EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EUCOPE

Town Hall Meeting

Virtual, 7 March 2023

Competition Law Compliance Policy

EUCOPE brings together representatives innovative companies to discuss common issues, challenges and trends affecting the pharmaceutical industry. This activity can be perfectly legitimate. However, certain competition law risks may arise in relation to EUCOPE's activities.

EUCOPE's European Union ("EU") compliance policy ("Policy") explains these competition law risks and aims to ensure compliance by all members and EUCOPE staff with the rules applicable in the EU. EUCOPE itself and its members are subject to these rules when engaging in any EUCOPE related activities. Any anticompetitive behavior adopted by a member can result in serious financial, criminal and/or disciplinary penalties, as well as other harm (e.g., reputational harm) for EUCOPE, represented companies and for meeting participants personally.

Competition Law Compliance Policy

There are certain matters which **should not** be discussed with competitors before, during or after any such meetings. These include:

- Territorial restrictions, allocation of customers, restrictions on types of services, or any other kind of market division;
- Prices, price changes, conditions of sale (including payment terms and guarantees), price differentials, discounts;
- Current market conditions and issues, including industry pricing policies or patterns, price levels; capacity (including planned or anticipated changes regarding those matters), except where limited to the discussion of historical or public information;

[cont'd]

Competition Law Compliance Policy

- Individual costs, cost accounting formulas, methods of calculating costs;
- Individual company figures on market shares, sources of supply, capacity;
- Information as to future plans of individual companies concerning technology, capacity, marketing or sales; and
- Matters relating to individual suppliers or customers.

Attention: these rules equally apply to informal discussions before, after, or during each meeting. If any sensitive information is discussed or disseminated, insist that the discussion be terminated immediately and make sure that your objection is recorded in the minutes. If necessary, leave the meeting and immediately inform EUCOPE's General Counsel.

Agenda (1/2)

I. Introduction and objectives

- Opening of the townhall
- Overview of EUCOPE advocacy priorities

Alexander Natz

II. Incentive review

- Short presentation by EUCOPE on (H)UMN, OME, RDP and launch conditionality
- Open discussion with Members

Victor Maertens & Stefano Romanelli

Break

Agenda (2/2)

III. Regulatory provisions

- Short presentation by EUCOPE on ERA, shortages and supply chains, EMA governance structure, early development and regulatory support
- Open discussion with Members

Axel Korth

IV. Open discussion

- Short presentation by EUCOPE on other topics of interest
- Discussion with Members of additional topics for consideration

EUCOPE

V. Closing and next steps

EUCOPE

I.
Introduction and objectives

Alexander Natz

The revision of the EU pharmaceutical framework

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

Current framework

General Pharmaceutical Legislation (GPL)

Medicinal Products Directive (2001/83/EC)

Dual legal path approval

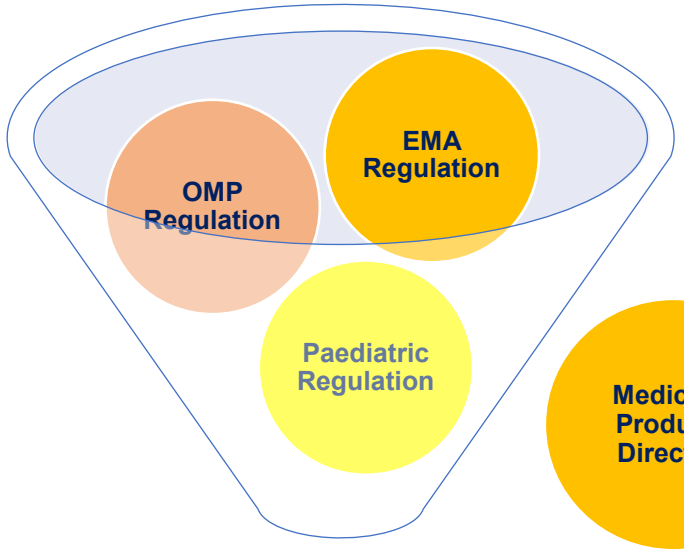
EMA Regulation (no. 726/2004)

OMP Regulation (no. 141/2000)

Paediatric Regulation (no. 1901/2006)

Planned review

29 March



Merged into a ‘Master Regulation’

