THE EU'S PHARMACEUTICAL STRATEGY: A REFLECTION PAPER, A YEAR AFTER THE STRATEGY'S LAUNCH

NOVEMBER 2021

epha european public health alliance

About EPHA

EPHA is a change agent – Europe's leading NGO alliance advocating for better health. We are a dynamic member-led organisation, made up of public health civil society, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe.

Co-funded by the
Health Programme of
the European Union

The European Public Health Alliance has received funding under anoperating grant from the European Union's Health Programme (2014-2020). The content of this document represents the views of the authors only and is their sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

Transparency Register Number: 18941013532-08

INTRODUCTION

The European Pharmaceutical Strategy is a milestone in the access to medicines debate in Europe. While taking stock of the developments so far, it offers an inventory of action, a roadmap for next steps for Member States and the European Commission. Meanwhile, the access to medicines debate is enriched with new topics arising from the pandemic, such as the need for a resilient and diversified supply chain. Public authorities strive to build expertise over issues that were not previously on their radar. The structured dialogue on supply chain resilience launched by the European Commission is an example of the striking asymmetry of information between companies and public authorities. The latter rely almost exclusively on companies' input which raises questions of how comprehensiveand unbiased the debate and eventual policy recommendations are. Industries set the agenda, highlight the bottlenecks and steer the debate towards solutions tailored to their business interests.

This is yet another illustration of the excessive concentration of power in this business sector, which adds to the series of imbalances recognized already in 2016 in the groundbreaking EU Health Ministers' Council Conclusions. This disproportionate concentration of power needs to be examined in the context of EU competition law and policies. Particular attention needs to be paid on the mergers and acquisitions in the pharma landscape and their impact on the quality of innovation, the performance of companies, the prices of medicines and the interlinkages with generics and biosimilar products.

INDUSTRIALIZATION OF HEALTH POLICIES

The experience with the structured dialogue exemplifies another potentially worrisome trend accelerated by the ongoing pandemic. There is a convergence of health and industrial policies with the latter prevailing over the former. Companies are pushing for flexibilities, public guarantees, more incentives and financial rewards, and use health as a convenient entry to get what they want. Governments however have insights, perhaps for the first time, into companies' manufacturing and pricing processes. These are topics which undoubtedly feed into the Pharmaceutical strategy and its implementation.

In the meantime, unwarranted prices remain a key concern for health care systems across Europe. This is why the recent Council Conclusions on the availability, accessibility, and affordability of medicines are a welcome development. It is important not to lose focus in the access to medicines debate in Europe. The EU should steer meaningful, needs--driven innovation towards better and affordable medicines and treatments. Following the seismic events caused by COVID-19, there seems to be renewed emphasis on speedier and earlier access to anything which is branded as innovation. This is déjà vu. Pharma has advocated for these agendas not long ago. It has now returned to these well-worn themes, encouraged by the dynamic created by the pandemic.

NEEDS-DRIVEN AFFORDABLE INNOVATION SHOULD BE THE GOAL

Robust evaluation of innovation is the answer, one of the topics listed in the Strategy itself. The conclusion of the EU Health Technology Assessment (HTA) regulation is a success but the long journey towards implementation only starts now. HTA took a back seat during the health emergency with most aspects being already decided at the time of approval by the European Medicines Agency (EMA). This should not be the new norm. On the contrary, there needs to be intensified collaboration between HTA, patients, the buyers, and the regulators to set the bar high for medicines' approval. The ongoing review of pharma legislation offers another prime opportunity to push for comparative effectiveness data. This will give us a much better idea of how medicines work and their true added therapeutic benefit. On a similar note, the review of the EU orphans and pediatrics legislation should not be further delayed.

There is a clear need for DG Sante and its public health mission to be strengthened. The explicit reference to the need for affordable medicines in the Health Commissioner's mandate is more pertinent than ever and should be a strong reminder of what the DG's focus should be in the months and years to come.

TRANSPARENCY IN PHARMA: A WORTHWHILE AMBITION

Undeniably, COVID19 illustrates and emphasizes the urgent need to further increase overall transparency in pharmaceuticals, and to strengthen collaboration amongst Member States. We have already seen examples of the benefits of increased transparency: for instance, the very experience of negotiating an EU-wide price for the COVID-19 vaccines creates a new dynamic for joint procurement, which by design brings about more price transparency than confidential discounts. It should be noted, however, that the push for transparency must go well beyond transparency of prices. Transparency in costs, as well as in funding to support the research and development of health products is also crucial – two issues identified by the European Commission in its Pharmaceutical Strategy.

