EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

WORKING GROUPS & TASK FORCES

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OUR WORK

We provide a platform for discussion on major healthcare topics and developments, provide ad hoc expertise and updates on national market access and HTA issues and ensure that **our members' voices are heard first in the early stages of policy-making and legislative procedures** at the EU and Member State level.

HOW WE WORK

WORKING GROUPS & TASK FORCES

In close collaboration with our members, we analyse, monitor and engage on several topics and themes in our Working Groups, Steering Groups and Task Forces.

NEW

HERA STEERING GROUP

ORPHAN MEDICINAL PRODUCTS (OMP)

CELL & GENE THERAPIES

INCENTIVES STEERING GROUP

PRICING & REIMBURSEMENT/ MARKET ACCESS

DIGITAL HEALTH

EU PHARMA STRATEGY

REGULATORY

GENOMICS

EU HTA REGULATION

WORKING GROUP

ORPHAN MEDICINAL PRODUCTS (OMP)

OPEN TO ALL EUCOPE MEMBERS

Shaping EUCOPE's response to the OMP Regulation and discussing EU, national and international developments in orphan medicinal products.

OBJECTIVES

The OMP Working Group offers an opportunity to discuss the latest legislative and policy developments on rare diseases and orphan drugs at the EU and Member State level without neglecting relevant global or international developments.

With almost half of our members involved in the research and development of therapies for rare diseases, this group feeds into public consultations and develops position papers that work towards creating better health solutions for persons living with rare diseases in Europe.

ACTIVITIES

- Updates and analyses on the latest EU and national developments on OMP and rare diseases
- Engage and network with institutional, non-profit, and academic stakeholders invited regularly to present and discuss legislative OMP and rare diseases developments
- Suggest topics of focus and speakers for the group meetings

MEETINGS

OMP Working Group Meetings take place once per quarter.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Victor Maertens maertens@eucope.org

WORKING GROUP

REGULATORY

OPEN TO ALL EUCOPE MEMBERS

Shaping EUCOPE's stakeholder representation in regulatory bodies and providing steady information and discussion on regulatory issues.

OBJECTIVES

The Regulatory Working Group offers strategic, concise and effective opportunities to discuss all regulatory matters at the national and the European level.

In order to focus on top priorities, the Regulatory Working Group has changed its approach by re-organising into nine (9) focus groups, each led regulatory policy leaders and subject matter experts.

ACTIVITIES

- Updates and analyses on the latest EU and national developments on regulatory affairs and priorities such as: R&D, Clinical Trials, MDR/IVDR Implementation
- Engage with regulatory policy leads and subject matter experts
- Suggest ad hoc topics of focus, raise awareness and suggest speakers for the focus group meetings

MEETINGS

Regulatory Working Group Meetings take place once per quarter.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Dr Seán Byrne byrne@eucope.org

WORKING GROUP

PRICING & REIMBURSEMENT / MARKET ACCESS

OPEN TO ALL EUCOPE MEMBERS

Discussing relevant pricing and reimbursement developments at EU and Member States level while forming EUCOPE's response to market access topics.

OBJECTIVES

The P&R/Market Access Working Group offers the opportunity to discuss the current legislative/regulatory developments in key European markets for pharmaceuticals and their impact on pricing and reimbursement/market access decisions.

This includes the exchange of up-to-date information as well as thorough legal analysis and concrete assessments of current legislative and regulatory proposals.

ACTIVITIES

- Updates and analyses on the latest developments related to pricing reimbursement and market access in the EU and Member States.
- Provides opportunities to suggest topics of focus and speakers for the group meetings.
- Offers members the opportunity to develop common positions.

MEETINGS

P&R/Market Access Working Group Meetings take place once per quarter.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Matias Olsen olsen@eucope.org

WORKING GROUP

CELL & GENE THERAPIES

OPEN TO INSTITUTIONAL MEMBERS ONLY

Informing EUCOPE's position and engagement on relevant EU policy discussions while advancing an appropriate assessment and reimbursement environment to improve access to ATMPs.

OBJECTIVES

The Cell & Gene Therapies Working Group is a forum to discuss developments and identify solutions to promote access to ATMPs.

The group provides a vehicle to address common challenges and present a shared vision for a paradigm-changing therapy.

ACTIVITIES

- Updates and analyses on the latest EU developments related to ATMP space.
- Provides an opportunity to feed into and shape the development of EUCOPE's positions.
- Engage and network with institutional, non-profit, and academic stakeholders invited regularly to present and discuss legislative developments.

MEETINGS

Cell & Gene Therapies Working Group Meetings take place once per quarter, with ad-hoc meetings on occasion.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Victor Maertens maertens@eucope.org

WORKING GROUP

GENOMICS

Working towards adequate pricing and reimbursement for advanced diagnostics in Europe.

OPEN TO ALL ADVANCED DIAGNOSTICS COMPANIES WITHIN EUCOPE

OBJECTIVES

The Genomics Working Group is made up of advanced diagnostics companies that have come together to ensure Europe will be able to draw benefit from the significant advances that have been made in genomic testing.

The group aims to facilitate a dialogue around these technologies at EU level and in key Member States, in order to make decision-makers and stakeholders more aware of their value and work towards fit-for-purpose assessment frameworks and effective pathways for reimbursement of genomic testing.

ACTIVITIES

- Monitoring and updates on changes to pricing and reimbursement frameworks for advanced diagnostics at the national level.
- Engagement on key EU dossiers, including Europe's Beating Cancer Plan and the EU Cancer Mission.
- Engaging in discussions with stakeholders and decision-makers around the value of advanced diagnostics.

