
EPHA2019

**TIME
FOR A NEW
DEAL**



*Challenging
the status quo
on medicines policy*

4TH EPHA UNIVERSAL ACCESS AND AFFORDABLE | **MEDICINES FORUM**

UNIVERSAL ACCESS AND AFFORDABLE
MEDICINES FORUM

14 NOVEMBER

Scotland House, **Brussels**



#newdeal4meds

epha european
public health
alliance

EVENT REPORT

A decorative graphic at the bottom of the page consisting of several overlapping, wavy, ribbon-like shapes in shades of orange and yellow, flowing from the left towards the right.

RE-LIVE THE DEBATE!

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THE 4TH EPHA UNIVERSAL ACCESS AND AFFORDABLE MEDICINES FORUM!

The fourth edition of the Forum, titled “Time for a New Deal: Challenging the status quo on medicines policy,” sought to set the scene and tone for the new European Commission and Parliament.

The Forum tackled the issues headlining the actual policy agenda namely EU’s cancer plans, affordability of new medicines, medicines shortages and transparency in pharmaceuticals.

“EU plans around cancer: Hype VS substance”, “Norway’s views on access to medicines”, “An old new problem: Solutions to medicines shortages in Europe”, “Pharmaceuticals, a secretive business: How to shed light into the black box?” were the themes for discussion at this year’s Forum guided by the priorities of EPHA members and the current policy agenda.

Many of the speakers were EPHA members. This is testament to the fact that EPHA and our members have been centre stage in influencing the agenda, forging new coalitions, highlighting the public health perspective and ensuring a more inclusive and balanced discussion around medicines policy.

EU PLANS AROUND CANCER: HYPE VS SUBSTANCE

- Denis Lacombe, Director-General, European Organisation for Research and Treatment of Cancer (EORTC)
- Kathi Apostolidis, President, European Cancer Patient Coalition (ECPC)
- Carin Uyl-de Groot, Professor, Health Technology Assessment, Director of the Institute for Medical Technology Assessment (iMTA), School of Health Policy & Management, Erasmus University Rotterdam
- Ward Rommel, Researcher, Kom op tegen Kanker, Access to Medicines Task-Force, European Cancer Leagues (ECL)
- Chantal Bélorgey, Head of the Health Technology Assessment (HTA) and Public Health division, French Health Authority (Haute Autorité de Santé – HAS)

The first panel brought together thought leaders from the field of oncology to look at research, the need for continuous assessment of medical innovation, the role of patient input and the complexities of pricing and reimbursement of new drugs. Panelists expressed concern over the real added therapeutic value of cancer drugs emphasizing that only 20-30% of all new medicines in oncology make a real difference in patients' lives. In this respect, overall survival and quality of life as opposed to surrogate endpoints should be the defining criteria when assessing new drugs to distinguish meaningful innovation from imitation (me-too drugs).

The fact that cancer drugs are today approved by the EMA faster and earlier than ever before was underlined as a worrisome development due to the paucity of evidence at the time of marketing authorization. That is why, Denis Lacombe of the European Organisation for Research and Treatment of Cancer (EORTC) commented that cancer



drugs should come on to the market with a starting price close to zero and then adapt accordingly. He called for a new balance between commercial and non-commercial research which would put treatment optimization at the heart of a patient-centric model as opposed to the current drug-centric model. In his view, we are missing crucial information about how medicines work or do not work due to the fact that all aspects of research are commercially driven leaving areas of no commercial interest uncovered. This leaves patients in the dark and contributes to waste in the health care systems.

Panelists agreed that pharmaceutical companies are disincentivised from generating and collecting the necessary additional data in the post-approval phase. Kathi Apostolidis of the European Cancer Patient Coalition (ECPC) reminded that it should not be only about medicines. She emphasized the importance of prevention and screening while underlining the importance of surgery and radiotherapy in beating cancer. She agreed that patients' aspirations need to be addressed by research and real patients with co-morbidities and others need to therefore be included in the research of new drugs.

Ward Rommel of the EPHA member European Cancer Leagues (ECL) and Prof. Carin Uyl de Groot talked about the need to promote transparency in pharmaceuticals as a way to negotiate a fair price for new medicines. Ward Rommel highlighted the disparities within and across EU and called on EU governments to share information on real prices. He also spoke of new ways of incentivising drug development through a health impact fund whereby companies will be rewarded if a drug is brought to market at production and distribution cost. He argued for new intellectual property models too so as to guarantee affordability and availability of new products.

