

A photograph of two elderly people walking away from the camera in a city street. The person on the left is a man with grey hair, wearing a light blue shirt and a black backpack. The person on the right is a woman with short grey hair, wearing a patterned scarf and a black backpack. They are walking on a sidewalk in front of a building with large windows. The image is partially obscured by a dark blue semi-transparent overlay containing text.

REPORT

SHARED **GOALS** DIFFERENT **STRATEGIES** COMMON **AGENDA?**

How the Netherlands and other EU governments respond to the challenge of sustainable access to medicines.

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INTRODUCTION

In 2018, Health Action International (HAI) issued a [report](#) tracing the fulfillment of Dutch government promises and commitments on access to medicines, looking at how they had fared on a number of relevant issues. Following this, in 2019, HAI issued a [policy paper](#) focusing on a few key areas and assessing whether any further progress had been made by the Netherlands in fulfilling its goals. The 2019 paper estimated that while there had been some important advancements in competition policy, results were more mixed in intellectual property (IP) and improvements were needed support alternative innovation mechanisms and pricing policy.

The Netherlands is not alone in attempting to address the impact of excessively high prices of medicines by enacting measures to achieve greater transparency or by taking action to ensure competition in pharmaceutical markets. Elsewhere in the European Union (EU), national authorities are responding to the demands of civil society and public opinion to seek a balance between private profits and public interests. Developments at the global level, such as the adoption of a resolution on transparency of pharmaceutical markets at the World Health Organization (WHO), and discussions, initiatives and actions by EU institutions complete a framework for action in which EU regulations play a major role.

CONTEXT

EU Member State governments have, for some time, been discussing the need to contain pharmaceutical expenditures to ensure the financial sustainability of public health systems and the viability of private insurers. The issues of excessively high prices and medicines shortages are an explicit part of the political debate, with civil society conducting advocacy and awareness-raising on issues such as the lack of transparency or misuse of IP rights (IPR), similar to HAI's actions in the Netherlands.¹

While there may be many shared concerns, national situations can also differ greatly, with procurement schemes, reimbursement mechanisms and granting of patents and ultimate enforcement of IP rights being mostly a national competence. These disparities are laid bare in some of the discussions within the EU on issues including Health Technology Assessment (HTA) and price transparency. The influence of initiatives from the European Commission and the differing priorities of rotating Presidencies of the EU in such deliberations goes some way to explain how some topics are addressed at national level.

“Yes, we’re delighted with new therapies that offer hope to sick people. We’re grateful to you for developing these drugs. But no, we cannot accept a state of affairs where healthcare costs are rising beyond people’s reach”.

– From an open letter to drug companies from former Dutch Health Minister, Bruno Bruins (2019)

POLICY AREAS

This document examines how national authorities in EU Member States have attempted to advance a more health-oriented perspective on the protection of IPR applied to pharmaceuticals. We will look particularly at the use of Trade Related Aspects of Intellectual Property (TRIPS) flexibilities, such as compulsory licenses or parallel imports, but also at the regulation of instruments including Supplementary Protection Certificates (SPCs) and other incentives originating from the EU legal framework.

We will also focus how European governments are enforcing transparency and accountability on two counts specifically: 1) how public resources being used in the development of health goods and ensuring public return on public investment in research and development (R&D); 2) how public interventions, legal amendments, and inter-country cooperation agreements build up a medicine pricing policy that enables better access conditions, including affordability. In both cases it is important to ascertain what the contribution of civil society should be.

Intellectual Property Management Tools

Protection and enforcement of IPR, most notably through patents on pharmaceutical products, constitutes one of the pillars of the current R&D system and, on occasion, presents a serious obstacle to access to medicines, enabling monopolies that can lead to high prices. In the case of the EU, which has a stringent and comprehensive IPR protection framework, patent protection terms are systematically extended through SPCs. This constitutes another case of EU regulation having an impact on domestic IPR enforcement.

SPCs have come under increasing scrutiny by national jurisdictions, mainly because the lack of clarity surrounding their use in high-priced medicines, such as adalimumab, trastuzumab and imatinib, among others. Just as the Dutch Parliament commissioned a study on the effects of supplementary protection mechanisms for pharmaceutical products in 2018, other

administrative and legal jurisdictions, including Belgium (2018), France (2019) and Germany (2018), have had to intervene, on occasion referring questions of interpretation to the Court of Justice of the European Union (CJEU). The approval of an [SPC manufacturing waiver](#) by the EU in 2019 did not close the debate as to the effectiveness of the instrument to promote innovation, while its negative impact on access has been firmly established.²

Pediatric formulations for rare diseases and orphan medicines are also granted de facto longer market exclusivity periods by being accorded an additional period of data exclusivity, supplementing the original patent term protection. This has consequences not only for access conditions (without competition, high prices can exist for longer periods of time), but it also considerably hinders the ability of national authorities to enact compulsory licenses: this is because generic manufacturers do not have access to critical information, for example, clinical trial data, which are protected and considered confidential.

