



**POLICY PAPER**

# REALITIES OF **ACCESS** **TO MEDICINES** IN THE NETHERLANDS

Commitments, Rights and Obligations

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## Commitments, Rights and Obligations

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# OUR MEDICINES, OUR RIGHT

Health Action International's (HAI) "Our Medicines, Our Right" campaign was launched in the run up to the 2017 Dutch Parliamentary elections, with the endorsement of 14 civil society organisations.\* The campaign added a civil society voice to the animated discussion taking place in the Netherlands about the prohibitive price of several medicines and pinpointed factors that enable excessive pricing. Among them the opacity of the costs of research and development (R&D) purportedly incurred by pharmaceutical companies; failure to acknowledge the contribution of public funds and publicly funded research institutions to the early development of newly-marketed medicines; and the lack of transparency in pricing decisions and procurement schemes.

## GOVERNMENT PROMISES

The Dutch government has been one of the most vocal in the European Union (EU) on the need to reframe the balance between innovation and access. Successive Ministers of Health have been adamant about the need to seek a balance between pharmaceutical companies' marketing strategies and national governments budgetary constraints, both within EU and at the global level.<sup>1</sup>

This paper follows up on HAI's 2018 report and gauges the current situation of access to medicines (especially affordability, transparency and accountability) following the three axes on which the campaign was built: transparency of government decisions, disclosure of R&D costs by pharmaceutical companies, and public return on public investment.

### Lack of transparency in government decisions vis-à-vis procurement and reimbursement

The Dutch government has failed to effectively address increasingly high prices of a selected group of medicines, such as newly marketed cancer treatments and orphan medicines. Legislative and administrative steps—including inter-institutional commissions, specific funds and other ad-hoc interventions—have not been enough to avoid well documented price-hikes, shortages and other disruptions to medicines supply.<sup>3</sup>

The stated willingness of the government to achieve greater transparency in the procurement process (including price negotiations) has been thwarted by the lack of cooperation by large pharmaceutical companies. The government has not made use of all legal and administrative capabilities at its disposal to protect, promote and advance public interest. This is particularly the case with market distortions and abuses rooted in monopolies and other forms of market exclusivity (i.e., patent evergreening<sup>4</sup>).

In 2018, a report by HAI mapped some of the public commitments made by the Dutch government on policy areas including intellectual property, alternative innovation and competition and pricing policies. The report scored them on the extent to which they had been achieved in terms of consensus building, transparency and implementation.<sup>2</sup>

\*A complete list of endorsing organisations, as well as the public petition and materials of the campaign available at [www.ourmedicinesourright.org](http://www.ourmedicinesourright.org)

# Regional cooperation, within and outside the EU

## European Union

Despite having been instrumental in shaping a new agenda for access to medicines after the 2016 Presidency of the EU, the Dutch government was not able to follow up in a consistent manner with most of the commitments set in its conclusions. However, several discussion processes such as those on the designation of orphan medicines and other intellectual property (IP) incentives can be attributed to the foundations laid by the Dutch Presidency. Its contributions to the debate within the EU were not, however, in line with some of their public statements regarding use of flexibilities and other mechanisms to improve access to medicines.

## Beneluxai

In 2015 the Belgian and Dutch governments formed a cross-country initiative to increase transparency in pharmaceuticals. They were joined by Luxembourg and Austria, and by Ireland in 2018, becoming Beneluxai. In mid 2019, as part of this initiative, Belgium and the Netherlands successfully negotiated lower prices for Spinraza, an orphan drug for Spinal Muscular Atrophy. Following months of negotiations, Spinraza was reimbursed under similar conditions in both countries: an example of how joint health technology assessments (HTA) and joint price negotiations can benefit patients and health care systems alike. However, while this is a positive indicator of government and industry's will to collaborate, there are some concerns that this remains the only major 'win' for the initiative since its inception with no information on agreed price having been made available.<sup>5</sup> The Beneluxai initiative also seeks to explore joint horizon scanning activities, as well as beyond it through a programme called IHSI.

Finally, the Netherlands is exploring the opportunity for countries outside the EU, such as Canada and Norway, to take the interim step of participating in the joint horizon scanning group.<sup>6</sup> Overall, although the initiative's success may be small in number there is reason to be optimistic about the impact this initiative will have on patients in the future.

