Health as a fundamental value.

Towards an equitable and inclusive pharmaceutical strategy for the EU

Presentation by:

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EUROPEAN ASSOCIATION of HEALTH LAW

THE EAHL INTEREST GROUP ON SUPRANATIONAL BIOLAW

*UMR 7318 International, Comparative and European laws (DICE) CERIC, Aix-Marseille University, Toulon University, France; members of the I-BioLex project.

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Who are we?

EUROPEAN ASSOCIATION of HEALTH LAW
THE EAHL INTEREST GROUP ON SUPRANATIONAL BIOLAW

The European Association of Health Law (EAHL)

Mission Statement:

to strengthen health and human rights, and to serve as a source of advice for the future of health law and policies in Europe

Guiding principle:

achievement of academic excellence and improvement of health law practice

Members:

experts in health law in their country mainly working in academia

The EAHL Interest Group on Supranational Biolaw

Aim

to promote research on biolaw at national and European levels, including training, scientific events and **exchanges with the society** at large

Guiding principle

to **promote supranational biolaw as valuable** in and of itself for the legal community and for the society at large

Members

Academic experts in the laws of the **European Union**, Council of Europe and European Patent Organization as well as in **various legal issues** arising from technological advances related to **medicine and biotechnology**

Three webinars on the EUHPP

	Dates	Topics	
1st Webinar	22 Nov. 2021	**EU values and health digitalization : the inclusion of vulnerable groups**	
		Markus Frischhut Mark Flear Pin Lean Lau	Elena Petelos François Houÿez
2nd Webinar	10 Jan. 2022	**Regulatory possibilities to enhance cooperation among the EU's governance structures and complementarity within the EU acquis**	
		Tamara Hervey Mark Flear Sabrina Röttger-Wirtz Inesa Fausch	Olivier Nègre Charlotte Godziewski
3rd Webinar	3 Mar. 2022	**Political and legal issues linked to financing the development of pharmaceuticals all along their life-cycle**	
		Tomislav Sokol Mary Guy Mathieu Guerriaud	Piotr Kolczyński Marcin Rodzinka-Verhelle

Methodology to build this Joint Statement

1. Writing of parts of the Draft Joint Statement by EAHL IG members after each webinar
   - Taking into account presentations from invited speakers
   - Taking into account DG SANTE's feedback during each webinar
   - Opened to comments both on the EUHPP and via emails to contributing health organisations and other EAHL IG members
2. Writing of parts of the draft Joint Statement by EAHL IG members and by contributing health organisations on specific identified issues and topics
3. Compilation of the various works and framing of the full draft Joint Statement by TN leaders
   - Opened to comments, edits, discussions from and with
     - All EAHL IG Members
     - Contributing health organisations
     - Registered persons on the EU HPP
4. Discussions and integration of comments/edits for the final Joint Statement

Why this Joint Statement?

The EU pharmaceutical legislation has mainly been built to pursue the internal market objectives due to **historical politico-legal reasons**

The Covid-19 pandemic has highlighted many **pre-existing loopholes** carrying on **health inequalities**

We believe **health as a fundamental** value could **tackle existing issues** and **favour an inclusive and equitable pharmaceutical strategy** for the European Union (EU):

A **transversal topic** for all EU stakeholders

EU's unprecedented solidarity to promote equitable access to medical supplies and vaccines should continue **beyond health emergencies only to build health resilience**

The society at large is **expecting all EU policies to be equitable and inclusive**, but **even more so in health** after the pandemic

Introduction to this Joint Statement

Context

- Renewed efforts to ensure equity of access to pharmaceutical
- To link abstract values of solidarity, equity and inclusiveness to concrete principles
- Interconnection between legal and political issues

Aim

To support the European Commission and Member States to promote an **inclusive and equitable European pharmaceutical strategy** in reaffirming **health as a fundamental value**

More important role of the European Commission and DG SANTE by coordinating health equity in all relevant EU and Member States policies on pharmaceuticals

Patient-centered approaches and inclusive research & development strategies by including the needs of vulnerable groups in the R&D of pharmaceuticals

Solidarity, trust and equitable access to pharmaceuticals by taking into account unmet medical and health needs

To guarantee equitable availability, accessibility and affordability of these pharmaceuticals

Main recommendations

- Call for action 1: Target **unmet medical needs** by identifying **vulnerability** situations
- Call for action 2: Optimise **specific incentive models**
- Call for action 3: Use **digital tools** as means for inclusiveness and integrity
- Call for action 4: Increase **institutional dialogue and cooperation** beyond emergency situations
- Call for action 5: Promote **affordability** throughout the pharmaceutical's lifecycle

Call for action 1: Target unmet medical needs by identifying vulnerability situations

EU institutions & Member States

Definition

- Wide approach of **vulnerability as inequitable access to pharmaceuticals**
- **Dynamic definition of unmet medical needs** in a multi-stakeholder setting

Responsibility

- Promote the role of **non-profit parties** through research funding
- Consider **new models** when suited to an unmet medical need
- Require investigators to identify vulnerable groups and elaborate **Vulnerability Investigation Plans**