Objectives

1. Present and validate EUCOPE advocacy priorities related to the EU Pharma Package

2. Address Members' questions and check for "white spots" or additional topics

3. Provide timeline with EUCOPE next steps

EUCOPE advocacy priority

Top-5 priorities

Incentive review

- (High) Unmet Medical Needs
- Orphan Market Exclusivity (OME) and “Global Orphan Marketing Authorization” (GOMA)
- Regulatory Data Protection (RDP)
- Launch Conditionality

- Regulatory Provisions

II.
Incentive review

Victor Maertens & Stefano Romanelli

Orphan Designation and Criteria

- Orphan prevalence threshold remains unchanged (5/10,000)
- In case a **treatment exists for the orphan indication**, **all existing methods should be taken into account** that at least partly overlap with the condition in question (Art 60)
- **Significant benefit definition**: clinically relevant advantage or a major contribution to patient care of an orphan medicinal product ***if such an advantage or contribution benefits a substantial part of the target population*** (Art. 2.7)
- **Orphan designation will be valid for 7 years** but can be extended, and **is required for the Orphan Rewards** (Art. 61)
  - "if the sponsor can provide evidence that the relevant studies supporting the use of the designated orphan medicinal product in the applied conditions are ongoing and promising with regard to the filing of a future application. Such an extension shall be limited in time, taking into account the expected remaining time needed to file an application for marketing authorisation."
- Introduces a global orphan marketing authorization (GOMA) – MAH cannot benefit from multiple separate exclusivity periods for the same active substance (Art. 67.6)

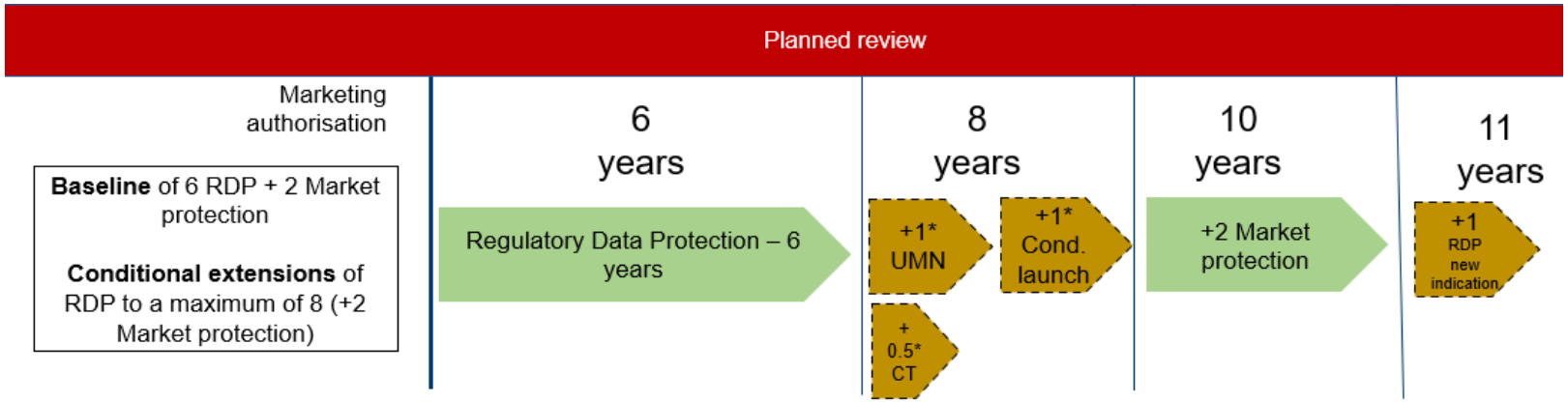
OME Modulation *(Art. 67 Regulation)*

- Orphan Paediatric incentive is removed
- Three ‘classifications’ of product are created. Exclusivity for products with 9/10 years OME can be extended if:
  - Expand into a new orphan indication
  - Launch in all Member States
- Orphans will not receive the RDP extensions for launching or moving into new (orphan) indication

RDP Modulation *(Art. 69-70 Directive)*

- Baseline:
  - 6 years RDP + 2 years market protection (MP)
- Conditional extension:
  - Maximum 8 years RDP + current 2 years MP
- Conditional RDP:
  - +1 year for UMN
  - +1 year for launch in all EU Member States
  - +6 months for comparative clinical trials
- +1 year extension for new indication remains in place as now, 8 years limitation does not apply
  - Not clear whether it will provide RDP (per Directive) or MP (per Regulation)

4 years RDP for repurposed medicinal products, but only once for each product, if it provides significant clinical benefit in comparison to existing therapies *(art. 74 Directive)*



*RDP can be extended, upon conditions to 6.5, 7, 7.5 or 8 years (as a cap)

