competent Authorities**  
~ 4000 European experts

## EU institutions



**~ 50 National regulatory authorities worldwide (ICH)**



# Oncology Working Party and European Specialised Expert Community



## Oncology Working Party

Human Corporate

**The European Medicines Agency's (EMA) Oncology Working Party (ONCWP) was set up by the Committee for Medicinal Products for Human Use (CHMP) in order to carry out specific tasks related to oncology.**

The working party's tasks include:

- preparing, reviewing and updating guidelines and concept papers on working party related matters;
- European and international co-operation relating to working party activities;
- liaising with interested parties, such as industry, patient organisations and healthcare professional organisations;
- providing trainings and workshops to assessors;
- providing product related support upon request from EMA Committees and the [Scientific Advice Working Party](#).



## Oncology European Specialised Expert Community

Share

Human

### Page contents

Role

Mandate, rules of procedure and work programme

Composition

Related content

**The Oncology European Specialised Expert Community (ESEC) is a platform for information-sharing among European experts on scientific and regulatory topics related to oncology.**

It operates under the [Oncology Working Party \(ONCWP\) Committee for Medicinal Products for Human Use \(CHMP\)](#).

In 2022, the Oncology ESEC took over the tasks of the former Radiopharmaceuticals Drafting Group.

### Role

The Oncology ESEC provides a platform for information-sharing about:

- emerging regulatory actions and guidelines from the European Medicines Agency's (EMA) [scientific committees](#);
- completed assessments of product-related procedures and guidelines;
- ongoing EU activities in the field of oncology;
- international regulators' input;
- important scientific developments outside the [European medicines regulatory network](#), such as new treatment guidelines.



# Innovation and support – available tools

