EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

HOW WE WORK

OUR WORKING GROUPS

Open to all EUCOPE Members

- ORPHAN MEDICINAL PRODUCTS
- LEGAL AFFAIRS
- REGULATORY
- PRICING & REIMBURSEMENT/ MARKET ACCESS
- CELL & GENE THERAPIES
- GENOMICS
- DIGITAL HEALTH

OUR STEERING GROUPS

- INCENTIVES

OUR TASK FORCES

Open to all EUCOPE Members

- PHARMA STRATEGY
- EU-HTA REGULATION

All Working Group, Steering Group and Task Force meeting dates can be found on the EUCOPE website.

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WORKING GROUP

ORPHAN MEDICINAL PRODUCTS (OMP)

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

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

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.

*This group is open to ALL MEMBERS

OMP Working Group Meetings take place once per quarter.

GROUP CONTACT INFORMATION

Vittoria Carraro carraro@eucope.org

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WORKING GROUP

LEGAL AFFAIRS

Providing information and discussion on European case law and relevant legal developments related to pharmaceuticals and biotechnologies.

ACTIVITIES

- Discusses ongoing legislative procedures, implementation and application of existing law and case law relevant for the life sciences sector.
- Prepares possible interventions by EUCOPE in proceedings before the European Court of Justice.
- Informs and supports the work of other EUCOPE Working Groups and Task Forces.

OBJECTIVES

The Legal Affairs working group provides legal insights and commentary to support the rest of the working groups and task forces within the wider association. It can also provide ad hoc advice to members when needed.

Aimed at in-house lawyers and lawyers in private practice, the Legal Affairs Working Group serves a complementary role within the EUCOPE organisation.

*This group is primarily intended for lawyers but still open to ALL MEMBERS.

Legal Affairs Working Group meets twice per year.

GROUP CONTACT INFORMATION

Oliver Sude sude@eucope.org

EUCOPE

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WORKING GROUP

REGULATORY WORKING GROUP

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

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

OBJECTIVES

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

*This working group is open to ALL MEMBERS

Regulatory Working Group meetings take place once per quarter.

GROUP CONTACT INFORMATION

Dr Axel Korth korth@eucope.org

EUCOPE

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WORKING GROUP

CELL & GENE THERAPIES

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

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

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.

*This group is open to INSTITUTIONAL MEMBERS ONLY.

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

GROUP CONTACT INFORMATION

Victor Maertens maertens@eucope.org

EUCOPE

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WORKING GROUP

PRICING & REIMBURSEMENT / MARKET ACCESS

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

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

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.

*This group is open to ALL MEMBERS.

Pricing & Reimbursement/Market Access Working Group meetings take place once per quarter.

GROUP CONTACT INFORMATION

Matias Olsen olsen@eucope.org

EUCOPE

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WORKING GROUP

GENOMICS

Working towards adequate pricing and reimbursement for advanced diagnostics.

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

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.

*This group is open to all advanced diagnostic companies within EUCOPE.

Genomics Working Group meetings take place on a monthly basis.

GROUP CONTACT INFORMATION

Matias Olsen olsen@eucope.org

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WORKING GROUP

DIGITAL HEALTH

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

ACTIVITIES

- Updates and analyses on the latest developments related to the European Health Data Space and Artificial Intelligence (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

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.

*This group is open to ALL MEMBERS

Digital Health Working Group meetings take place twice per year.

GROUP CONTACT INFORMATION

Leander Vranken vranken@eucope.org

EUCOPE

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STEERING GROUP

INCENTIVES STEERING GROUP (ISG)

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

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

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.

**ISG membership is conditional to an additional fee

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

GROUP CONTACT INFORMATION

Vittoria Carraro carraro@eucope.org

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TASK FORCE

PHARMACEUTICAL STRATEGY TASK FORCE

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

ACTIVITIES

- Updates and analyses on the latest developments related to the GPL and Pharma Strategy
- Provides 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 institutional, non-profit, and academic stakeholders invited regularly to discuss legislative developments

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.

*This group is open to ALL MEMBERS

The Pharmaceutical Strategy Task Force meetings take place on a monthly basis.

GROUP CONTACT INFORMATION

Victor Maertens maertens@eucope.org

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TASK FORCE

EU HTA REGULATION TASK FORCE

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

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

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.

*This Task Force is open to ALL MEMBERS

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

GROUP CONTACT INFORMATION

Matias Olsen olsen@eucope.org