(H)UMN

Unmet Medical Needs (UMN)
– art. 73 Directive

- A medicinal product is designated as UMN if:
  - At least one of its indications relates to a life-threatening or **severely** debilitating conditions ("disease level"); and
  - no medicinal products is authorized in the EU or it does not offer satisfactory method of diagnosis, prevention or treatment of the disease; and the use of a medicinal product results in **meaningful** reduction of **morbidity or mortality** for the relevant patient population ("product level")
- All OMPs are designated as UMN

Highest UMN (HUMN)
– art. 65 Regulation

- At least one of the product's indications diagnoses, prevents or treats an orphan condition for which:
  - No satisfactory diagnosis, prevention or treatment method exist;
  - or a satisfactory diagnosis, prevention or treatment method exists and it has been demonstrated by the applicant that such a product will bring **exceptional therapeutic advancement**;
  - The product must **meaningfully reduce** disease morbidity or mortality for the **relevant part of the population**
- The EMA will develop additional scientific guidelines to define HUMN

Crucial aspect: who will decide which products address (H)UMN in real-life (besides the definition)
A consultation mechanism is envisioned

Launch Conditionality

Art. 70-71 Directive

- Launch in all EU Member States (unless MS opt-out):
  - +1 year RDP
  - +1 year OME
- "The medicinal product should be released and continuously supplied in a sufficient quantity and in the presentation necessary to cover the needs of the patients in the Member States in which the MA is valid"
  - Within 2 years from MA or
  - In case of SMEs, **within 3 years from MA**
- MAH shall apply for variation of MA between 34-36 months, or 46-48 months for SMEs, after initial MA
- Within 60 days from MAH request, Member State shall issue a confirmation of compliance, a statement of non-compliance or provide a waiver

Open discussion

Probing questions

- Where would you want to see EUCOPE make the biggest change regarding the review of the OME and RDP modulation frameworks?
- What are the major barriers in the proposed incentive framework for ‘second to market’ therapies? Would the current system discourage or reduce the likelihood of investment?
- What are the biggest sources of ‘unpredictability’ that are introduced into the system?
- To what extent would the new definition of UMN impact investment decisions or priorities for your companies?
- Based on your internal assessments, how many therapies would no longer quality as an orphan therapy based on changes to the significant benefit definition?
- How significant is the introduction of the GOMA system and would to what extend do you see it impacting your launch and research decisions?
- What would be the impact of RDP reduction on the company business model? Would it reduce R&D, investments, or delay launch in the EU?
- Would there be interest in a 'launch in Europe first' incentive?

Break
(10-min)

III.
Regulatory provisions

Axel Korth

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EUROPEAN COMMISSION

Brussels, XXX
PLAN/2021/10601
[…](2023) XXX draft

SENSITIVE*

Pharmaceutical package

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

(Text with EEA relevance)

- Context
- Environmental Risk Assessment
- Medicines shortages and security of supply
- Revised EMA Governance Structure
- Early development and regulatory support

Context of Proposed Changes

Specific Objectives

- Simplify regulatory framework, reduce the regulatory burden and provide a flexible regulatory framework, streamlining and acceleration of procedures
- Enhanced coordination of the European medicines regulatory network
- Enhanced digitisation (re-use of data, eSubmissions, ePI, etc.)
- Promoting innovation and novel technologies in areas of unmet medical need
- Access to affordable medicines
- Enhancing security of supply of medicinal products
- Reducing the environmental impact of the pharmaceutical product

Reducing environmental impact

More comprehensive requirements for Environmental Risk Assessment (ERA)

- **Context**:
  - European Green Deal, COM(2019) 640 final
  - EU Action Plan “Towards a Zero Pollution for Air, Water and Soil”, COM/2021/400 final
  - European Union Strategic Approach to Pharmaceuticals in the Environment, COM (2019), 128 final
- **Complementary** to the main environmental legislation
  - Revision of the Urban Waste Water Treatment Directive(91/271/EEC)
  - Revision of the Industrial Emissions Directive (2010/75/EU)
  - Revision of the list of surface and groundwater pollutants under the Water Framework Directive (2000/60/EC)
  - Environmental Quality Standard Directive (2008/105/EC)
  - Groundwater Directive (2006/118/EC)
  - Drinking Water Directive (2020/2184)
- **Consequence** and overall objectives:
  - Tighter requirements for Environmental Risk Assessment (ERA) **in the marketing authorisation**
  - Evaluation of risk, limitation of potential adverse effects to the environment and public health
  - Scope of ERA extended to cover the entire product lifecycle
  - New protection goals such as risks for antimicrobial resistance (AMR)

