ACCESS TO MEDICINES

FORUM

EVENT REPORT

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ABOUT EPHA'S ACCESS TO MEDICINES ADVOCACY

The access to medicines (A2M) Forum is a yearly event organised by EPHA to foster a meaningful and inclusive dialogue on access to medicines and pharmaceutical policies in Brussels and beyond.

The 2022 EPHA A2M Forum was the first edition after the pandemic. It followed a period of increased political attention for access to medicines, which has brought high expectations but limited results in terms of equitable access to affordable medicines at global, EU and national levels.

THE CONTEXT

While the COVID-19 pandemic has brought access and affordability of medicines to the spotlight, it has also underscored the need for more balance, transparency, and accountability in the pharmaceutical sector.

The Forum coincides with the preparation by the European Commission of a proposal for the revision of the **EU pharmaceutical legislation** and the **EU legislation on medicines for children and rare diseases**, which bring unique opportunities to restore the balance and ensure affordable access to quality, safe, innovative, and effective medicines at EU level. This major revision is taking place against a background of increased focus on addressing antimicrobial resistance, global negotiations on a potential Pandemic Treaty, and the recently launched multi-stakeholder platform to facilitate dialogue on better access to high-cost medicines by the WHO Oslo Medicines Initiative.

EPHA, its members and partner organizations in our hosted European Alliance for Responsible R&D and Affordable Medicines have been centre stage in contributing to policy debates, forging new coalitions, highlighting the public health and patient-centric perspectives, and advocating for more inclusive and balanced discussion around medicines policies.

The 2022 edition of EPHA's A2M Forum provided a unique opportunity for further exchanges and cross-fertilization of ideas between different stakeholders (patients, healthcare professionals, payers medicine agencies, European policymakers, health law experts) on key A2M issues

AUDIENCE

Health NGOs (including EPHA members and partners) representing patients, healthcare professionals, disease-specific groups and community-based NGOs representing vulnerable groups, representatives of European institutions, representatives of the pharmaceutical industry (innovators, generic producers, parallel traders, and distributors). 103 participants registered to attend on site and 137 to attend online. Of this, 46 people attended on-site and more than 40 followed the event online.

DISCUSSION

The debate ranged over the following topics:

Joint procurement

- The EU wants to improve access to medicines for all and joint procurement could play a role in this. However, current joint procurement processes have limitations.
- Stopping countries from negotiating bilateral deals for medicines while the EU is also jointly procuring would be important as these parallel negotiations may undermine the (EU) system.
- Joint procurement should be used to improve competition and fight against dominant (market) positions.
- Beyond joint procurement, the review of the EU general pharmaceutical legislation needs to consider incentives that may lead to lower competition and higher prices.

Transparency and affordability

- The need for transparency on R&D costs and net prices was highlighted as transparency can encourage predictability and trust. Lack of transparency regarding fair prices became evident during COVID.
- Transparency is the main requisite to develop (balanced) pharmaceutical incentives.
- Some research shows the impact of different types of transparency—results showed much lower impact of price transparency obligations compared to both R&D transparency and price transparency going together.
- Transparency on R&D costs can be achieved in different ways. The exchange and assessment of impacts from national practices would be beneficial.
- Conditionalities for publicly funded research and innovation, including non-exclusive licensing could help to improve the affordability of medical tools.

- Considering medicines as common goods requires a different way of looking at incentives and affordability.
- A new model is needed to (stimulate) investments in pharma innovation that benefits the public.

Innovation to address AMR and other unmet health needs

- There is an urgent need to develop new antibiotics and foster their responsible use as well as equal access to them. These issues must be considered through an end-to-end approach and require public oversight of the entire drug lifecycle.

- The public health sector can learn from CERN and other institutions, which enable private collaboration while keeping ownership of key projects and infrastructure. The creation of a EU public infrastructure to support the development of medical products should be considered.
- We need stronger global leadership with public health at its core, and this could include a non-profit global or EU body for antimicrobial drug discovery. R&D needs to address global inequities.
- Increased public oversight and control of end products from production and procurement to distribution and patient access to ensure funding offers returns to public investors (and not just to pharmaceutical shareholders) is crucial.
- Multiple sectors, including civil society and patients and global partners (including LMICs) need to be involved.
- More and improved coordination is also needed to set up and fine-tune push (early stage/translational research) and pull (milestone prizes) funding.
- Transferable vouchers for new antibiotics are likely to impact affordability of cancer and other “blockbuster” drugs. There are concerns about how vouchers will impact patient access and the sustainability of health systems.
- AMR needs to be a priority across multiple stakeholders beyond the scientific community and the industry sector and key organisations such as the EU HERA should involve all stakeholders.

