

EU PRIORITIES, 2020–2024

MEDICINES **POLICY THAT WORKS** FOR PEOPLE



INTRODUCTION

The European Union (EU) and its institutions plays a major role in promoting and improving access to safe and effective medicines in its 27 Member States. It does so by addressing challenges in the development, production, supply, trade and use of pharmaceuticals in the EU and beyond.

Health Action International (HAI) follows these processes and provide expertise and insight when necessary. We advocate for greater transparency, and accountability on key issues such as research and development (R&D) costs, pricing decisions and reimbursement mechanisms.¹

HAI engages in constructive dialogue with stakeholders in the European Parliament (EP), Commission and European Council, as well as the European Medicines Agency (EMA), and contributes evidence and interventions to strengthen EU wide medicines policies.

PRIORITY AREAS

This paper outlines the priority issues in medicines policy in the EU, and gives recommendations for action and policy initiatives that, when implemented, can serve to improve access to affordable, safe, effective and quality-assured medicines for all EU citizens. This paper covers:

- Intellectual property incentives
- Transparency and clinical trials
- Health Technology Assessment
- Trade discussions
- Public-funded research
- Medicine shortages
- Antimicrobial resistance

INTELLECTUAL PROPERTY INCENTIVES: IMPACT ON ACCESS AND INNOVATION

The 2016 European Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States recognised *‘that further analysis to examine the current functioning of the pharmaceutical system in the EU and its Member States would be useful, in particular in relation to the impact of certain incentives in EU pharmaceutical legislation, the use thereof by economic operators and the consequences for the innovation, availability, accessibility and affordability of medicinal products for the benefit of patients.’*² The European Council also called for an overview of the entire Intellectual Property (IP) incentives framework, including how it impacts innovation and access to medicines.

HAI believes that IP incentives should be limited both in scope and duration so as not to hinder access by, for instance, enabling excessively high prices. The definition of treatment for orphan disease must be narrowed and its use monitored to avoid abuses.³ It is of concern that governments’ ability to make legitimate use of TRIPS flexibilities at the national level is seriously hindered by current EU data exclusivity regulation.⁴

Recommendations:

- Ensure that a review of IP incentives and their impact on innovation and access to medicines brings about necessary changes in the EU IP protection framework in relation to pharmaceuticals to accelerate the introduction of generic and biosimilar medicines, lowering prices through enhanced competition.⁵
- Close loopholes and exceptions allowing for abuses of the orphan disease designation. Policy coherence between industrial policy objectives and public health priorities must be ensured.
- Increase scrutiny and vigilance of anticompetitive practices by pharmaceutical companies, such as blocking or delaying generic competition and apply dissuasive sanctions.
- Consider the use, by Member States, of compulsory licenses to guarantee affordable access to high-priced medicines of assured safety and added therapeutic value. EU data exclusivity regulation should not be an obstacle for the use and exercise of TRIPS flexibilities.

European Parliament Working Group on Innovation, Access to Medicines and Poverty-related Diseases (EPWG).

HAI and the Médecins Sans Frontières (MSF) Access Campaign co-host an informal alliance of Members of the European Parliament (MEPs) gathered to seek “structural solutions so that every patient gets the treatment they need, when they need it”.

With members from across the party and political spectrum, the EPWG policy priorities for the 2019–2024 legislature are to increase transparency, explore new models of medical innovation, ensure improved access to medicine, and strengthen public health safeguards.

The EPWG is a space for discussion and dialogue about the wide array of issues related to access to medicines examined by various EP Committees.

TRANSPARENCY AND CLINICAL TRIALS: OVERCOMING OBSTACLES AND CHALLENGES

The Clinical Trial Regulation (Regulation (EU) No 536/2014) constitutes an important step forward in the quest for greater transparency of clinical trial design, implementation and results.⁶ Making the disclosure of information the norm—and commercial confidentiality the exception—heralds a new milestone in transparency and places the EU closer to the standards set out by the World Health Organization (WHO).⁷

Implementation of the regulation and the roll-out of the European clinical trials database (EudraCT)⁸, however, has been slow due to an apparent lack of interest from Member States, and a lack of support from other stakeholders.

HAI applauds the steps taken by the EMA in recent years to facilitate reporting of clinical trial data, but more could be done in order to facilitate greater access to information and, therefore, greater transparency.⁹ Recent developments at the Court of Justice of the European Union (CJEU) may further hinder the application of the Clinical Trial regulation by prioritising commercial confidentiality over public interest.¹⁰

Recommendations:

- The EMA must develop and publish clear criteria for approving deferrals to making information on clinical trials public. Deferrals must only be granted in exceptional cases. Where a deferral is approved, the justification for that deferral must immediately be made public on the registry. The public interest must be put ahead of commercial considerations in all cases.
- The EMA should ensure that redactions of any kind to clinical study reports (CSR) are kept to an absolute minimum. Information must be disclosed where there is an overriding public interest, even if it is considered commercially sensitive, and any anonymisation techniques used to protect personal data should safeguard the scientific utility of disclosed CSRs.
- EU institutions, including the EP and the European Ombudsman, should vigorously defend EMA policy on access to documents (0043) from legal challenges.