Investigators with assistance from EMA

Call for action 2: Optimise specific incentive models

EU institutions, Member States, health stakeholders

Orphan and Paediatric Medicines

- Dedicated **public funding** and financial incentives
- **Dynamic & flexible definition** of unmet medical needs agreed in a multistakeholder setting
- **Precise incentives** to correct or add in the context of the current revision

Antimicrobial Resistance

Leverage incentives **in novel and creative ways**

Advanced Therapy Medicinal Products

- Establish a simplified and **centralised approval access for clinical trials** of ATMPs including GMOs
- Establish a **specific EU entity within DG-SANTE** with close links to other agencies and a network of advanced therapies centres in the EU

Generics and Biosimilars

- EU coordinated monitoring model and reference **list on essential medicines**
- New types of incentives

Call for action 3: Use digital tools as means for inclusiveness and integrity

EU institutions, Member States, health stakeholders

- Endorsement, promotion and implementation of the **European Declaration on Digital Rights and Principles for the Digital Decade**
- **Unified interpretation of the General Data Protection Regulation** across all countries in Europe
- To entrench the **importance of representation of vulnerable groups** throughout the lifecycle of pharmaceutical product development
- To promote the **role and expertise of non-profit parties** in new technologies through funding
- To pay crucial attention for ensuring the **coherent interplay between upcoming pharmaceutical and AI legislation**

Call for action 4: Increase institutional dialogue and cooperation beyond emergency situations

EU institutions

Promote **inter-institutional collaboration** through the best use of the variety of existing tools

Use the **"health in all policies" approach** to encourage more holistic health governance structures through involvement of competent health stakeholders

Strengthen **global alliances** with a wide range of low- and middle-income partner countries, and with international organisations through the use of EU external competences

Take into account the **EMA's Engagement Framework** through a discussion platform

EU institutions & health organisations

EU health stakeholders

Call for action 5: Promote affordability throughout the pharmaceutical's lifecycle

Research funding

EU institutions & Member States

- **Better communicate** on public financial incentives at EU and national levels
- **Link public funding to increased requirements** of equitable research benefits for patients and return on investment for public funders

Transparency

EU institutions, Member States, Health stakeholders

- To ensure the **180-days delay** of the Transparency Directive is respected
- Acknowledge the **'knock-on' effects of a lack of transparency**
- Stipulate and effectively enforce **clear and stringent rules on actual, apparent or potential conflict of interest**
- Require **more cost transparency** when filing the marketing authorisation documentation
- Require pharmaceutical companies to **better communicate on and coordinate their market launch & continued commercialisation of pharmaceuticals** + **more than 2 months to notify intent of withdrawal**
- Only **good quality individual (raw) patient data** to be taken into account

Call for action 5: Promote affordability throughout the pharmaceutical's lifecycle

Health Technology Assessment

EU institutions, Member States, health stakeholders

- **Involve payers (**and **defining them)** in the exchange of information in the field of HTA
- Clarify the **different procedures at stake** (joint and parallel procedures)
- Establish **early multi-stakeholder dialogue**: HTA bodies, EMA, industry, academia & patients
- Explore the potential for **using HTA to increase financing and affordability** (unmet needs)

Competition law, fiscal & social insurance policy

EU institutions & Member States

- Develop policy and guidance to **show how competition law and pharmaceutical regulation can interact**
- Consider the policy option of **creating a fund dedicated to the balancing of health insurance systems**

Joint Procurement Agreements

EU institutions & Member States

- Promote the **use of JPA for essential medicines**
- Organise joint action to put in place **plans to prevent and manage shortages**, especially of essential medicines

Endorsement of this Joint Statement

- Full Joint Statement available on the online page of our thematic network on the EU Health Policy Platform
- To endorse it
  - Please contact us on the EU HPP
  - Or send an email directly to the TN leaders: Éloïse Gennet (eloise.gennet@univ-amu.fr) & Aurélie Mahalatchimy (aurelie.mahalatchimy@univ-amu.fr)
- Organisations that have already endorsed this Joint Statement

EUPHA
EUROPEAN PUBLIC HEALTH ASSOCIATION

G&CTI
Gene & Cell Therapy Institute

EUROPEAN ASSOCIATION of HEALTH LAW

SIOPE
SIOP Europe
the European Society for Paediatric Oncology

Valdecilla
Instituto de Investigación Sanitaria
IDIVAL
CANTABRIA CAMPUS INTERNACIONAL

PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

Towards a permanent Stakeholder Network

- Why?
  - Both the general pharmaceutical legislation and the specific orphan and paediatric legislations are currently under revision: process of adoption, implementation and control to be followed, discussed & commented
  - Follow-up on our recommendations
- Where?
  - On the EU HPP Stakeholder Network
  - Via emails to the moderators of the Stakeholder Network
- How?
  - Posts on the EU HPP Stakeholder Network: relevant news, comments & discussions
  - Organisation of webinars on the EU HPP on specific issues/topics

Thank you for your attention!

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