ACCESS TO MEDICINES - HIGH AND UNSUSTAINABLE PRICE LEVELS

Keynote & brief exchange with Bjørn-Inge Larsen

The first panel was followed by a keynote and a brief exchange of views with the Secretary General of the Norwegian Ministry of Health. He emphasized the following points:

- Norway is concerned over the high prices of some new medicines. The Norwegian Minister of Health has stated that their pricing is unethical and unsustainable.
- As a public official, he expressed his discomfort for having to keep prices confidential. Secrecy creates issues of trust for citizens who have a hard time understanding which medicines are approved for reimbursement and which aren't.
- He reaffirmed Norway's support to the transparency resolution negotiated and adopted at the 2019 World Health Assembly (WHA). He highlighted the imperative need for international collaboration as no single country can make it alone. He noted that Norway is exploring ways to translate the resolution in national legislation and is open to suggestions and technical assistance to make this happen.
- He commented that regional initiatives of collaboration such as Beneluxa are promising. He announced that Norway is joining forces with Iceland and Denmark to explore the prospect of joint negotiations, including price negotiations.
- Out of the various provisions and asks outlined in the transparency resolution, he prioritized the exchange of information on the real, net prices paid by countries.



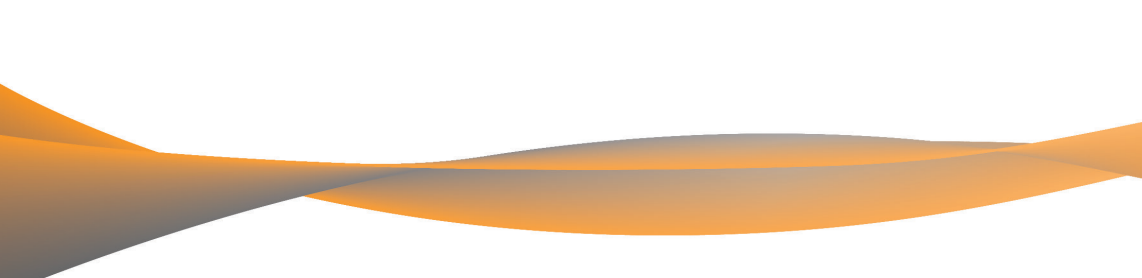
AN OLD NEW PROBLEM: SOLUTIONS TO THE MEDICINES SHORTAGES IN EUROPE

- Vlad Mixich, Coordinator, Romanian Health Observatory – Board member, EPHA
- Charlotte Roffiaen, EU advocacy advisor, France Assos Santé (FAS)
- Aida Batista, Vice-President, European Association of Hospital Pharmacists (EAHP)
- Kasper Ernest, Secretary-General, European Association of Euro-Pharmaceutical Companies (EAEPC)

Medicines shortages is not a new problem for the EU but it is now affecting all Member States, across many different therapeutic areas. In other words, the problem now touches upon many more medicines. During the panel discussion, it was clear that the issue of shortages is one that highlights divisions between East and West Europe, North and South. Although there is renewed attention and political noise by all sides (Member States and outgoing and new European Commission), it was made clear that there is no clear political direction as to how effectively tackle and resolve this growing challenge.

Panelists agreed that transparency in pharmaceutical systems overall (for instance on European levels of stocks of medicines) would mitigate the problems caused by supply disruptions. To this end, they called for a thorough and detailed mapping of the root causes of shortages as well as a monitoring system to be put in place. The findings of such a survey could guide decisions on possible new legislation or review of existing tools. Panelists agreed that EU action and coordination could play a defining role in the prevention of shortages.

The representative of hospital pharmacists presented the extensive work of her



organisation and how hospital pharmacists are called to address the problems caused by shortages. She explained that the causes vary such as poor planning and forecasting, increased demand for specific product (such as when old long established and widely used drugs are withdrawn from the market with no commercial value, this puts pressure on the existing alternatives).