WELCOME AND SETTING THE SCENE

The EU pharmaceutical strategy

Sylvain Giraud, European Commission

The A2M Forum opening session started with a keynote speech by Sylvain Giraud from the European Commission (DG Sante) focusing on the Pharmaceutical Strategy for Europe. The audience was reminded that work on access to affordable medicines was explicitly included in the Mission letter sent by the President of the European Commission to the Health Commissioner Stella Kyriakides at the beginning of the current mandate. The Pharmaceutical Strategy was then adopted on 25 November 2020 with the aim to create *"a future proof regulatory framework"* and *"support industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs while addressing market failures"*.

The Strategy includes legislative and non-legislative action and one of its 4 pillars is *"ensuring access to affordable medicines for patients, and addressing unmet medical needs"*. The audience was reminded that along with the major upcoming revision of the general pharmaceutical legislation, and the revision of the legislation on rare diseases and children, other important non-legislative initiatives are also foreseen to support access to affordable medicines. Non-legislative initiatives in the form of cooperation, public-private partnerships, and exchanges, are crucial as there is much that can be done through cooperation and exchanges and also as EU legislation has limitations as to how far it can go (given the competences of Member States in this area).

As the implementation of the Pharmaceutical Strategy is guided by a holistic approach to the full lifecycle of medicines, and in addition to the revision of the basic legislation Other actions have addressed among other issues:

(1) unmet needs: boosting antibiotics development and collaborating to address unmet needs and evidence generation through the implementation of the HTA regulation;

(2) accessibility: improving access to generics and biosimilar medicines;

(3) affordability: enabling mutual learning and best practices exchanges on pricing payment and procurement policies; and

(4) availability: fostering cooperation to address shortages of medicines.

Re-thinking medical innovation for epidemics: building a common goods approach for health technologies

Els Torreele, UCL Institute for Innovation & Public Purpose (IIPP)

> *"Despite massive public investments in medical research, there is a growing misalignment between the outcomes of commercial R&D and what we need for public health, which includes equitable access to novel health technologies that can improve people's health outcomes. Covid-19 has put public responsibility for health innovation back at the centre of the political discourse. We must seize this momentum to transform the medical R&D ecosystem to make it fit-for-purpose again."*
>
> **Els Torreele**
> UCL Institute for Innovation & Public Purpose (IIPP)

In her keynote presentation, Els Torreele highlighted the growing misalignment between the financial and economic interests of pharmaceutical companies on one hand and the health needs and medical objectives on the other. During the COVID pandemic unequal global access to vaccines happened while profits for some pharmaceutical companies were growing significantly. Similar misalignments have taken place in other R&D areas as many products end up having none or inferior therapeutic benefits; antibiotics get little or no attention; and some products are too expensive.

While there are big gaps in terms of innovation that addresses peoples' needs, many incentives and ways to de-risk innovation have been developed over the past decades-spanning from growing public spending on health research, patent protection, R&D tax credits, advance purchase agreements and regulatory incentives. A contributor to these gaps and misalignment between incentives and needs, is the lack of transparency around R&D costs and around the value of some therapies. These issues call for substantial changes in the current model to align incentives to purpose (improving people's health).

EU JOINT PROCUREMENT & CROSS-BORDER COLLABORATIONS: WHAT ELSE CAN BE DONE TO IMPROVE ACCESS AND AFFORDABILITY?

Reflecting on the experience during the COVID-19 pandemic and monkeypox outbreak, the second session EU Joint procurement & cross-border collaborations: what else can be done focused on the future of EU joint procurement for medicines and vaccines.

"There is still work that needs to be done to ensure sustainable and prudent procurement procedures across Europe. Best practice sharing is key to inspiring each other and improving procurement in European hospital pharmacies and beyond."

Stephanie Kohl
European Association of Hospital Pharmacists (EAHP)

"Recent health crises have taught us a lot – we need to use these lessons to our benefit."

Olivier Girard
Head of Unit HERA, European Commission

"Joint procurement mechanisms could help improve patient's fair access to the medicines they need, especially in the area of very rare diseases. This, however, requires solidarity among Member States and transparency of price negotiations."

Charlotte Roffiaen
France Assos Santé

"We all have a right to health. Research and technologies should be shared broadly, fast, across the globe. A private company shouldn't have the power to decide who has access to treatments or vaccines and at what price."