Environmental Risk Assessment (ERA)

MAA must include an ERA – General requirements (Art. 14 (1)

- Evaluation of the risks to the environment due to the use and disposal (Art. 14 (2), Annex II)
  - For manufacturing, ERA shall provide information on discharges and emissions of the active substance and other environmentally relevant substances (Annex II of DIR)
- Proposed risk mitigating measures to reduce discharges and emissions of the medicinal product (Art. 14 (3))
- ERA shall also include information whether the risk mitigation measures take the main environmental standards **under any applicable legislation** into account
- **Antimicrobial MoA**: ERA shall include an evaluation of the AMR selection and specific requirements in Art. 17
- Ongoing obligation to update the ERA (Art. 14 (6)) and resubmission in accordance with Art. 87 (2) if new information becomes available including updates on the emissions (manufacturing), relevant information from environmental monitoring (DIR 2000/60/EC), from eco-toxicity studies, new or updated risk assessments under other legislation and the collation of sales data
  - In any event 5 years after issuance of the MA (Art. 14 (7))
- EMA to coordinate with ECHA, EFSA, EEA and draw up scientific guidelines to specify technical details in Annex II to Directive

Environmental Risk Assessment (ERA)

Market authorisation applications must include an ERA

- **Medicinal Products authorised prior to October 2005 (prior to submitting an ERA)**
  - Specific provisions to be introduced to set up a programme for the ERA of those products potentially harmful, Art. 15
- **Environmental Monograph**: EMA (in collaboration with NCAs) shall setup system of monographs of the environmental properties of active substances that are used in an authorised medicinal product and identified as potentially of concern to the environment
- **Issuing of MA** with assessment report including ERA, Art. 34 (4)
- **Conditional MA** – conduct post-authorisation ERA studies, collection of monitoring data, AMR (Art. 35 (1) lit. (h) DIR
- **Refusal of MA regarding insufficient ERA** – Art. 38 (1) para. (d) DIR, Art. 15 Reg
- Rx requirement where active substance contains hazardous property for the environment and Rx as risk mitigation measures (Art. 46 (1) lit. (f) (2), special Rx requirements for **antimicrobial** products, Art. 46 (2), (4) (d)

Environmental Risk Assessment (ERA)

Specific provisions for medicinal products consisting of GMO

- MA for medicinal products containing or consisting of genetically modified organisms (GMO) shall be accompanied by an ERA identifying and characterising possible hazards for human health, animals and the environment
  - ERA to be based on the principles set out in DIR 2001/18/EC taking the specificities of the medicinal products into account
  - Art. 13 – 24 of DIR 2001/18/EC not applicable for GMO medicinal products
  - Art. 6 – 11 of DIR 2001/18/EC as well as Art. 4 – 13 DIR 2009/41/EC not applicable with respect to operations related to supply and clinical use of GMO relevant product
- ERA shall cover the following elements:
  - Description of the GMO and the modifications introduced as well as characterisation of the finished product
  - Identification and characterisation of hazards for human health, animals and environment
    - Re treated patient: risk part of the benefit-risk assessment
  - Exposure characterisation: likelihood that identified hazards materialise
  - Risk characterisation: magnitude of each possible hazard and likelihood of AE
  - Risk minimisation strategies to address identified risks
- ERA to be submitted to EMA and assessed by CHMP
  - CHMP opinion must take ERA assessment for GMO into consideration
  - CHMP may establish ERA working party

Security of supply and medicines shortages

Context – Evolving EU framework

- Shortages are an increasing problem in the EU and has been for the past 15-20 years
- Pharmaceutical Strategy for Europe (25 November 2020)
- HMA/EMA TF AAM (2016) and Work Programme (2021 – 2015)
- DG HERA (since 16 September 2021) – health emergencies
- Joint Action on Shortages (3-year-plan, started end of 2022)
- **EMA's Extended Mandate** (Regulation (EU) 2022/123) – public health emergency/major event
  - "*First step towards improving the Union's response to a persistent problem*"
  - Bodies established: MSSG, SPOC (single point of contact) Working Party, Emergency Task Force (ETF)
- HMA/EMA multi-stakeholder workshop on shortages on 1 & 2 March 2023

