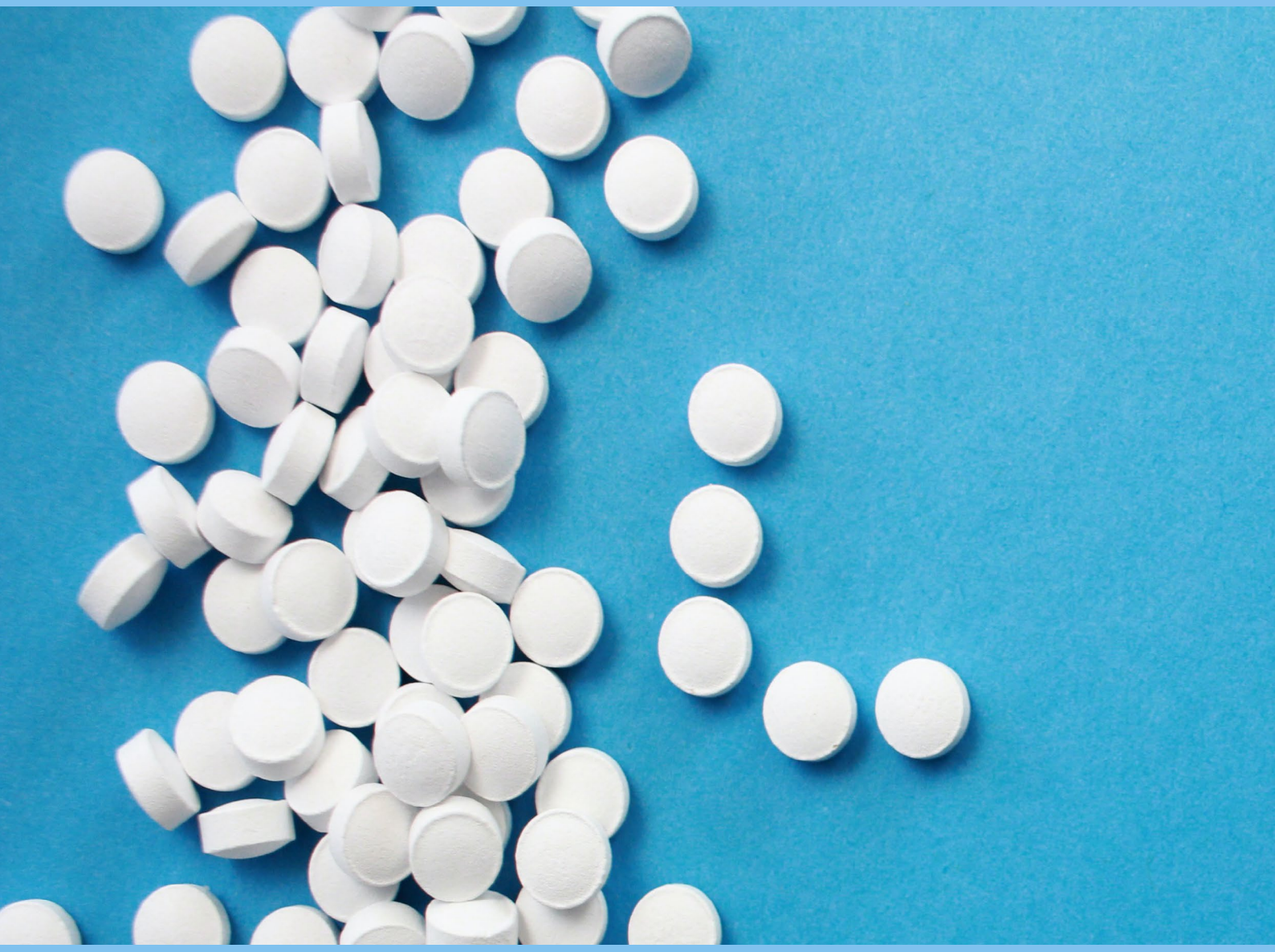

IMPROVING TRANSPARENCY AND ACCESS TO AFFORDABLE, QUALITY, AND SUSTAINABLE MEDICINES IN EUROPE

Joint position paper on the Pharmaceutical Strategy for Europe

July 2020

INTRODUCTION

Human medicine is not an ordinary commodity. As the European Commission strives to develop a new Pharmaceutical Strategy for Europe, it is imperative that the new action plan looks beyond the economic significance of the pharmaceutical sector and the need to boost innovation. It must ensure access to affordable and quality medicines in Europe whilst guaranteeing everyone's right to a healthy and sustainable environment, including in producing countries outside Europe. The COVID-19 pandemic has demonstrated the need for the EU to play an enhanced role in this area amid looming health crises such as antimicrobial resistance (AMR).

Public interest and public health should prevail as leading priorities when regulating the pharmaceutical sector. This particularly requires improved transparency in the sector at different levels, including product research and innovation (R&I), market authorisation, availability of medicine, and environmental risks. The challenge of promoting a vibrant pharmaceutical sector in Europe will not be solved by intellectual property (IP) rights, tax incentives and subsidies to facilitate technological innovation of the pharmaceutical industry alone, nor is it sufficient to only encourage local manufacturing of key medicines and ingredients, moving away from highly complex, globalised supply chains.

The European Commission should rather consider key principles for a responsible and transparent pharmaceutical sector, and how such principles should be applied in the years to come in line with the EU's ambitions to tackle environmental and industrial challenges. Europe needs a clean and fair pharmaceutical sector, which operates without harming human rights nor the environment. This requires clear actions in four key areas.

1. ACCESS TO AFFORDABLE AND QUALITY MEDICINES

The excessive price of medicines has become one of the key barriers for patient access in Europe. This 'financial toxicity' is also one of the causes for rationing of treatments, a concern for the sustainability of healthcare systems, and a test for social cohesion. There is no value in a medicine that sits on the shelf due to its high price; affordable access to efficient and safe medicines should be high on the EU agenda in the pursuit of equitable and sustainable healthcare.