HEALTH TECHNOLOGY ASSESSMENT: ACHIEVING CONSENSUS TO COMPLETE REFORM

Health Technology Assessment (HTA) embodies one of the most effective regulatory instruments to inform marketing authorisations or reimbursement decisions. As such, HTA should be executed in a transparent, predictable manner. HAI strongly supports EU collaboration on HTA and values the opportunity for sharing best practice and achieving high standards that the proposed EU Regulation on HTA would provide.¹¹

However, from its inception, the initiative has also raised a number of concerns:

- Industry's financial contribution to initiatives like EUnetHTA could put the independence of the regulatory system in jeopardy and affect the quality of HTA.
- While collaborative efforts have the potential to strengthen health systems, flexibility should be shown on the grounds of specific national needs. Further, considering the vast differences in HTA between Member States, full joint assessments could reduce standards to those of the lowest common denominator, rather than support increased standards across the continent.

The position adopted by the EP was an improvement on that of the Commission, but agreement at the Council of Europe and implementation of this regulation have been hugely delayed.¹² Urgent action is required to end this deadlock.

Recommendations:

- Additional flexibility in the proposed Regulation must be incorporated to allow member states to carry out additional assessments where their specific needs demand it and to facilitate well-resourced and well-managed uptake of EU wide assessments in a step by step process.
- The key pillars of a successful EU-wide HTA system are: a commitment to the provision of freely available scientific advice; robust conflict of interest processes; protection of the position of the EMA; and the preservation of high-quality standards that incentivise genuine medical innovation. These pillars must be upheld by all parties.
- All evidence submitted by health technology developers should be made publicly available, and public health must always come before commercial interests. Input provided by stakeholders in consultation processes must be reported, and declarations of conflicts of interest made public. Outputs resulting from joint work must be freely available and reflect dissenting views.
- Legal and administrative safe-guards should be put in place to ensure the process remains independent from undue corporate influence.

MONITORING TRADE DISCUSSIONS AND THEIR IMPACT ON ACCESS TO MEDICINES.

The EU has one of the world's most stringent IP legal and regulatory frameworks. It enables the high prices of newly marketed drugs and, in some cases, hinders competition. In several instances, the EU has sought to impose its IP protection standards on trade partners despite the negative effects that its implementation may have for their pharmaceutical policy objectives.¹³ It is a positive step that the recent trade agreement signed with Mercosur does not include clauses that go further than those prescribed in the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. This allows signing parties to make use of TRIPS flexibilities agreed as part of the Doha Declaration of 2001. These include compulsory licensing and patentability criteria. The Commission's negotiations with Indonesia and Australia should also follow this pattern.

The European Parliament must also step up its involvement in monitoring the Commission's external trade strategy and negotiating mandates. This is particularly important if prospective new negotiations with the United States or a new free trade agreement with the United Kingdom (UK) were to involve pharmaceuticals.

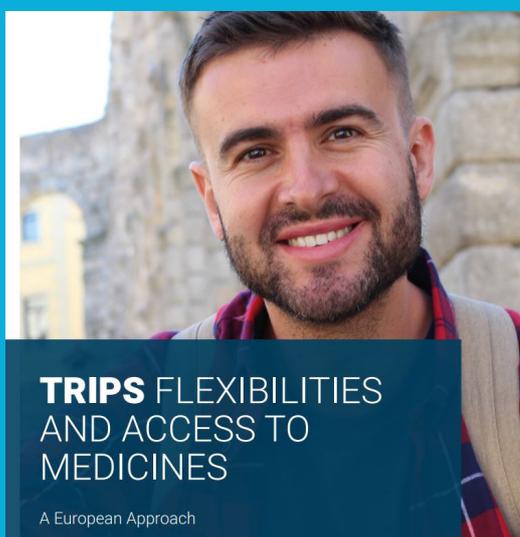
Recommendations:

- The European Commission must heed the call to consider the impact on public health of provisions that go beyond the requirements of the TRIPS Agreement when negotiating trade agreements. These include Supplementary Protection Certificates (SPC) and other IP incentive mechanisms.
- Negotiations should be as transparent as possible and meetings between Commission officials and industry representatives should be limited by conflicts of interest policies and rules already in place.
- The EU position on IP protection measures and pharmaceuticals should abide by the Doha Declaration while contributing to the fulfillment of the Sustainable Development Goals (SDG), especially SDG 3.8 and the achievement of Universal Health Care (UHC) for which access to medicines is a fundamental factor.¹⁴ Furthermore, an investor-state dispute settlement-like mechanism should not be part of negotiating texts.