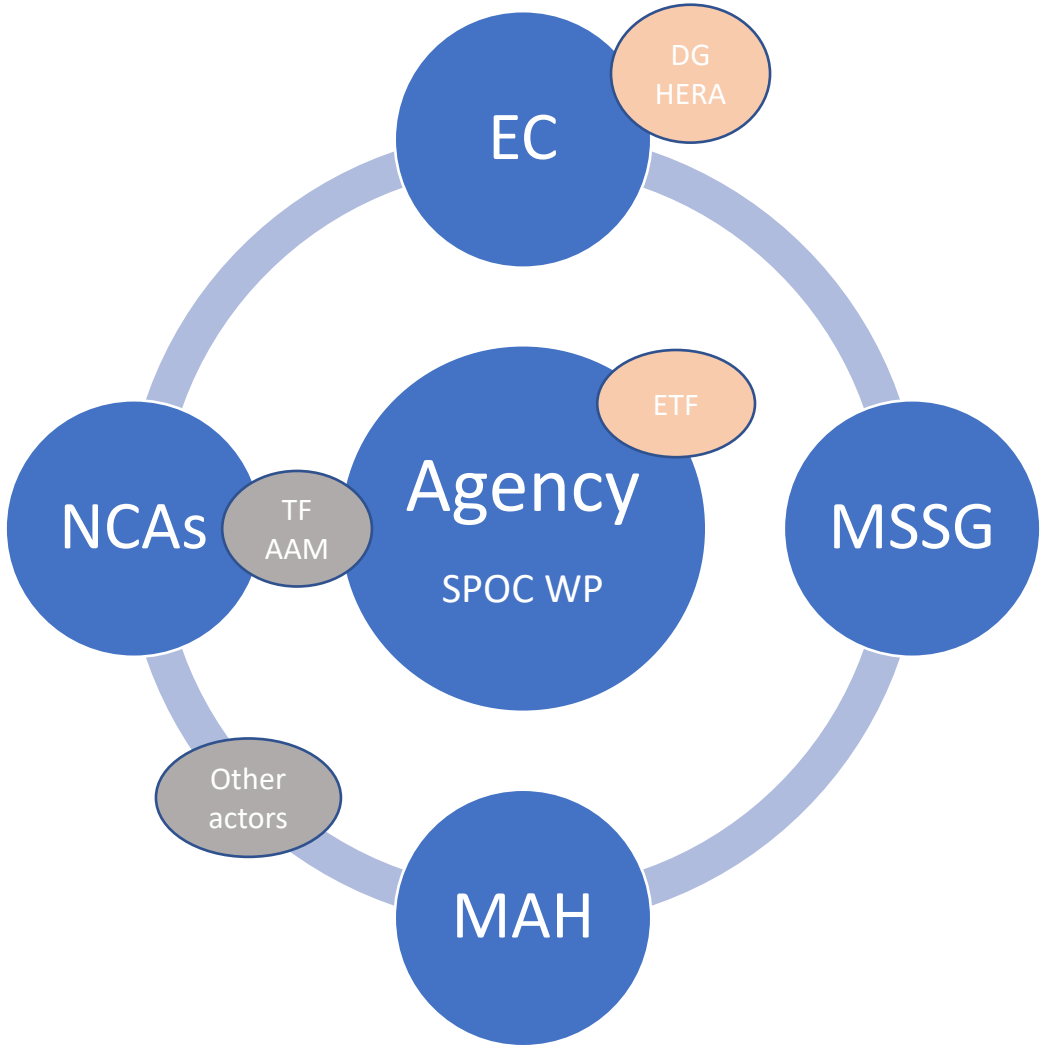
→ Inform future legislative decision-making

Pharma Package

- Very **comprehensive framework** for activities to be deployed on Union level and Member States' level
- **Objective**: enhance EU's capacity to react efficiently and **coordinated** to support shortages management and security of supply of medicines, particularly **critical medicines**, to EU citizens at all times

Complex framework with multiple actors

Further strenghtened role of the Agency in shortages prevention and management



Role of the MSSG

- Continuation of Regulation (EU) 2022/123
- Composition: EMA, EC, NCAs
- Adoption of "*Union list of critical medicinal products*" and of "*List of critical shortages of medicinal products*"
- Consultation with Agency, SPOC WP and NCAs
- Amend and update lists
- Provide recommendations on security of supply and shortages mitigation/resolution measures to MAH, NCAs, EC or other entities
- Review status of critical shortages
- Information and coordination