Marc Botenga
Member of the European Parliament

TRANSPARENCY OF PHARMACEUTICAL R&D COSTS: WHAT, WHO AND HOW?

Current studies show significant differences in the range of estimated R&D costs for new medicines. While the 2019 World Health Assembly resolution WHA72.8 called for improved transparency of markets for medicines, asymmetries of information between the private and public sector affect drug pricing negotiations. Panellists discussed potential solutions to improve transparency of pharmaceutical R&D cost and addressed questions such as what type of pharmaceutical R&D transparency we need, what should be disclosed and to whom, and whether a disclosure obligation for industry R&D costs help to bring more affordable medicines into the market, and potential risks with introducing transparency obligations at EU or national level.

"I think it is unbearable that some medicines are out of reach for patients. In my work as global health advocate at Wemos, I strive to raise awareness about this among politicians and decision makers to initiate change."

Ella Weggen
Senior Global Health Advocate, Wemos

"R&D costs may increase predictability and trust between industry and policymakers, and it is a pre-requirement for establishing fair prices."

Nora Franzen
European Fair Pricing Network (EFPN)

"The next step to improve access to care in the EU is to make benefitting from R&D incentives conditional to transparency of R&D costs. It is the only way to better understand the market and design the appropriate response to ensure access and affordability of medicines for European patients."

Tilly Metz
Member of the European Parliament

CAN A MULTI-STAKEHOLDER PLATFORM SUPPORT AFFORDABLE ACCESS TO MEDICINES?

The Oslo Medicines Initiative (OMI) was launched in 2020 as a collaboration between the WHO European Region and the Government of Norway. In September 2022, Member States gave a mandate to the WHO Europe to launch a multi-stakeholder platform between different stakeholders including the public and private sectors, patients, and civil society to co-create solutions for improving access to novel (high priced) medicines.

This session explored the plans for the newly launched multi-stakeholders' platform, and what will be needed for it to contribute to better access to (affordable) new medicines. Panellists expressed their diverse views on questions such as how discussions in the multi stakeholder platform should be organized, which topics should be discussed (e.g., joint procurement, transparency, pricing & reimbursement, etc.), and how will the platform ensure a level playing field among non-state actors.

"We support the establishment of a multi-stakeholder platform to discuss affordable access to medicines. It is important to ensure a balanced representation of stakeholders in the platform. The voice of patients and health NGO's should be clearly heard. We hope that the platform will discuss how a definition of fair price can be adopted and how we can move towards increased transparency in pharmaceutical markets. The platform can explore new ways of drug development, for example by giving academic medical centres a big role in the development and manufacturing of cell and gene therapies. These new approaches should make it possible to tackle more unmet needs and develop affordable treatments."

Ward Rommel
Association of European Cancer Leagues (ECL)

"Access to Medicines and Health Products is dependent on a complex series of interactions between the public and private sector. WHO/Europe is supporting better collaboration through the multistakeholder Novel Medicines Platform."

Sarah Garner
Senior Policy Advisor for Access to Medicines and Health Products,
WHO Regional Office for Europe

"We believe a novel approach to public procurement and reimbursement of health goods is necessary as the current situation is not economically sustainable in the long-term for public systems. Any initiative seeking to involve all stakeholders needs to prioritise transparency, accountability and the primacy of public interests. Only by doing so will we be contributing to a better governance of pharmaceutical markets."

Jaume Vidal
Health Action International (HAI)

"The EU pharma revision is an unprecedented opportunity to set the bar higher for the approval of better medicines for all patients. It can also lead to a robust competition in the pharmaceutical systems which is a prerequisite for affordable medicines. As the European Commission is developing its proposals, the affordability of new products should be on top of the agenda. Excessive prices undermine solidarity and social cohesion in Europe."

Yannis Natsis
Director, European Social Insurance Platform (ESIP)

TOWARDS GLOBAL ACCESS TO NEW & EFFECTIVE ANTIBIOTICS: THE ROLE OF THE EU

While antimicrobial resistance is on the rise, the scarcity of new antibiotics and a currently dry clinical pipeline is leaving the world with few options to combat multiple resistant germs. Incentives to stimulate the development of new antibiotics are currently being discussed at global level as well as in the EU in the context of the revision of the EU pharmaceutical legislation, the development of HERA activities and other innovative ideas such as the creation of a European Biomedical Infrastructure.