Recommendations:

- **Support medical research for better health outcomes, not to consolidate monopolies**

Abuse of incentives, leading to extra profit instead of compensating investment should be avoided. There is a need to review the impact of IP-related exclusivities and monopolies on the accessibility, affordability, and availability of medicines and health technologies. To this end, the ongoing evaluation of the EU orphan and paediatric legislation is a welcome step. A legislative review and scale back of all TRIPS+ exclusivities and protections could be considered necessary to enhance faster and increased price competition resulting in increased affordability and more diversified supply chains.

- **Adopt transparent methods and systems to evaluate the therapeutic value of new medicines**

Such methods can improve decision-making informed by evidence as well as better inform the public of benefits and risks related to new treatments. Stronger cooperation in the pre-launch and post-marketing authorisation phases should be pursued between regulators, the industry, payers, Health Technology Assessment (HTA) agencies, and patients on criteria and standards to encourage meaningful innovation driven by public health needs.

- **Create a space for alternative business models**

The COVID-19 pandemic has highlighted the need for an open and collaborative medicines discovery system. Patent-driven innovation may work for profit-driven drug development but it reflects an R&I agenda which favours profit prospects and market dominance. Additionally, it leads to excessive, unaffordable prices due to monopoly. The EU must encourage alternative de-linkage models that untie the R&I cost from the prices of products, while supporting R&I for new diagnostics, medicines and vaccines.

- **Encourage coordination among Member States when engaging with the pharmaceutical sector**

The EU has a key role to play in facilitating and strengthening existing dialogue and cooperation between Member States. Policy fragmentation, power and information asymmetries, and market failures can only be effectively tackled through coordinated responses. Pooled procurement, joint price negotiations, and information exchange are just some of the tools that Member States have at their disposal to use as leverage.

