



REPORT

NEW AND AFFORDABLE MEDICINES IN **THE NETHERLANDS**

Tracing the Dutch Government's
Policy Commitments and Actions

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INTRODUCTION

“We cannot achieve any real progress without acknowledging that the current patent-based business model and the way we apply international patent rules need to change. The system is broken.”

- Former Dutch Ministers, Lilianne Ploumen and Edith Schippers, November, 2016

These bold words from the former Ministers of Foreign Trade and Development Cooperation, and Health, Welfare and Sport about achieving access to essential medicines for all set the Dutch government apart from most other European countries. Similar to its European Union (EU) neighbours, the Netherlands struggles to afford the ever-increasing prices for new medicines. One of the first signals of a turning tide came in 2015 when nivolumab was marketed at a total projected cost of €200 million per year to treat patients in the Netherlands with advanced stage, non-small-cell lung cancer.¹ This exorbitant cost, roughly equivalent to an eighth of the Netherlands' total expenditure on inpatient pharmaceuticals, triggered a landmark decision by the Dutch government to stop automatically reimbursing new, expensive medicines used in hospitals and, instead, negotiate better prices.²

This momentum continued during the Dutch Presidency of the Council of the EU from January to June, 2016. The official programme of the Presidency committed to examining how medical innovations can reach patients faster ‘at a socially acceptable cost’.³ It emphasised the importance of safeguarding access to innovative and affordable medicines, therefore committing to strengthening Member State voluntary cooperation on issues of pricing and market access.

Since then, the Netherlands has been among the few EU Member States to resolutely and vocally commit to addressing the systemic problems that permit and sustain high medicines prices. The Dutch government has openly questioned the business model for pharmaceutical innovation and its reliance on patent and other intellectual property (IP) and regulatory exclusivities.⁴ Recently, the government made strong statements about safeguards for the flexible implementation of patent rules for public health.⁵ In doing so, the government effectively broke ranks with other EU countries in multilateral fora; instead, the Netherlands seems to try to find new paths synonymous with its changing domestic policies for drug development and pricing.

Towards the end of her term, then Minister of Health, Welfare and Sport (from 2010–2017), Edith Schippers, called for urgent and far-reaching revisions to Dutch medicines policy. Some of these policy initiatives are now being continued by the current Minister for Medical Care and Sport, Bruno Bruins. Both Ministers are members of the People’s Party for Freedom and Democracy (Volkspartij voor Vrijheid en Democratie or VVD), a conservative liberal political party. Now, one year into the term of the Rutte III Cabinet, this report collects the Dutch government’s commitments to the development and marketing of new, affordable medicines and, where possible, assesses their implementation.

METHODS

This report aims to collect the Dutch government's policy commitments for the development and marketing of new, affordable medicines in the Netherlands. It also aims to assess the degree to which the Dutch government has implemented these commitments through concrete policy measures to date. Commitments of interest relate to pharmaceuticals and (1) IP and Trade-related Aspects of Intellectual Property (TRIPS) flexibilities, (2) alternative innovation models, (3) competition policy, and (4) pricing policy.

This is a mixed-methods policy tracing study, based on a document review validated through two expert interviews. Data are the written and oral commitments made by representatives of the Dutch government in political fora and print media between 1 January, 2016, and 1 October, 2018. We included commitments and actions made one year before the most recent general election (2016) to the present day. Data was cross-checked against available literature, policy documents, grey literature, and the interview results. The commitments in the four domains are the reference against which policy action is judged.

Document Review

A detailed methodology for this document review is available in Annex 2 of this report. A systematic online search strategy was used to locate material from policy sources (i.e., the Dutch government, multilateral institutions), academic literature (i.e., PubMed search, articles published in the Dutch medical journal, *Nederlands Tijdschrift voor Geneeskunde*) and grey literature (i.e., the IP Health and EU Alliance listservs).

The online search was executed in August, 2018, and updated in October, 2018, using search terms in English and Dutch. In addition to this online search, information was crowdsourced from experts by requesting a list of pharmaceutical policy initiatives from national health advocates. Material was included if it expressed a government commitment or policy action

specifically related to the pricing and/or affordability of medicines in the Netherlands, was published after 1 January, 2016, and was the most recent version available in full text.

Three experienced researchers with backgrounds in law and pharmaceutical policy analysis independently selected text from the retrieved material into a data extraction sheet. A descriptive analysis was generated by summarising the commitments and actions taken within each of the four domains. Although it is relatively early to judge the achievements of these policy actions, we considered them in relation to three overarching objectives that can advance access to new medicines:

- Does the government build political consensus for a new narrative and policy measures to lower medicines prices?
- Does the government enhance the transparency of research and development (R&D) costs, medicines prices, and profits?
- How is the government facilitating the implementation of its policy commitments?