Role of the Agency

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

- Continuous information exchange between EMA (MSSG, SPOC WP) and NCAs including reporting obligations
- Develop methodology to identify critical medicinal products and critical shortages
- Specify procedures and criteria for establishing and reviewing lists
- Specify methods and criteria for reporting by NCAs or MAHs, monitoring and recommendations by the MSSG
- Specify methods for the provision and review of recommendations by the MSSG on **security of supply and shortages mitigation measures**
- Maintenance of web-portal and provision of recommendations
- Draw up guidance for SPP and SMP
- Continuous monitoring of ***actual and potential shortages*** and ***critical shortages*** of CAPs in collaboration with NCAs
- Regular reports and information on shortages monitoring to MSSG and EC including potential major event (Extended Mandate Regulation)
- Far-reaching information rights (NCAs, MAH) and obligations (MSSG)

Role of the Commission

- Take recommendations into consideration and implement measures
- Facilitate coordination between MAHs and other relevant entities
- Consider need for guidelines and recommendations to MAHs, MS or other entities (including supply chain)
- EC may request an opinion from MSSG on recommendations
- Implementing acts to improve security of supply

Role of the MS/NCAs

- Identify critical medicinal products using common methodology
- MS/NCAs **through single points of contact (SPOC)** report to Agency any critical medicinal product identified or critical shortage
- Provide information to Agency regarding lists and comply with information requests and reporting obligations
- Take recommendations and guidelines into consideration
- Inform MSSG on any measures taken
- Continuously monitor any actual or potential shortage
- Publish information on shortages

Role of the MAH

- Prepare and keep up-to-date a **shortage prevention plan** (SPP) after MA has been granted (template), Art. 40 (1) DIR
- Shortages Mitigation Plan (SMP)
- **Notification** requirements to the NCA, Art. 40 (2) DIR (as part of the responsibilities of the MAH)
  - Permanently cease marketing
  - Temporarily suspend marketing
  - Permanently withdraw the MA
  - Temporary disruption in supply (actual or potential shortage)
  - Permanent withdrawal of a critical medicinal product
- Compliance with information requests from Agency/NCAs

Role of other actors

- Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products to the public (pharmacies, HCPs, HCOs, etc.) ***may*** report a shortage of medicinal product to the NCA
- Comply with information requests by NCA provided that actors have information regarding shortage

Revised EMA Governance Structure

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

Context and Reasons

- Agility, functioning and efficiency of European regulatory system
- EMA and NCAs confronted with increasing number of procedures, duplication of work, challenges with innovative/complex therapies
- Capacity limitations exacerbated during Covid-19

Measures

- EMA committee structure reduced from 5 to 2 > **CHMP and PRAC (as main safety committee)**
- CAT, COMP, PDCO and HMPC to be organised in working parties and pool of experts to provide specific input to CHMP, PRAC and CMDh
- CHMP/PRAC > experts from members states and **first-time patient representative**
- Model of rapporteurs remains unchanged
- Representation of patients and HCPs with expertise shall be increased
- More resources for **early SA** to promising medicines and repurposing, lifecycle approach
- More training opportunities and capabilities enhanced

Enhanced pre-authorisation scientific and regulatory support

- Enhanced legal framework for scientific advice (SA) and accelerated assessment and authorisation of medicines if they offer **exceptional therapeutic advancement in areas of UMN**
- Experienced gained with **PRIME scheme broadened**, i.e. phased review of data (Art. 57 Reg)
- Dedicated support scheme for SMEs and not-for-profit entities
- EMA will be able to provide SA to developers in **parallel** with the SA given by HTA bodies under the HTA Regulation or by expert panels (Art. 56)
- EMA will be able to provide scientific opinions related to the classification of products, advising developers and regulators on whether a particular product is a medicine or not (Art. 58 Reg)
- Protocol assistance and R&D support for OMPs, Art. 68 Reg
- EMA – coordinate a mechanism of consultation of public authorities active along the medicines lifecycle, to promote the exchange of information and pooling of knowledge on general issues of scientific and technical nature relevant for the development, evaluation and access to medicines

Reducing regulatory burden and ensuring flexible regulatory framework for innovation and competitiveness

Other simplification, streamlining and future proofing measures

- Electronic submissions
- Electronic Product Information (ePI) – MS to decide if paper or electronically
  - EC empowered to adopt delegated acts to make ePI mandatory from 2035 onwards
  - If qualified majority of MS allowed ePI, package leaflet always to be provided on patient's demand
- Abolishment of the renewal and the sunset clause
- Emerging developments in science
  - Adapted clinical trials (CT)
  - Use of RWE
  - Secondary use of health data
  - **Regulatory sandboxes** (can be linked to an adapted approval framework, Art. 115 - 117)
- **Evolutionary** and simplified Paediatric Investigation Plans (PIPs) subject to conditions regarding timing and substance (Art. 75 ff.)
- SA for paediatric developments (Art. 86)