This session addressed the challenges of creating incentives for the development of new and effective antibiotics while guaranteeing access and antibiotic stewardship. Panellists discussed the best policy options available to spur the development of new and effective antibiotics, how can consistency across EU policies as well as with global cooperation be built and what should the EU do to provide better incentives for the development of new antibiotics.

"Patients' lives depend on the access to effective antimicrobials. EPF supports the development of new effective antimicrobials through a transparent and predictable system of incentives balanced with the need for availability and affordability of antibiotics. This must not replace, but complement a broad multi-stakeholder strategy to keep the antibiotics we have working through proven methods including prudent use, antibiotic stewardship at the point of care, and using the tools in the EU's One Health Strategy."

Anca Toma
Executive Director, European Patients Forum (EPF)

5th EPHA Universal Access and Affordable Medicines Forum

Equal access to affordable medicines: Global, EU and National voices

09:00-09:15 **REGISTRATION AND COFFEE**

09:15-09:45 **WELCOME AND SETTING THE SCENE**

- Milka Sokolović — Director General, European Public Health Alliance (EPHA)
  @EPHA_EU @milkasklvc
- Sylvain Giraud — Head of Unit at DG SANTE, European Commission
  @EU_Commission @GiraudSylvain
- Els Torreele — Policy Associate,
  UCL Institute for Innovation & Public Purpose (IIPP)
  @IIPP_UCL @ElsTorreele

09:45-11:00 **EU JOINT PROCUREMENT & CROSS-BORDER COLLABORATIONS: WHAT ELSE CAN BE DONE TO IMPROVE ACCESS AND AFFORDABILITY?**

Moderated by Stephanie Kohl, European Association of Hospital Pharmacists

- Marc Botenga — MEP, European Parliament
  @Europarl_EN @BotengaM
- Olivier Girard — Head of Unit HERA, European Commission
  @EU_Commission @EC_HERA
- Momir Radulović — Director, Slovenian Medicines Agency
  @AgencijaJAZMP
- Charlotte Roffiaen — European Affairs Advisor, France Assos Sante
  @Fr_Assos_Sante @EU4Ublog
- Maja Graf— Markets Director, Medicines for Europe
  @medicinesforEU

11:00-11:30 **COFFEE BREAK**

11:30-12:30 TRANSPARENCY OF PHARMACEUTICAL R&D COSTS: WHAT, WHO AND HOW?

Moderated by Ella Weggen, Wemos

- Nora Franzen — European Fair Pricing Network (EFPN)
  #EFPNforMeds
- Nicola Magrini — Director, Italian Medicines Agency (AIFA)
  @Aifa_ufficiale

- Tilly Metz — MEP, European Parliament
  @Europarl_EN @MetzTilly

- Els Torreele — Policy Associate, UCL Institute for Innovation & Public Purpose (IIPP)
  @IIPP_UCL @ElsTorreele

12:30-13:30 **LUNCH**

13:30-14:30 **CAN A MULTI-STAKEHOLDER PLATFORM SUPPORT AFFORDABLE ACCESS TO MEDICINES?**

Moderated by Alba Gil, European Public Health Alliance (EPHA)

- Sarah Garner — Senior Policy Advisor, World Health Organization - Europe (WHO)
  @WHO_Europe @drsarahgarger

- Simone Boselli — Public Affairs Director, Eurordis
  @eurordis

- Yannis Natsis — Director, European Social Insurance Platform (ESIP)
  @ESIP_EU @YNatsis

- Ward Rommel — Researcher, Kom op tegen Kanker, Access to Medicines Taskforce, European Cancer Leagues (ECL)
  @WardRommel @CancerLeagues @komop_tgkanker

- Jaume Vidal — Senior Policy Advisor, Health Action International (HAI)
  @HAImedicines @OnadaExpansiva

14:30-15:00 **COFFEE BREAK**

15:00-16:30 **TOWARDS GLOBAL ACCESS TO NEW & EFFECTIVE ANTIBIOTICS: THE ROLE OF THE EU**

Moderated by Rosa Castro, European Public Health Alliance (EPHA)

- Kerstin Åkerfeldt — Policy Expert, ReAct Europe
  @reactgroup @KAkerfeldt

- Malin Grape — Swedish AMR Ambassador

- Massimo Florio — University of Milan

- Anca Toma — Executive Director, European Patients' Forum (EPF)
  @eupatientsforum @ Anca4health

16:30-16:45 **CLOSING REMARKS**

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#Access2Medicines

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