Recent high-profile cases (see box below) exemplify the problems with the current system.³ The revision of the EU legislation on medicines for childhood and rare diseases, initiated by the European Commission in late 2020, may be a step in the right direction towards addressing such abuses.

High Profile Examples of a Broken System

- In 2017, Leadiant Biosciences increased the price of chenodeoxycholic acid (CDCA) 500-fold in the Netherlands after securing market authorisation as an orphan medical product for the treatment of cerebrotendinous xanthomatosis (CTX).⁴
- The exorbitant price-tag placed by Novartis on Zolgensma (purportedly EUR 2 million per treatment) for the treatment of spinal muscular atrophy (SMA), which made headlines in 2019 and 2020.⁵

It is worth noting the increasing role of the judiciary and civil society in countering IPR excesses in pharmaceutical products, with special emphasis on patentability criteria. In October 2020, a Dutch court sided with a health insurer and against pharmaceutical company AstraZeneca, who was accused of artificially maintaining a high price on a medicine thanks to a patent that had been declared invalid due to lack of an inventive step. In December 2019, following a campaign by non-governmental organisations (NGOs) Médecins du Monde (Mdm) and Public Eye on the lack of merit, pharmaceutical company Novartis withdrew a patent application before the European Patent Office (EPO) for the personalised cancer treatment Kymriah.⁶ Even though the therapy is protected by other patents, this was the first time that an opposition initiated by NGOs has led to a European pharmaceutical patent being withdrawn.

Effective use of TRIPS flexibilities by EU Member States had been rare before the COVID-19 pandemic, with the Netherlands engaged in long multi-stakeholder discussions about compulsory licenses that ultimately collapsed in 2020. The difficulties in gaining access to critical medical supplies in the initial stages of the crisis convinced several governments—Germany and Hungary among them—of the need to adapt their patent law to make it easier to enact compulsory licenses. Other countries, such as Greece, suggested EU-wide efforts to buy out patents for essential medicines.

Transparency

A lack of transparency in issues such as costs of R&D, procurement schemes, and pricing and reimbursement decisions, among other topics, fuels information asymmetries in pharmaceutical markets which in turn hinders the effectiveness of public interventions aimed at improving access to medicines. This was one of the main demands of HAI's campaign in the Netherlands—and echoed elsewhere in the EU—which focused on assessing the specific contributions of the public sector in the development of medicines and vaccines and to establish on which grounds (or estimated costs) prices are adopted.

Both counts have huge implications on how relevant authorities engage in purchasing or reimbursement decisions.

The adoption by the WHO in May 2019 of resolution [WHA 72.8 *Improving the transparency of markets for medicines, vaccines, and other health products*](#), presented by Italy and co-sponsored by several EU Member States, represented an historic achievement, and was a result of the joint efforts of a diverse coalition of countries and civil society. For the first time the need for greater transparency on prices of medicines and disclosure of R&D costs was endorsed by a WHO governing body. Its development and implementation at national or subregional level has, however, been slow and only Italy has so far issued a decree explicitly ordering the release of relevant data.

As in other domains of pharmaceutical policy, the outbreak of COVID-19 brought a new sense of urgency to long-standing demands. The need for researchers and health professionals to have timely access to relevant data has spurred efforts by the European Commission to make the results of public-funded COVID-19 research accessible to the scientific community as quickly as possible. Unfortunately, this drive for openness has not reached the exclusive vaccine procurement contracts negotiated between the European Commission and pharmaceutical companies, and despite criticism and opposition by national and European lawmakers and civil society, only heavily redacted versions of the contracts have been made available.

Research & Development

In a pattern replicated across the EU, the long-standing push for public research institutions to seek additional revenues through collaboration with private actors has, on too many occasions, led to publicly funded scientific endeavour being marketed at excessively high prices. Specific examples include those in the Netherlands concerning cancer drugs Keytruda (pembrolizumab) and Lutathera (Lutetium-Octreotate), the latter benefitting from orphan medicine designation; Belgium with HIV and

Hepatitis antiviral Viread (tenofovir disoproxil), and France with the above mentioned Zolgensma (gene therapy Onasemnogene abeparvovec). Public backlash against these and other particularly blatant episodes, combined with pressure from academia and civil society, has gradually created an agenda of greater transparency and public return on public investment. Effectively fulfilling such an agenda remains a challenge.

Efforts to independently estimate the amounts spent by pharmaceutical companies on the R&D of newly marketed medicines have found renewed impetus in the last decade with the arrival of highly priced treatments for hepatitis and cancer, including gene-therapies. Pharmaceutical companies routinely argue that high prices are the only possible way to recoup earlier investments in the development of new medicines, including failed attempts or unsuccessful candidates. Critics counter that to achieve affordable prices estimated costs and final prices should be de-linked. HAI supports the notion of delinkage and suggests that novel innovation models, such as prize funds, voluntary non-exclusive licenses, or pooling mechanisms for IP should be explored.