Regulatory Sandbox

Definition and Elements

(1) A **controlled environment** for a **limited period of time**

(2) pursuant to **sandbox plan** for developing and testing innovative or adapted solutions

(3) that facilitate the development and authorisation of products that ***might*** be regulated as medicinal products

- Agency to monitor field of emerging medicinal products for potential regulatory sandbox cases
- Agency to request information from MAH, developers, experts, researchers, HCPs and patients and engagement in preliminary discussions

Regulatory Sandbox

Mandatory Conditions

(1) **Not possible** to develop the medicinal product or category of products **in compliance with the requirements applicable** to medicinal products due to **scientific or regulatory challenges** arising from characteristics or methods related to the product

(2) Characteristics or methods **positively contribute to the quality, safety or efficacy** of the product/category or provide **major advantage contribution to patient access to treatment**

Regulatory Sandbox

General provisions

- Competent authorities can always take immediate action to suspend or restrict use of sandbox in case of risk to public health or safety concerns
- MAH remains fully liable under EU and national laws for any harm infliced on third parties as a result from testing a product within a sandbox
- MAH obliged to inform Agency of concerns regarding safety, quality or efficacy of sandbox product
- All modalities and conditions of the operation of regulatory sandboxes, eligibility etc. shall be set out in implementing acts
- Annual report by Agency to EC to inform decision-making

Regulatory Sandbox

Governance and Scrutiny

- Regulatory sandbox may be set up by the **Commission** through **implementing acts** based on **recommendation** by the Agency
- **Development of sandbox plan by the Agency** based on data submitted by developer of eligible products
- Plan must set out **clincial, scientific** and **regulatory justification** for the sandbox, derogation from regulatory requirements and alternative / mitigation measures
- **Direct supervision of the competent authorities** to ensure compliance with Regulation and other EU and national laws
- Member states shall take sandbox plan into consideration when authorising a clinical trial
- Product developed as part of a regulatory sandbox may be placed on the market when authorised under the Regulation (MA not to exceed duration of sandbox)
- Suspension or revocation by EC at any time (conditions, public health)

EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

Thanks for your attention!

Q&A

IV.
Open Discussion

EUCOPE

ATMPs

GMO provisions – *Regulation Art. 172*: Investigation medical products will be exempt from the relevant GMO Directive articles and instead submit an ERA

CAT – *Regulation recital 35*: The CAT will be dissolved as a permanent body, ATMPs are now considered more common

Hospital Exemption (HE) – *Directive Art. 3*: Principle remains unchanged. However, stricter data collection requirements are put in place regarding the safety, efficacy, and use of HE. The Commission will have the option to **create a pathway for less complex ATMPs 3 years after the Directive goes into effect**

R&D Transparency

Art. 41 Directive

The Commission will introduce a notification to report public funding for **transparency of R&D costs**. MAH shall list public funding or financial support to conduct any clinicals trial relevant to MA, and this report shall be accessible to public

Paediatric

Chapter VII Regulation

- **6-month SPC extension** remains in place as a reward for the PIP completion *(art. 92 Regulation)*
- **5 years deferral cap for PIP** has been included in the report; in case of justified reasons, prolongation of referrals can be granted *(art. 79-80 Regulation)*
- **Market exclusivity** for Paediatric OMPs has been removed
- **Dissolution** of the Paediatric Committee (PDCO) but there is the plan to maintain its pool of expertise

AMR

Art. 40-42 Regulation

- Innovators that discover new “priority antimicrobials” will be eligible for a Transferable Exclusivity Voucher (TEV), which will allow its holder one additional year of Regulatory Data Protection (RDP)
- A maximum of 10 vouchers can be granted over a 15-year period, after which all TEV provisions will cease to apply
- The TEV proposals come with several caveats, including the threat of invalidation if the antimicrobial is withdrawn from the market, or if certain access requirements are not met
- The value of the TEV that is sold must also be disclosed to the European Medicines Agency (EMA) and made public