## Lack of disclosure of R&D costs by pharmaceutical industry

While the Dutch government has on a number of occasions expressed scepticism about R&D investment figures used by the pharmaceutical industry to justify high prices, it has been unwilling or unable to establish independent reliable assessment mechanism of the actual cost of bringing a new medicine to market.<sup>7</sup>

Despite having vocally opposed the application of TRIPS+ measures, labelling them an excessive use of IP Incentives, the Dutch government has failed to actively participate in some of the policy discussions around the topic, such as deliberations around a manufacturing waiver for Supplementary Protection Certificates (SPC) that would have eased the entry of generic versions of medicines into the EU market.\* The Dutch government also followed the example of some of its fellow European countries by introducing patent exemptions to allow pharmacists to prepare some low-cost medicines.<sup>8</sup>

The Dutch government has explicitly endorsed alternative innovation mechanisms not dependant on IP incentives to counter a R&D model skewed by commercial interests, favouring instead delinkage models where prices are not based on development costs.\*\* Such support encompasses domestic and international projects and has been consistent despite changes in government composition.\*\*\*

## At the World Health Organization

The Netherlands has for the last three years been a leading advocate on access to medicines globally. The Dutch delegation co-sponsored a decision at the 142nd Session of the WHO Executive Board to create a roadmap on global access to medicines and vaccines that included actions and deliverables for 2019-23, adopted as decision WHA71(8) at 71st World Health Assembly (WHA71) in May 2018. The delegation expressed the need for urgency on the issue of access to medicines and said that all obstacles should be addressed—not just the simple ones.<sup>9</sup> At a side event hosted by HAI and Knowledge Ecology International during WHA71, Dutch representatives also made clear commitment to fair pricing, use of intellectual property in stimulating innovation, and ensuring affordable and available medicines in the future.<sup>10</sup> In 2019, the Netherlands played a pivotal role in the drafting and approval of Resolution WHA72.8<sup>11</sup> (known as transparency resolution) which calls for Member States to take steps to ensure greater transparency of prices, patent status and other critical data related to pharmaceutical markets.<sup>12</sup>

\*Of note in this context is the letter drafted by Wemos and endorsed by HAI, Commons Network, SOMO, Farma ter Verantwoording and Aidsfonds, signed 3 December 2018. Available at [https://www.wemos.nl/wp-content/uploads/2018/12/Joint-State-ment-ABCs\\_Final.pdf](https://www.wemos.nl/wp-content/uploads/2018/12/Joint-State-ment-ABCs_Final.pdf)

\*\*See for instance the Dutch contribution to the works of the United Nations High Level Panel on Access to Medicines (UNHLP): ‘While we recognise that patents have an important role in innovation, we recommend that the UNHLP encourages the development and implementation of a wider variety of innovation financing models that do not rely on creating additional market exclusivities (through patents or otherwise). Such models should be based on “delinkage” principles, and thus the premise that costs and risks associated with R&D should be rewarded, other than through the price of the product.’ Ministry of Foreign Affairs Kingdom of the Netherlands, 27 February 2016 <http://www.unsgaccessmeds.org/inbox/2016/2/27/ministry-of-foreign-affairs-the-kingdom-of-the-netherlands>

\*\*\*In the Netherlands, the Ministry of Health, Welfare and Sport has provided financial support for the Fair Medicine and Oncode Institute as proof of concept of non-commercial development of medicines. Globally it supports the efforts of the Drugs for Neglected Diseases Initiative (DNDI) and the Global Global Antibiotic Research and Development Partnership (GARDP) among other endeavours to respond to health needs rather than commercial returns.

## Lack of public return on public investment

The Dutch government invests huge amounts of resources in biomedical research through research grants subsidies and other tax breaks among other public measures. Public research institutions linked to universities and other non-profit outfits conduct all stages of biomedical research in occasions partnering with pharmaceutical industry. Safeguards of public interest are theoretically in place but not always heeded or respected.<sup>13</sup>

A number of voices have expressed the need for more robust mechanisms to promote public interest in public-funded research as safeguards of public interest are theoretically in place, but not always heeded or respected.\* This need to guarantee a public return on public investment is what drove, in part, the public consultation and drafting of the guidelines on socially sustainable licensing policies by the Netherlands Network of Universities Medical Centres.<sup>14</sup>

## Citizens paying twice for their medicines

In the 1980's and 90's, Erasmus MC conducted research on the precision treatment for neuroendocrine tumours (NETs). In 2001, a few individual researchers from Erasmus MC established and became shareholders in their own start-up company, Biosynthema, to further develop the application of lutetium-octreotate. Erasmus MC had no stake or control in the company.