MEETINGS

Genomics Working Group Meetings take place on a monthly basis.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Matias Olsen olsen@eucope.org

WORKING GROUP

DIGITAL HEALTH

Leading the discussion on digital health topics and shaping EUCOPE's position on EU's digital health policy.

OPEN TO ALL EUCOPE MEMBERS

OBJECTIVES

The Digital Health Working Group was formed to respond to members' needs and the current political impetus on artificial intelligence (AI) and digital health.

EUCOPE is also part of the eHealth Stakeholder Group, an expert group that provides advice and expertise to the European Commission on topics related to the digital transformation of health and care, such as health data, digital health services or the use of artificial intelligence.

ACTIVITIES

- Updates and analyses on the latest developments related to the European Health Data Space (EHDS) and AI Act.
- Opportunities to feed into and shape the development of EUCOPE's positions.
- Opportunities to engage and network with institutional, non-profit, and academic stakeholders invited regularly to present and discuss legislative developments.

MEETINGS

Digital Health Working Group Meetings take place on a bi-annual basis.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Leander Vranken vranken@eucope.org

STEERING GROUP

INCENTIVES (ISG)

Working to ensure the European incentives framework remains attractive and functional for industry.

ADDITIONAL FEE REQUIRED FOR MEMBERSHIP

OBJECTIVES

The Incentives Steering Group (ISG) offers the opportunity to discuss the current legislative developments in relation to the European Commission's revision of pharmaceutical incentives, in particular, the revision of the Orphan Medicinal Products (OMP) Regulation.

The group defines strategies to engage on the Orphan Medicinal Products Regulation review and develops advocacy and dissemination activities on incentives related to orphan drugs in Europe.

ACTIVITIES

- Political analyses and intelligence on the OMP Regulation incentives review and related issues.
- Ad hoc technical analyses from expert service providers.
- Close involvement in engagement and dissemination activities and shaping of the EUCOPE strategy on incentives for OMPs.
- The opportunity to input in EUCOPE's approach to multistakeholder partnerships on rare diseases.

MEETINGS

Incentives Steering Group meetings take place on a monthly basis and work in close coordination with other Working Groups.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
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STEERING GROUP

HEALTH EMERGENCY PREPAREDNESS & RESPONSE (HERA)

NEW

OPEN TO MEMBERS WORKING ON HERA-RELATED TOPICS

Working to strengthen EU preparedness and response to serious cross-border health threats.

OBJECTIVES

The HERA Steering Group aims to set common goals and objectives for engagement with stakeholders related to serious cross-border health threats such as pathogens with high pandemic potential, chemical, biological, radiological and nuclear threats (CBRN), and threats resulting from antimicrobial resistance (AMR).

EUCOPE is a participant of the HERA Advisory Forum and the Joint Industrial Cooperation Forum (JICF).

ACTIVITIES

- Political analyses and intelligence on HERA and serious health emergencies.
- Ad hoc technical analyses from expert service providers.
- Close involvement in engagement and shaping of the EUCOPE strategy within HERA and Joint Industrial Cooperation Forum (JICF)
- Keep up to date on all HERA-related activities such as timelines, legislative developments and outreach.

MEETINGS

HERA Steering Group meetings take place on a bi-monthly basis and work in close coordination with other Working Groups.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
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TASK FORCE

EU PHARMACEUTICAL STRATEGY

OPEN TO ALL EUCOPE MEMBERS

Driving EUROPE's response and engagement on the Commission's Pharmaceutical Strategy, with a specific focus on the General Pharmaceutical Legislation review.

OBJECTIVES

The Pharmaceutical Strategy Task Force was formed in response to the launch of the Pharmaceutical Strategy. The group analyses Commission initiatives and tracks key developments.

With a specific focus on the review of the General Pharmaceutical Legislation (GPL), the Task Force is a mechanism to develop and deliver a shared industry position to the most fundamental review to the EU pharmaceutical legislations, and engage broadly on policy developments that will inform the EU pharmaceutical landscape in the coming decades.

ACTIVITIES

- Updates and analyses on the latest developments related to the GPL and Pharma Strategy.
- Opportunities to engage with the EU's formal review process of the GPL.
- Offers opportunities to feed into and shape the development of EUCOPE's positions.
- Engage and network with multiple stakeholders invited regularly to discuss legislative developments.

MEETINGS

EU Pharma Strategy Task Force meetings take place on a monthly basis and work in close coordination with other Working Groups.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
Stefano Romanelli romanelli@eucope.org

TASK FORCE

EU HTA REGULATION

OPEN TO ALL EUCOPE MEMBERS

Coordinating with members on the engagement for the preparation of methodology and procedural rules for the EU HTA Regulation

OBJECTIVES

The EU HTA Regulation Task Force has been set up to closely coordinate with members on the engagement with the European Commission and EUnetHTA21 for the development of the procedural rules and methodology respectively.

The EU HTA Regulation has now entered into force. Starting from 12 January 2025, cancer medicines, ATMPs and certain medical devices and IVDs will be subject to joint clinical assessments at the EU level.

ACTIVITIES

- Discuss specific methodological considerations and prepare input for EUnetHTA 21 consultations.
- Develop common positions and priorities for engagement with the EU institutions in preparation for implementing acts.
- Engage and network with patients, clinicians and other experts in EU-HTA and discuss legislative developments.
- Covers options for early dialogue / joint scientific consultations in the EU procedure.

MEETINGS

EU HTA Regulation Task Force meetings take place on a monthly basis.

All meeting dates will be sent via email and can also be found on the EUCOPE website.

GROUP CONTACT INFORMATION
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THANKS FOR LISTENING

For more information:

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