Open discussion

Probing questions

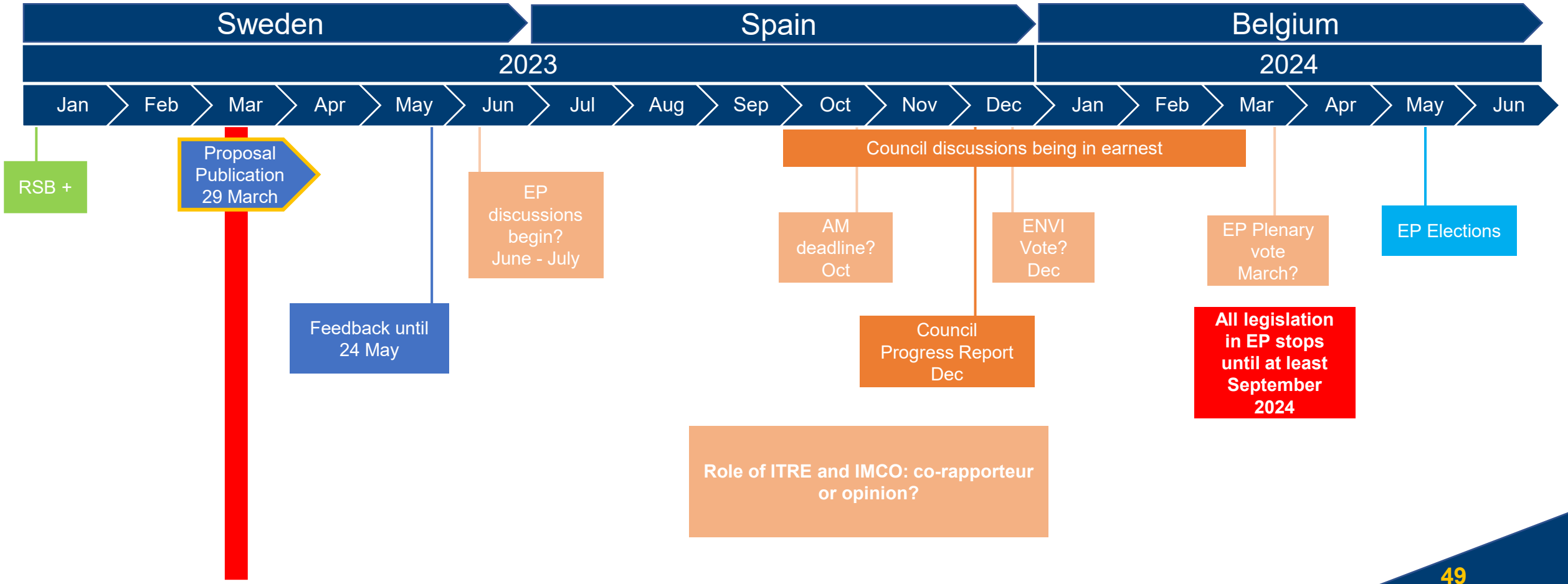
- The regulatory sandboxes are currently vaguely described. As an industry, what would we want to see for these sandboxes to be helpful in approving innovative therapies?
- Would it be feasible to disclose, and keep up-to-date, public funding for clinical trials relevant to MA, as in the leak proposal?

V.
Closing and next steps

EUCOPE

Legislative Process Overview

European Parliament will have **less than 11 months** to effectively discuss the proposal



NB: These timings are indicative and rough estimates, not official – it assumes a 'fast' process

Proposal Feedback

EUCOPE has begun developing 8-week feedback report (4,000 characters)

- Expectation is that it will be a single response for full Pharmaceutical Package
  - Short response will outline EUCOPE key concerns
- EUCOPE is developing an extended ‘response’ to be submitted as an attachment

Key themes for EUCOPE’s feedback

2-3 sentence response
- (H)UMN
- Orphan incentive review
- Regulatory Data protection
- Launch conditionality

List of additional areas of concern
- ERA requirements
- Medicine shortages requirements and notifications
- Compulsory licensing
- PIP deferral
- R&D transparency
- Regulatory reforms

List of welcome changes
- Scientific advice
- Electronic submissions
- ePI
- Adaptive clinical trials

EUCOPE will maintain our pre-existing positions in the feedback, as opposed to offering compromises

Proposal Feedback: timelines

EUCOPE will share **Feedback** with Members for their input:

- 12 April – EUCOPE shares first draft with full membership
- 24 April – Deadline member comments on feedback
- 10 May – EUCOPE circulates updated feedback for final comments or ‘red flags’
- 18 May – deadline members final comments
- 24 May – EUCOPE publishes feedback

Thank you for your attention!