Interviews

Two semi-structured interviews were conducted with representatives of the Dutch Ministries of Health, Welfare and Sport, and Economic Affairs and Climate. Interviewees were selected based on their expertise in relation to this report. They were provided with a draft of this report (including the results of the document review) in advance of the interview. At the outset of each meeting, informed consent was sought in line with the 'Ethical Guidelines for Interviewing Public Personalities', published by the University of Toronto's Social Sciences and Humanities Research Ethics Board. The interviews followed a semi-structured guide (Annex 3). These interviews aimed to complement the document review by clarifying uncertain commitments, as well as the status and preliminary outcomes of their implementation. Therefore, the interviews served to validate the results of the document review.

RESULTS

Overview of Policy Commitments

Nineteen policy documents were included in this study (see Annex 2 for a complete list of the source documents). Nine core policy commitments to access to medicines in the Netherlands were distilled from those policy documents (see below).

Intellectual Property and TRIPS Flexibilities

Determine the positive and negative effects of current IP protection, specifically for pharmaceuticals, including by:

- Examining if the existing EU protection mechanisms (i.e., supplementary protection certificates, data exclusivity, and orphan medicines) yield the desired results.

Safeguard TRIPS flexibilities and oppose the overuse of IP rights, specifically by:

- Facilitating an expert meeting to explore options to ensure the protection of flexibilities.
- Studying and examining the possibilities of domestic accessibility measures (i.e., compulsory licensing, pharmacist preparations, and import of medicines) available in patent and pharmaceutical legislation.
- Enhancing efforts to prevent the adoption of TRIPS-plus measures in EU trade agreements and agreements between high-income countries and low- and middle-income countries (LMICs).

Alternative Innovation Models

Create space for alternative development/business models and marketing of pharmaceuticals at a socially acceptable price, specifically by:

- Forming a coalition of stakeholders and experts to examine these alternatives.
- Setting conditions for collective financing of medicines R&D and 'socially responsible licensing'.
- Investigating innovative business models to develop and produce (orphan) medicines.

Competition Policy

Investigate possible anti-competitive cases and intervene to reach a solution, including by:

- Prioritising national investigations into competition on the prescription drug markets for 2018–2019;
- Discussing with the Dutch Authority for Consumers and Markets (ACM) whether a manufacturer demanding an excessive price for a new medicine constitutes abuse of a dominant position.

Pricing Policy

Encourage and pressure the pharmaceutical industry to lower prices, specifically by:

- Discussing price transparency measures with the Dutch Association for Innovative Medicines, the European Federation of Pharmaceutical Industries and Associations, and Chief Executive Officers (CEOs) of pharmaceutical companies.
- Advocating for a change in the business model of the pharmaceutical industry in areas with proven market abuse.
- Pursuing the principle that a medicine's price should be related to its actual (development) cost.

Support health insurance companies and hospitals to tackle high prices, specifically by:

- Ensuring every hospital has a medications commission responsible for determining policies on expensive medicines.
- Establishing an up-to-date overview of expensive medications purchased by hospitals and patients' experiences with these drugs.
- Offering education and establishing guidelines on the legalities and administrative procedures of collective procurement (i.e., by hospitals and insurance companies) under national competition law.
- Examining the possibility of concluding financial arrangements with the pharmaceutical industry at the national level while leaving scope for decentralised negotiations, where needed.

Take national measures to improve the affordability of medicines, specifically by:

- Amending the Medicine Prices Act ('wet geneesmiddelenprijzen', WPG) and assess whether the objection and appeal procedures and the enforcement instruments are still adequate.
- Legally embedding the concept of the 'lock' ('sluis') to evaluate high-priced medicines for reimbursement and lifting contingencies on new price negotiations, and continuing and expanding the number of financial arrangements on expensive medicines (i.e., postponing insurance coverage until lower medicines prices can be negotiated).
- Revising the WPG by replacing Germany as a reference country with another country that has a comparable level of prosperity and lower prices.

Modernise and reform the medicines reimbursement system ('Geneesmiddelenvergoedings-systeem', GVS), specifically by:

- Imposing reimbursement limitations for expensive hospital medicines that currently receive automatic approval.
- Recalculating medication groups to create lower limits for reimbursement.

Initiate international cooperation to keep medicines affordable, specifically by:

- Leading dialogue on medicines pricing transparency during the 2016 Dutch Presidency of the Council of the EU to improve price transparency and information sharing.
- Welcoming other countries to the (then) Benelux Cooperation, which focuses on horizon scanning, information sharing, plan procurement, and health technology assessment (HTA), regardless of whether they are members of the EU.
- Taking the initiative to discuss new flexible forms of market authorisation (i.e., adaptive pathways) to bring innovative products for a genuine unmet need faster, safely, and affordably to the patient.