Making Use of IP Management Tools

HAI's 2018 publication, 'Trips Flexibilities and Access to Medicines: A European Approach' lays out the tools available to EU policymakers wishing to improve access to medicines. The legitimate use of tools to achieve public health goals should be widespread and growing given that low-, middle-, and high-income countries alike face increasing economic burdens linked to the procurement of pharmaceuticals.

Find out more at www.haiweb.org



HORIZON EUROPE: PUBLICLY FUNDED RESEARCH FOR PUBLIC NEEDS.

The EU is one of the world's largest public funders of scientific research, including R&D of medicines and vaccines. However, the results of these efforts are not always accessible for the general public, being used instead by private actors to develop highly priced medicines that put sustainability of health systems at risk.

The latest incarnation of the EU research programme, Horizon Europe, reportedly seeks to guarantee public return on public investment.¹⁵ Despite such promises, close collaboration with the pharmaceutical industry and other for-profit institutions in several projects, and the introduction late in the drafting process of an industry-friendly innovation principle that could be used to undermine safety regulations, are matters of concern.¹⁶

The EU could champion the transition from the current IP-centred R&D model—shaped by eventual market returns—to needs-driven, open models of innovation based on delinkage of R&D costs from the final price of medicines. Such a measure will bring us closer to more affordable medicines.

Recommendations:

- Ensure that innovation and biomedical knowledge, derived in whole or in part from publicly funded health R&D, results in medical products that are appropriate and accessible at prices that reflect the public contribution. Trackability of public funding, transparency of R&D costs and of public support is essential.
- Consider attaching conditions to public funding of biomedical R&D that mandate non-exclusive or equitable licensing open data and affordable access to resulting medicinal products.
- Ensure R&D investments support global health priorities and not guided exclusively by potential market returns.



MEDICINES SHORTAGES: TACKLING AND PREVENTING CRISIS

Medicines shortages are happening with increasing frequency in the EU, affecting the wellbeing and health of millions of citizens whose pharmacological treatments are disrupted.¹⁷ It's critical that shortages are prevented rather than solved, given that it can take years to replenish stocks once a shortage occurs.

Cooperation between the EMA and national regulatory authorities is fundamental to guarantee the integrity of medicines supply.¹⁸ Civil society contribution is also necessary in order to align priorities and advocate for access to affordable medicines.¹⁹

Over the period 2019–2024, it is imperative that the European Commission, Member States, civil society and other stakeholders work together to tackle this increasingly endemic issue. The EP could play a role as honest broker gathering all relevant actors and concerned parties around the same table for a shared discussion.

Recommendations:

- Create an EU-wide database recording shortages and promoting wider information sharing about causes and projected shortages.
- More effective enforcement of Directive 2001 (83) and sanction breaches of public service measures; respecting legitimate parallel import activities but curtailing stocking out and price hiking.²⁰
- Explore and scrutinise solutions being suggested or discussed across the EU to better understand the potential legislative solutions to medicines shortages. For example, six month stockpiling, “pharma funds”, special needs authorisations, and moving production of pharmaceutical active materials and end products back to the EU.

El desabastecimiento de medicamentos aumenta el 40% en un año

el Periódico

Het medicijntekort loopt al acht jaar op

Trouw

Prescription Drug Shortages Could Plague The 2020's

Forbes

«A cause de la pénurie de médicament, ma chimiothérapie est en stand-by»

LE SOIR

Quase 40% dos hospitais sofre com falta de medicamentos todos os dias

Diário de Notícias

ANTIMICROBIAL RESISTANCE: THE NEED FOR NEW EFFECTIVE ANTIBIOTICS

The rise of antimicrobial resistance (AMR) and the dearth of new effective antibiotics constitutes a major challenge to global health, and the EU is not an exception. It is a complex threat that involves a wide range of factors, including food safety, rational use of medicines and innovation, among others, as well as stakeholders and constituencies.

The European One Health action plan against AMR, launched by the European Commission in 2017, is a laudable initiative that requires consistent follow up and buy in from all concerned parties.²¹ While the leadership from the Commission is important, the political will of Member States is critical to implementation of national action plans .

Organisations from across civil society have come together to contribute a joint response to the dangers posed by AMR.²² The contribution of industry in delivering new and effective antibiotics should not come at the cost of further incentives such as subsidies or extended market exclusivity periods.

Recommendations:

- Attach conditions to publicly funded R&D for antibiotics that favour global access and conservation. Including (a) making resulting data and reports publicly available at defined points in time; (b) requiring pro-public health management of research results; (c) including a clawback mechanism when the funding recipient does not meet specified conditions.
- Set targets and performance indicators to measure progress against AMR.
- Help countries mobilise resources for better implementation of national AMR policies and close the existing collaboration gap between civil society and EU policy-makers.
- Develop target prospective product profiles (TPPs) to guide priority setting in antibiotic R&D investments. This includes using the WHO's list of global R&D priorities for resistant pathogens.

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ENDNOTES

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