In 2010, Biosynthema was sold to Advanced Accelerator Applications (AAA), a large French pharmaceutical company that named the medicine Lutathera. In the meantime, Erasmus MC still conducted the research with patients. From 2000 to 2015, a total of 1214 people received Lutathera, which proved to be effective in treating NETs. AAA successfully applied for an 'orphan designation' in both the United States and EU.<sup>16</sup>

## Lack of transparency in government decisions

In 2017, Lutathera officially entered the market and in 2018, Novartis acquired AAA and increased Lutatheras' price from between €16,000 to €92,000 per treatment regimen. At present, Erasmus MC is excluded from the use of a medicine to which they contributed the R&D and also now depend on Novartis for the raw materials they need for producing their own. All of this is perfectly legal yet morally unsound and financially unsustainable.

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\*The report 'Development of new medicines - Better, faster, cheaper' by the Council for Public Health and Society endorsed the idea of socially responsible licensing conditions. Available at [https://www.raadrvs.nl/binaries/raadrvs/documenten/publicaties/2017/11/09/development-of-new-medicines--better-faster-cheaper/Development\\_of\\_New\\_Medicines\\_Better\\_faster\\_-cheaper.pdf](https://www.raadrvs.nl/binaries/raadrvs/documenten/publicaties/2017/11/09/development-of-new-medicines--better-faster-cheaper/Development_of_New_Medicines_Better_faster_-cheaper.pdf). Also, the 'BIG FARMA: NIET GEZOND! Initiatiefnota om de macht van de farmaceutische industrie te doorbreken', presented in the Tweede Kamer on 21 November 2018 by PVDA, Groen Links and SP proposed, among the measures to counter imbalances in the pharmaceutical markets, setting up a National Fund for drug Research that would guarantee public funding for research at universities with no need of involvement by the pharmaceutical industry. Available here: <https://groenlinks.nl/sites/groenlinks.nl/files/downloads/newsarticle/Initiatiefnota%20Big%20Farma.pdf>

# CONCLUSIONS AND RECOMMENDATIONS

While the Dutch government reportedly remains committed to improving access to medicines, it is not clear if the actions being taken to achieve these goals are the most effective, or if there is a consistency across government departments.

## Competition

Policy decisions regarding use of TRIPS flexibilities, such as compulsory licenses to counter anticompetitive practices in the pharmaceutical markets, have been announced several times but have yet to be implemented. Positive steps, like the conformation of a commission with diverse stakeholders to discuss the issue, lack the transparency and accountability needed to be considered as a valid policy platform. The use of TRIPS flexibilities, including but not limited to compulsory licenses, should be seriously considered at Cabinet level with the necessary legal amendments (and exceptions to EU data exclusivity regulations) drafted and discussed.

## Dutch Influence on EU Medicines Policy

Dutch stances on access to medicines at EU Council level have been instrumental in spurring policy initiatives by the European Commission, which have resulted in discussions and processes that may ultimately lead to legal changes with positive implications for access to medicines. Dutch authorities should continue to insist on marketability of all European Medicines Agency (EMA) approved medicines in all EU Member States and support for greater accessibility of medicines prices data and sales volumes between EU Member States. Dutch authorities should also reject TRIPS+ clauses in EU trade negotiations. As with the SPC discussion, Dutch parliament should address relevant pharmaceutical policy issues at the European level. These include the IP incentives mechanisms review, HTA reform and the Clinical Trial Regulation.

## Alternative Innovation Mechanisms

Support for alternative innovation mechanisms, particularly those based on delinkage, has been consistent both at the domestic and international level. Initiatives like Oncode and Fair Medicine in the Netherlands, or GARDP at the global level should be maintained, and best practices replicated where possible.

## Universities and Public Research Institutions

Activities of all institutions receiving public resources must incorporate transparency requirements, especially collaboration and partnership agreements with the private sector. The enactment of NFU guidelines on socially responsible licensing is an important step forward that needs Parliament involvement to make them enforceable. Clinical trial transparency is a domain where Dutch universities can improve. Academic authorities should encourage and facilitate the reporting of clinical trials design, development, costs and results. The Netherlands should also be vocal and explicit in its support for the transparency (access to documents policy) in EMA management of Clinical Results Studies in relation to recent developments in the Court of Justice of the European Union.

## Regional Cooperation

Existing cooperation agreements like BENELUXAI should continue, and deeper collaboration schemes involving joint procurement and price negotiation pursued in a transparent way. Possibilities of coordination with other cooperation schemes, such as the Valletta declaration or the Visegrad group, should be explored.

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