Areas of Policy Action

NOTE: To validate the results of the document review, the authors conducted key informant interviews with representatives of the Dutch Ministries of Health, Welfare and Sport, and Economic Affairs and Climate. In the following findings, an asterisk (*) denotes information obtained from a key informant interview.

Intellectual Property and TRIPS Flexibilities

The *Council Conclusions on Strengthening the Balance in the Pharmaceutical Systems in the EU and its Member States* ('Council Conclusions'), adopted by the Council of the EU during the Dutch Presidency (January–June, 2016) questioned the suitability of IP incentives for access to innovative, affordable medicines and committed to assess the supplementary protection mechanisms.⁶ There is neither a formal EU implementation plan, nor EU-level coordination mechanism to follow-up these Conclusions.* Nevertheless, some conclusions to explore IP incentives mechanisms have been subsequently realised by two reports commissioned by the European Commission and the 'shadow' Technopolis report, commissioned by the Dutch government (see below).

In a 2017 letter to the Dutch House of Representatives regarding the Annual Report on Policy Coherence for Development, the Minister for Foreign Affairs stated that the Netherlands was taking the position in the EU against TRIPS-plus demands and public health-restricting provisions in EU trade agreements with LMICs.⁷ He requested clarification of the TRIPS-plus provisions in EU proposals for agreements with Philippines and Indonesia, and monitored negotiations with Mexico and the Southern Common Market (MERCOSUR) in this regard. The letter also stated that the Netherlands made its position clear regarding TRIPS-plus measures at the 2017 World Health Assembly.

On 22 November, 2017, Minister Bruins informed the Dutch Parliament that he plans to "extensively explore" the use of compulsory licensing of medicines patents that are too expensive and to probe if he can authorise pharmacists to prepare medicines at lower cost for individual patients.⁸ These statements are consistent with the recommendations of the Netherlands Council for Public Health and Society (RVS) report published earlier that month.⁹

In June, 2018, the Netherlands did not take the opportunity to align themselves with the six EU Member States calling for a quicker application of the waiver from supplementary protection certificates (SPCs). By contrast, Minister Bruins stated that the Netherlands was in favour of encouraging competition, but had "not reached a position on the proposal".¹⁰ It is important to note that the positive effect of the waiver on medicines prices in the EU will be limited because the waiver is for production for export to countries where patents are expired or non-existent. Representatives of the Dutch government hold different views about the SPC waiver. On one hand, it is seen as tangential to the core question of how widely SPCs should be permitted (i.e., to cover 100–200 protectable elements).* On the other hand, the SPC waiver is seen as a positive development that would level the playing field for generic products in Europe.* Moreover, issuing the waiver would be straight-forward in the Dutch political context where neither side is really vocal on this issue.*

Intellectual Property and TRIPS Flexibilities (continued)

The Ministry of Health, Welfare and Sport, together with the Ministry of Economic Affairs and Climate, commissioned a report, entitled, *Effects of Supplementary Protection Mechanisms for Pharmaceutical Products*, which was published in May, 2018, by Technopolis. This report studies the effectiveness, uncertainties, and unintended/undesired effects of SPCs, paediatric extensions, orphan regulation, and data and market exclusivity mechanisms. It found that these supplementary protection mechanisms provide companies with adequate compensation, but that the effect on innovation is limited, referring to the continued unmet need for new paediatric and rare disease treatments. The study concludes: "... whilst overall the supplementary protections mechanisms function to a significant extent in the ways for which they were designed, there is ample space for improvement." Improvement would require a combination of actions to: 1) improve their effectiveness, 2) resolve remaining uncertainties, and 3) reduce or eliminate unintended and undesired effects.¹¹

A representative of the Dutch government confirms that this conclusion is not being followed up, in particular, as further studies of the impact on our health system, among other concerns, is needed.* At the European level, multiple Member States are discussing the conclusions of the report.* The Dutch government foresees a re-think of the incentives for paediatric and orphan medicines in an EU context.*

In June, 2018, Minister Bruins committed to working with the Minister of Economic Affairs and Climate, Eric Wiebes, to establish a Commission to explore the legal and economic aspects of using compulsory licences in the Netherlands (i.e., criteria, consequences, proportionality, alternatives), as advised by the RVS report.¹² The Commission is expected to begin work after Summer, 2018.