Apart from that, price transparency per se applies differently to countries and regions, depending on their negotiating position, purchasing power, experience, and know-how. In other words, a one-size-fits-all solution would potentially be counter-productive. Nevertheless,the implementation of the WHA Resolution 72.8 on transparency offers a concise list of next steps, yet it requires strong political support and international coordination.

The Pharmaceutical Strategy and the processes it triggers pave the way for a frank, comprehensive discussion on how to rebalance pharmaceutical systems in the face of ever-increasing prices for medicines and vaccines and debatable innovation.

To this end, in the coming months it will be important for the EU to make progress on the following fronts:

1. Map, track, streamline and coordinate the multilayered public support that goes into biomedical R&I (particularly in the context of HERA and the Innovative Health Initiative, as explained below). Since public guarantees and flexibilities are used to de-risk the R&D process, the public needs to get a fair share of the returns, but also to have a clear say in steering the innovation. This, for instance, can be achieved through non-exclusive, voluntary licensing and affordable pricing guarantees;
2. Foster the collaboration amongst buyers, to address the information asymmetry, mitigate its effects, and boost their negotiating power;
3. Guarantee a robust regulatory ecosystem, which gives us medicines with proven added therapeutic value;
4. Invest into new delinked approaches and non-market-based solutions for the development of new antibiotics, to mitigate the devastating consequences of antibiotic resistance;
5. Identify policy solutions to prevent or mitigate the impact of medicines' shortages, and to increase supply chain security.

GETTING HERA RIGHT

The Pharmaceutical Strategy rightly prioritized the establishment of HERA also in line with the early lessons learnt from the COVID19 pandemic. The creation of the European Health Emergency preparedness and Response Authority (HERA) is indeed a step in the right direction but if the public is to share the business and R&D risks with the health industries in preparedness and in emergency times, it will have to share the rewards as well.

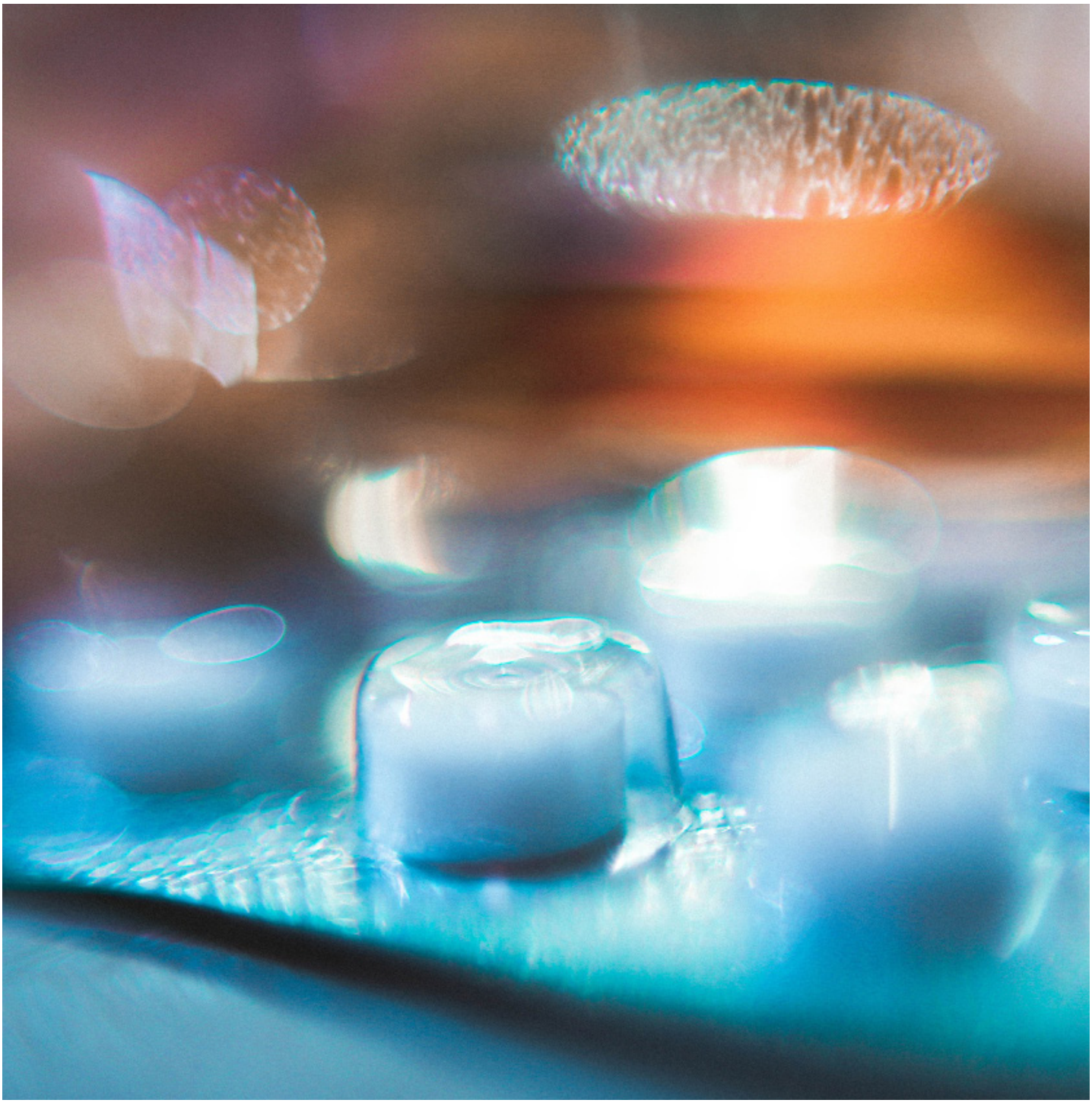
To this end, HERA needs to foresee clauses to protect the public interest in its contracts with private companies. Among other issues, these contractual obligations should ensure the affordability, accessibility and availability of medical countermeasures, introduce open access and open data requirements, prioritise public ownership, control and management of resulting intellectual property rights when possible, or use equitable licensing clauses in other cases. Additionally, in order for HERA not to be perceived as industrial policy in disguise and for it to serve its public health mission, it needs to go beyond offering advance payments to companies. Not-for-profit EU infrastructure should be prioritised. Doing so will boost many non-commercial research institutions across the Union by offering them new possibilities of cooperation and by bringing them closer to the EU medicine regulatory system. To this end, HERA should provide for manufacturing infrastructure at EU level to facilitate the production of medicines as a non-profit public activity. This is put forward by the European Parliament as well, namely the creation of one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture affordable medicinal products of health and strategic importance for healthcare. HERA should cooperate with other non-commercial research institutions and support the development phase by facilitating the pre-clinical development and the clinical trials phase. This would ensure much-needed transparency of clinical trials data and research and development costs.