2 - SHORTAGES OF MEDICINES

Medicine shortages are a growing concern across Europe - it is a systemic problem with diverse root causes such as manufacturing difficulties, quality issues in a vulnerable distribution chain, and a lack of commercial interest. Amid the COVID-19 pandemic, this issue was exacerbated by extraordinary trade restrictions introduced by countries. Shortages of antibiotics, in particular, are a double challenge for many countries that lead to poorer treatment options for patients and can be a driver for antibiotic resistance when treatment providers are forced to prescribe alternative antibiotics.

Recommendations:

- **Strengthen the EU legislative framework to ensure supply of medicines**

Pharmaceutical manufacturers can decide to discontinue the production or the supply of medicines in a given country based on investment and marketing decisions. The EU legislative framework should therefore reinforce obligations for the Marketing Authorisation Holders (MAHs) and wholesalers to supply the market and could also present an opportunity for non-compliance sanctions.

- **Streamline monitoring across Member States and introduce early warning systems to prevent medicine shortages**

The notification system of medicine shortages needs to be improved. As national reporting requirements vary widely, a greater harmonisation of shortage monitoring across Member States will contribute to better understand the root causes of shortages. Additionally, the EU should create early warning systems and a permanent system for monitoring medicine shortages - requiring all medicines marketed in the EU to have accompanying European shortage management and prevention plans.

- **Address antibiotic shortages in global discussions as part of the EU's external policies**

There is a need to consider how the shortages problem can be addressed in the development of new antibiotics through requiring a diverse Active Pharmaceutical Ingredients (API) base, providing pooled or joint procurement, and rethinking the economic model so that revenues are not dependent on the volume of sales. Such considerations should be part of deliberations of a global agreement.

- **Publish new EU guidance on prudent procurement practices to help prevent occurrence of shortages in generic medicines**

Medicine shortages are often associated with a lack of suppliers in the market. Procurement practices focusing solely on price can result in suppliers pulling out of national markets, contributing to market consolidation, and therefore increasing the risks of medicine shortages. Allowing more than one winner for tenders of pharmaceutical products lowers the risk of depending on a single supplier. Diversification requirements for the supply sources should also be inserted in public tenders with a view to reducing systemic risk.

3 - RESEARCH AND INNOVATION OF MEDICINES

There is a need to ensure that R&I priorities are solely driven by the public interest, and not just by the commercial interests of the private sector, which may be driven by profitability or wish to align priority setting with what is already in the pipeline. The medium to long term focus should be on financing and implementing a combination of push and pull incentives along the development cycles based on the principles of de-linkage and ensure a fair return on public investment, guaranteeing that end products are affordable and subject to public health-driven stewardship and conservation efforts.

Recommendations:

- **Guarantee full transparency for R&I efforts**

The EU should ensure transparency in the terms and conditions negotiated between funders and recipients of R&I funding. The share of public and private contributions and the actual cost of R&I for each new product should also be publicly available in such R&I efforts and joint partnerships. Transparency should equally be ensured in preclinical and clinical trial data as well as in prices paid across the public and private sectors.

- **Ensure public return on public investment and safeguard equitable access to publicly funded biomedical R&I**

Public sector contributions are a significant percentage of R&I funding, in particular for high-risk early research stages - and the demand is growing. Taxpayers' money invested into biomedical R&I should ensure public return and societal benefit. The EU needs to ensure that EU investments are driven by public health needs and that parties receiving EU biomedical R&I funding agree on provisions to address the end product's affordability, accessibility, availability, and efficiency along all the R&I stages. The European Commission should explore various forms of IP management and licensing, including equitable licensing.

- **Foster healthy competition and support real innovation to create a sustainable system for governments and patients**

New R&I models should be explored, including de-linking the R&I costs from the price of a medicine, innovation inducement prizes as well as socially responsible and other pro-public forms of licensing. Open source research through pilot programs, feasibility studies, and new funding schemes along with open science (e.g. open data and access to publications) should become standard practice.

