

Recommendations towards fair medicines prices in Europe

Medicines, given their role in our healthcare systems, should be considered a public good. They are an essential element of countries' strategies to deliver on the Sustainable Development Goals' health targets. However, current pharmaceutical price levels play at the expense of access for the patients and healthcare systems in Europe and in the world. In addition, not all new medicines have a proven, measurable added therapeutic benefit. Still, the pharmaceutical sector remains among the most profitable globally. Therefore, over the past years, a reflection on fair medicines prices has gained traction. As part of its work on the issue, the World Health Organization defined fair prices as prices that are *"affordable for health systems and patients and at the same time provide sufficient market incentive for industry to invest in innovation and the production of medicines"*. 12 European and international organisations have developed and endorsed the recommendations below, for the European Union to bring fairer drug prices in Europe through the use of its legislative and non-legislative instruments.ⁱ

- **A radical rethinking of the way pharmaceutical markets and health systems operate in Europe is needed.**
 - **Transparency of medicines prices and their research and development, production, marketing and regulatory costs, as well as a methodology to calculate them, is needed.**
 - **The European Commission should include accessibility, affordability, transparency clauses in all forms of public funding and/or public-private partnership in pharmaceutical research.**
 - **The forthcoming EU Pharmaceutical Strategy must address the abuse of the current model of pharmaceutical incentives, which are particularly acute in the orphan and paediatrics regulations.**
 - **The European Commission should uphold strong scientific, regulatory standards to assess added therapeutic benefit**
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- **A radical rethinking of the way pharmaceutical markets and health systems operate in Europe is needed.**

It is urgent to change the current pharmaceuticals supply-driven business model for innovative products. Currently, the bulk of pharmaceutical companies' revenues are generated by high prices charged in specific therapeutic areas in some countries, while other less attractive therapeutic areas are underinvested and a majority of countries experience delays or never get the product before it has a generic alternative.ⁱⁱ A number of alternative pricing models have been developed, in order to secure access to medicines: technology pools, open science models, scientific progress models, delinkage models. The World Health Organization has itself already organized two Fair Pricing Forums, showing the relevance of the issue. We now invite the European

Commission to address the topic and believe that more collaboration is needed between Member States to reach affordable and accessible medicines for all European citizens. In this respect we welcome that the public consultation on a European Pharmaceutical Strategy addresses medicines affordability.

- **Transparency of medicines price and their research and development, production, marketing and regulatory costs, as well as a methodology to calculate them, is needed.**

The lack of transparency all along the lifecycle of medicines reduces countries' ability to negotiate fair prices. Society needs to have access to clinical trials results, to information on medicines' underlying costs and on final prices. More research on the underlying costs of drugs, as well as on how to calculate them, would also give more leverage to pricing and reimbursement authorities. The signatories invite the European Commission to reinforce and strengthen the EURIPID database to better reflect the prices actually paid by participating countries. The development of managed entry agreements (MEAs) and the confidentiality clauses that are attached to them further add to the intransparency of pharmaceutical markets. They take away opportunities to exercise public scrutiny and accountability on the use of healthcare resources, hamper international discussion and best practice sharing about the use of critical medicines under MEA and prevent the building up of future knowledge on dealing with such medicines. These agreements should therefore only be used in specific, restricted cases, with a clear definition of the intended benefits of such agreements, what follow-up on those agreements will be in place, as well as a report on how they performed.

- **The European Commission should include accessibility, affordability, transparency clauses in all forms of public funding and/or public-private partnership in pharmaceutical research.**

Through its flagship programmes Innovative Medicines Initiatives (IMI), the European Commission is a strong contributor to pharmaceuticals research and development. Society can't pay twice for drugs and it is time that the European Commission uses its position to include strong clauses promoting accessibility and transparency in future public-private partnerships as well as public research funding for pharmaceuticals. These should be underpinned by the inclusiveness and transparency of managing structures, inclusiveness in the setting of research priorities under these programmes and the creation of mechanisms to promote access to research results and end products. Such an approach should also be promoted at national level, where a significant amount of public resources is also dedicated to supporting early stages of biomedical research.

- **The forthcoming EU Pharmaceutical Strategy must address the abuse of the current model of pharmaceutical incentives, which are particularly acute in the orphan and paediatrics regulations.**

An urgent review of the incentives system is needed, especially to make sure that the patent system does not lead to abuses of dominant position and lack of competition, which lead to artificially high prices. The orphan medicinal products area deserves a specific attention in this respect. The system of incentives was created to help compensate for the low expected return on investment for orphan medicinal products development. This is now turning into a commercial opportunity for many companies. Conditions to access and retain orphan medicinal products incentives must be revised in order to take stock of 20 years of operation of the Orphan Medicinal Products Regulation and to keep the spirit of this legislation. Appropriate action includes a better scrutiny of the final patient population of orphan medicinal products and the definition of "sufficient" and "excessive" profitability.

- **The European Commission should uphold strong scientific, regulatory standards to assess added therapeutic benefit.**

We welcome the European Commission's efforts to strengthen European cooperation on health technology assessment. A number of products that reach the market do not deliver the innovation that we need today, despite increases in terms of prices. In cancer, according to the World Health Organization (WHO), 35% of the medicines approved by the European Medicines Agency in 2009–2013 had established prolonged survival at the time of approval. Survival for those new medicines often was a few months or sometimes only weeks longer in comparison with already existing medicines. Only 10% of these approved cancer medicines had evidence of improvement in the quality of life. The proliferation of early access schemes shifting evidence generation to the post-marketing phase is worrying. Digital tools could be used to analyse the data accumulated in the post-marketing phase to reassess medicine prices. However, as a rule, medicines that reach pricing and reimbursement authorities must do so with enough evidence on added therapeutic benefit. Clinical trials remain the gold standard for the investigation of added therapeutic benefit and real-world data (RWD) should come as a complement, with careful definition of the purpose of the use of RWD, their end users and the desired outcome from the use of RWD.

Signatories

- AIM – International Association of Mutual Benefit Societies
- CEO - Corporate Europe Observatory
- CPME – Standing Committee of European Doctors
- ECL – Access to Medicines Task Force, Association of European Cancer Leagues
- EPHA – European Public Health Alliance
- EPSU - European Public Service Union
- ESIP – European Social Insurance Platform
- European Alliance for Responsible R&D and Affordable Medicines
- GHA - Global Health Advocates
- HAI - Health Action International
- Médecins du Monde International Network
- Prescrire

ⁱ The European Commission has launched a number legislative and non-legislative initiatives to support the recovery of healthcare systems following the COVID-19 outbreak: the EU4Health Programme, the European Recovery Instrument, the Pharmaceuticals Strategy for Europe to name a few. These initiatives rightly aim to find solutions to the lack of access and unaffordability of healthcare products, including beyond products needed to treat COVID-19. Given the ambition of these initiatives and taking into account the legislative and non-legislative instruments that it has, the European Commission should rebalance the pharmaceutical markets towards fairer prices. A reflection on the careful balance between what is feasible and desirable to do respectively at national and at European level, will need to take place too.

ⁱⁱ Access to meaningful pharmaceutical innovation has become an acute issue for healthcare systems. It endangers the ability to deliver universal health coverage and improve health. Although they should be considered public goods, a growing and worrying number of medicines are launched at excessive and unaffordable prices that don't allow countries to offer

reimbursement to their whole patient population - if these medicines are launched in these countries at all. With the arrival of advanced, targeted and individualised therapies, we foresee this trend to be reinforced. At the same time, pharmaceuticals are sold at prices allowing manufacturers to consistently and continuously rank among the highest profit-making industries.