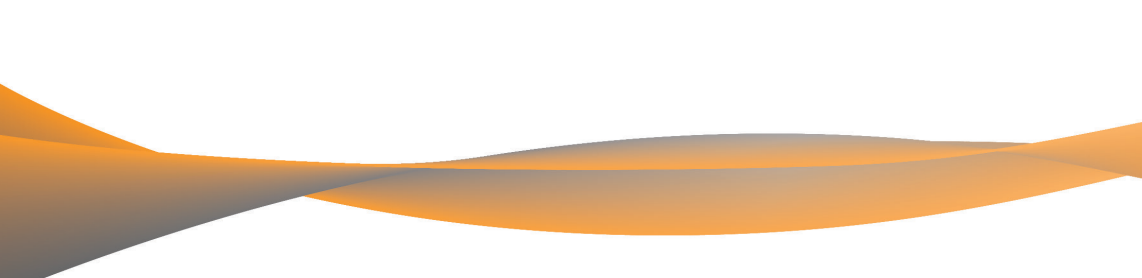
All panelists agreed on the need to look at the supply chain and Europe's dependence on India and China for the provision of raw material including active pharmaceutical ingredients (APIs). The issue of restoring some manufacturing capacity back to Europe was also touched upon by panelists. They agreed that some incentives to manufacturers could be discussed as long as this does not turn into an unconditional transfer of public funds to pharmaceutical companies. They also debated the pros and cons of parallel trade as it is often listed as one of the root causes of shortages. At the same time, there was consensus that parallel trade can be a necessary tool for many stakeholders. For example the representative of the European Association of Hospital Pharmacists (EAHP) on the panel reminded everyone that in her country Portugal, her colleagues oftentimes depend on parallel trade to cover their needs. The representative of parallel traders (EAPC) argued for proportional and reasonable export restrictions.



PHARMACEUTICALS, A SECRETIVE BUSINESS: HOW TO SHED LIGHT INTO THE BLACK BOX?

- Ellen t' Hoen LLM, PhD, Medicines Law & Policy
- Audun Hågå, Head, Norwegian Medicines Agency
- Marcel van Raaij, Director of Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare, and Sports, The Netherlands
- Fergal O' Regan, Head of Enquiries, European Ombudsman
- Alexander Roediger, Executive Director Oncology Policy, Europe, Middle East, Africa and Canada (EMEAC), MSD International

The last panel debated extensively the role of transparency in pharmaceutical systems in Europe and beyond. Panelists agreed that transparency is a crucial issue with numerous layers. Different panelists prioritized different aspects of pharmaceuticals such as transparency in pricing and reimbursement systems and decision-making processes, in assessing the value of medicines, in net prices, in R&D costs, in clinical trials data, in the patentability landscape to name but a few. A lot was said about the pending threat by the ongoing case at the European Court of Justice with the case against the European Medicines Agency. The representative of the European Ombudsman expressed his serious concerns over the possibility of reversing years of public interest accomplishments depending on the Court's decision on this case. The industry representative reaffirmed pharmaceutical companies' commitment to clinical trials data transparency. The representative of the Dutch government explained the contribution of initiatives such as Beneluxa to bringing about more transparency in pharmaceutical systems by addressing and mitigating the effects of information asymmetry. He added that the International Horizon Scanning Initiative (IHSI), a Beneluxa spin-off is conducive to a more level-playing field in the negotiations



between governments and pharmaceutical developers.

Another issue highlighted was the possible abuse, overuse or misuse of the incentives granted by the legislator for orphan drugs (medicines for rare diseases). Most panelists welcomed the ongoing incentives review within the evaluation of the respective pieces of legislation. As far as the issue of value-based healthcare is concerned, the Norwegian regulator on the panel expressed his growing frustration with value-based pricing methods. With confidential agreements it is easy to make unsubstantiated claims he argued. He cautioned against following the value-based pricing philosophy and wondered how would electricity or education be priced if the same models were attached to those sectors. There was also consensus on the need to factor into the final price of medicines, the multifaceted contribution and support offered by the public sector. Speakers remarked that the public support into medical R&D in Europe is substantial and needs to be acknowledged when taking into account when pricing a drug. Ellen 't Hoen agreed and reminded the audience that it is the public pot, that pays for the research and development (R&D) in many ways including through high prices of medicines.

The panel concluded that increased transparency in pharmaceutical systems would benefit all stakeholders involved from the industry, to the healthcare systems and patients.



ABOUT THE FORUM

18 speakers
230 participants
173011 people reached on Twitter

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14 November 2019

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