Pricing

Since 2016, the Dutch government has been increasingly vocal about the need to control medicine prices and has publicly taken on a more active role to ensure an adequate balance between pharmaceutical activities and societal needs. Following in the footsteps of reform in Germany in 2011, Belgium and Spain have also introduced clauses that commit pharmaceutical companies to justify (to a certain extent) the requested prices for given medicines. However, most contracts are still confidential and pharmaceutical companies consistently oppose disclosure of net prices, without rebates.

The lack of decisive action, due not only to the lack of competence but also as a result of the

inability to garner consensus among Member States, has spurred on voluntary inter-country cooperation schemes in price negotiation and joint procurement. Since 2017, several sub-regional coalitions, such as the [Beneluxa Initiative](#) and the [Valletta Declaration Group](#) have begun to engage in negotiations with pharmaceutical companies.⁷

The [EURIPID Collaboration Initiative](#)—another voluntary cooperation exercise between regulatory and health authorities from 26 European countries with funding from the European Commission—is seeking to shed light on prices of pharmaceutical products.⁸ The database has achieved [some degree of success](#) in sharing information, but still faces serious obstacles that prevent it being in an operational way.

The fact that in 2017 the European Commission, for the first time, opened a formal investigation into concerns that a pharmaceutical company had engaged in a pattern of excessive pricing for several life-saving cancer drugs, constituted a defining moment.⁹ Since then, both the European Commission and European Parliament have been closely watching pharmaceutical companies' market behaviour, looking for evidence of collusion and abuse of market dominance or other anticompetitive practices. Market regulatory authorities in [the Netherlands](#) and France have also been active on the issue.

With the outbreak of COVID-19, a sea-change in approach may have been hoped for, but the way in which the upper echelons of the European Commission have assumed a leading role in the negotiation of vaccine contracts has not adhered to the minimum requirements set out in EU legislation for public contracts. The investigation opened by the EU Ombudsman in mid-January 2021 follows repeated attempts by a pan-European coalition of NGOs (HAI among them) to have access to contracts worth billions of euros of public money.

CONCLUSIONS

- Political will is not enough if not translated into specific, legally binding acts. This has been a problem, not only in the Netherlands, but also in other countries, such as France, where proposals which would have effectively countered the lack of transparency on public investment in R&D have been thrown out after initial approval at Parliament level.
- National authorities and courts seem increasingly willing to confront and address specific instances of misuse and abuses of IPR protection, for example, the evergreening of patents to block competition. But there seems to be no appetite for the comprehensive policies (involving several ministries and institutions) that would advance a health oriented IPR protection agenda and include administrative and legal proceedings to make systematic use of TRIPS flexibilities.
- The COVID-19 pandemic has been a catalyst for national authorities, with countries such as Germany and Hungary amending their patent laws, and the Netherlands engaged in legislative reform to streamline the use of compulsory licenses.
- Reform proposals from the European Commission contained in the Intellectual Property Action Plan and the European Pharmaceutical Strategy proposal would in principle facilitate the use of TRIPS flexibilities. However, no EU country has yet issued a compulsory license and risks of backlash from pharma industry or pressure from non-EU countries remain high.
- Transparency of critical stages of the access to medicines continuum is high on the agenda at almost every level of discussion, with WHO and the European Commission seemingly endorsing the need to disclose information and data on clinical trials, R&D costs, and prices. However, the fulfilment of such commitments is lagging.
- The fight against COVID-19 has put more emphasis on the critical role of transparency; from accessing the results of clinical trials to ascertain the efficacy of tentative vaccines, or acknowledging the degree of public support in developing therapeutic responses when taking pricing decisions.
- The importance of public sector support, for example through direct funding, in-kind expertise and/or tax breaks and other forms of subsidy to the development of health technologies marketed in EU member, is substantial. Civil society efforts to ensure public return of this public investment still fail to gain traction in the legally-binding sphere. Debates in the French Senate in 2019 and 2020 about the need to publicise the amount of public money invested in the development of privately marketed medicines did not make into law due to pro forma objections.¹⁰
- The lack of transparency around R&D costs poses a challenge to the establishment of adequate compensation for pharmaceutical companies and to set prices in a fair and just manner. This distorting factor of a key element of pharmaceutical policy is increasingly challenged by several European governments, such as Italy, the Netherlands, Belgium, and Portugal, who, on their own or in cooperation with others, seek to frame a new narrative where pharmaceutical companies and governments uphold their respective responsibilities in a constructive manner.
- Despite some legislative steps forward in Italy and administrative reforms in Spain and Portugal, justification for prices of medicines remain largely opaque across the EU. The fact that health and importantly, the procurement of pharmaceuticals, is largely a national competence complicates Member States' bargaining positions and it is clear that pharmaceutical companies rely on such information asymmetries for leverage.

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