- **Take an end-to-end approach to antibiotic R&I and ensure the effectiveness of antibiotics**

The EU should consider the entire chain of actors, investments, and regulatory measures needed to overcome current challenges in developing and bringing novel antibiotics to patients in an effective and sustainable manner. It should also introduce financial support for the development of new antibiotics that seek to separate the cost of R&I from sales revenue (prices and volumes), as a means to ensure both affordability and rational use for conservation of effective antibiotics. Such de-linked mechanisms could include milestone prizes, public funding for end-to-end development of a new antibiotic and public buyouts of new compounds.

4 - ENVIRONMENTAL AND HUMAN RIGHTS RISKS

Innovation in the pharmaceutical sector must extend to policies and regulatory mechanisms that promote a toxic-free environment in line with the goals of the European Green Deal and the New Industrial Strategy for Europe. There is a need for both legislative and non-legislative measures to regulate environmental risks. These measures should encourage environmental due diligence in the pharmaceutical sector that promotes responsible and transparent production, procurement, consumption, and disposal of pharmaceuticals. These measures need to apply throughout the supply chain - adherence to strict environmental and human rights standards needs to be guaranteed to protect the wellbeing of local communities and their environment, notably from the development of AMR.

Recommendations:

- **Improve supply chain transparency to ensure accountability of pharmaceutical companies to environmental and human rights risks**

It is crucial for pharmaceutical companies to disclose supply chain information regarding the origin of medicinal products and APIs, as well as information regarding environmental and human rights risks involved in production and use of pharmaceuticals. Public disclosure of information is necessary to improve accountability of industries towards consumers and public procurers seeking to engage in responsible consumption and procurement of pharmaceuticals.

- **Adopt a life-cycle approach to regulate the release of pharmaceutical effluents into the environment from production, consumption, and disposal**

There is a need to establish an EU-wide regulatory framework with environmental quality standards and concentration limits to restrict the release of pharmaceutical effluents into the environment to mitigate the risks of spreading AMR, water pollution, and additional long-term impacts on human health and the environment. It should also include amendments to the EU Good Manufacturing Practices (GMP) to regulate the environmental release of pharmaceutical residues, including antibiotics and anti-infectives, from manufacturing facilities throughout the supply chain.

- **Assess all environmental risks of pharmaceuticals and implement stronger rules on marketing authorisations**

The risk-benefit analysis of medicinal products for human use must take into account their Environmental Risk Assessments (ERAs) in the market authorisation process to ensure that pharmaceutical companies deliver quality data on time. The risk assessments should include risks associated with manufacturing discharges and their cumulative impact on the environment and human health. It is also crucial to develop a clear procedure to assess the environmental risks of harmful pharmaceuticals that have been approved for market sales without any formal risk assessments.

- **Add requirements to assess and mitigate the risk of antimicrobial resistance in the Environmental Risk Assessment of medicinal products**

AMR is the most important risk for human health in relation to pharmaceuticals in the environment. It is crucial to explicitly include requirements that consider the risks of increased AMR emerging from the production stage to the final usage of medicines in ERAs of medicinal products. This would provide a more accurate picture of the risks linked to antimicrobials in the environment and allow for the adoption of proper mitigation measures across their life cycle.

- **Promote green public procurement as a tool to switch to medicines with a lower environmental impact**

The healthcare sector should leverage its significant purchasing power to encourage greener pharmaceutical design and manufacturing through sustainable procurement criteria. The EU must promote and improve green public procurement policies to increase demand for more sustainable production of medicines and the development of pharmaceuticals that are less harmful for the environment. This will encourage pharmaceutical companies to meet higher manufacturing standards in their supply chain that will improve the security of supply and reduce pharmaceutical pollution that contributes to AMR.

SIGNATORIES

Changing Markets Foundation
www.changingmarkets.org

European Alliance for Responsible R&D and Affordable Medicines
www.medicinesalliance.eu

European Public Health Alliance (EPHA)
www.epha.org

Health Care Without Harm (HCWH) Europe
www.noharm-europe.org

ReAct - Action on Antibiotic Resistance Europe
www.reactgroup.org

Stockholm International Water Institute (SIWI)
www.siwi.org

Swedwatch
www.swedwatch.org

Wemos
www.wemos.nl/en