The upcoming negotiations in the Council will be crucial in spite of the fact that HERA is already operational with its Board holding its first meeting on October, 1, 2021. EPHA and the European Patients Forum, we have articulated our shared vision on HERA with concrete recommendations. Shockingly enough, the current EC proposal creating HERA does not foresee civil society engagement. European Commission and national delegations need to listen to the voice of patients and the public health community and guarantee that decisions about them are not taken without them.

IMPLEMENTING THE EU'S PHARMACEUTICAL STRATEGY & THE POLITICIZATION OF MEDICINES' POLICIES

One of the defining parameters for the successful implementation of the strategy will be the effective and timely coordination between the Commission and the Member States. It is true that the management of the pandemic has increased both the number of issues on the agenda and the daily workload of Ministries of Health with numerous initiatives being launched and/or requiring simultaneous attention. In light of the health emergency, many of the pharma-related decisions are now taken at the highest political level, namely by the national Ambassadors to the EU (COREPER II) and the Commission's President. Pharma CEOs pick up the phone and talk directly to EU heads of state and governments. This politicization of pharma presents risks and opportunities. On one hand, companies are elevated to key political interlocutors, with disproportionate clout and little accountability. On the other hand, governments perhaps for the first time are exposed to and gain a better understanding of the internal workings of a very complex business sector.

Time is of the essence when handling emergencies and while the need for swift and effective action is understandable, it does not justify the sidelining of the European Parliament. Informing the Parliament ex-post as opposed to properly consulting it ex-ante has become a worrisome trend since the start of the pandemic. The European Parliament and civil society are excluded from HERA too. Given the fact that Europe's latest Authority comes with considerable priority setting power, a sizable budget, and very strong connections with the industries, it is imperative to have democratic scrutiny and checks and balances in place to ensure that HERA serves public health and patients, not disproportionately health industries' business interests. This should be seen as a broader warning against a possible institutional crisis whereby accountability and transparency are sacrificed under the pressure of an emergency. The increasing influence of industries must be counter-balanced with stronger transparency and guarantees against corporate capture. The politicization of health and pharmaceutical policies should serve the public interest and public health as opposed to narrow and short-sighted business agendas.



EUROPEAN PUBLIC HEALTH ALLIANCE (EPHA)
Rue de Trèves 49-51 • 1040 Brussels (BELGIUM) • +32 (0) 2 230 30 56 • https://epha.org/ • epha@epha.org