In 2018, Minister Bruins expressed his support for the production of expensive, exclusive medicines by pharmacies to work around the high price asked by a patent holder manufacturer in a monopoly situation.¹³ Together with the Dutch Healthcare and Youth Inspectorate, the National Health Care Institute, and the Dutch Healthcare Authority, the Minister pledged to examine any obstacles to the entitlement to, funding of, or provision of pharmacy preparations in cases permitted by the Medicines Act. In June, 2018, Ministers Bruins and Wiebes clarified that, according to the Dutch Pharmacy Law, pharmacy preparations do not constitute patent infringement. The relevant Regulation clarifying this instance will enter into force in the Autumn.¹⁴

Alternative Innovation Models

The Zorginstituut Nederland was one of the nine EU Member State government bodies that participated in the European Medicines Agency's (EMA) adaptive pathways pilot programme, which ended in August, 2016.¹⁵ The Dutch National Institute for Public Health and the Environment reported in October, 2016, that they investigated the adaptive pathways concept developed by the EMA, finding it would have added value for the Netherlands.¹⁶

In 2016, the Ministry of Health, Welfare and Sport awarded €2.8 million to Fair Medicine to develop alternative business plans for the pharmaceutical industry.¹⁷ This subsidy represents a 60 percent contribution towards Fair Medicine's five-year plan, which must be co-financed through fundraising. Fair Medicine forms coalitions to develop new, affordable medicines by assembling financial and knowledge investments from all actors who "agree to a fair price and acceptable profits in advance."¹⁸ According to a representative of the Dutch government, Fair Medicine and the Oncode Institute are 'proof of concept' initiatives.* The ultimate goal is to achieve delinkage of costs of medicines development from the price of the product.* Therefore, initiatives, such as Fair Medicine, are part of the long-term vision for sustaining affordable prices.*

In 2017, Fair Medicine reported its first coalition agreement to develop the small molecule product to treat a rare kidney disease.¹⁹ Fair Medicine projects are supported by a group of interested parties, including patient organisations and physicians. In 2018, Fair Medicine plans to hire a project leader to explore a new business model for the development of existing products for other indications (i.e., repurposing).²⁰ It also plans to work on improving the quality of patents.²¹

A report from the RVS, entitled, *Development of New Medicines: Better, Faster, Cheaper*, was published in November, 2017.²² The report outlines a number of actions the Dutch government can take to immediately address high drug pricing, including the use of compulsory licensing to strengthen the government's position in price negotiations. It also includes alternative model scenarios from a previous report by the Belgian Health Care Knowledge Centre and Dutch National Health Care Institute.²³ There is no consensus about the report's recommendations within the Dutch government.*

The Oncode Institute for R&D of novel cancer diagnostics, medicines and innovative treatments was launched in 2018, supported by the Ministries of Economic Affairs, Health, Welfare and Sport, and Education, Culture, and Science and other partners (totalling €119 million over five years).²⁴ Oncode seeks to improve affordability through 'rationalised selection of patients in clinical trials' during the early stage of R&D, and by funding research to re-purpose abandoned and patent-expired medicines (i.e., by partnering with generic manufacturers to develop innovative but "de-risked" medicines with low margins).

The Netherlands Federation of University Medical Centers' Commission has not taken much action on socially responsible licensing, apart from fostering a shared understanding of its potential benefits for patients.*

Competition Policy

ACM increased its capacity to investigate anti-competitive behaviour in the pharmaceutical sector.²⁵ In June, 2018, ACM announced it would investigate the sector for TNF-alpha-blocker drugs used for the treatment of rheumatoid arthritis.²⁶

In September, 2018, the ACM received a request from the Pharmaceutical Accountability Foundation (Stichting Farmater Verantwoording), a Dutch citizens' initiative, to look into the price hike for the medicine chenodeoxycholic acid (CDCA) by the company Leadiant Biosciences Ltd (formerly Sigma-Tau).²⁷ To date, it is not known if the ACM will commence an investigation based on this request.

Pricing Policy

In 2016, ACM published a guideline for cooperation in the procurement of medicines by Dutch insurance companies and hospitals.²⁸ This clarifies the legal position of purchasers in relation to national competition law.

The Belgian and Dutch governments initiated the Drug Pricing Scenarios Project and, in a 2016 report, *Future Scenarios About Drug Development and Drug Pricing*, listed the first 'building block' for alternative drug development and pricing mechanisms to be increasing of transparency in this context,²⁹ clarifying that transparency not only from developers, but also from payers, was necessary.³⁰ The report concluded by stating that increased transparency was an essential ingredient "of all futures imagined in this project".³¹

An analysis of the clusters for the medicines reimbursement system (GVS) was commissioned by the Ministry of Health, Welfare and Sport and conducted by APE Public Economics in May, 2016.³²

The Expensive Medicines Procurement Platform ('Platform Inkoopkracht Dure Geneesmiddelen') was established in 2016 by Minister Schippers to exchange expertise and information on the procurement of medicines. Its first meeting was held on 7 January, 2018.³³

Under the leadership of the Dutch government, the World Health Organization (WHO) Fair Pricing Forum brought key stakeholders together in Amsterdam on 11 May, 2017, to discuss options for fairer medicines pricing. Key issues debated were alternative business models for medicines R&D, the joint procurement of medicines, and increased information sharing and transparency in relation to R&D costs, prices, and profit margins.³⁴ A follow-up meeting is planned to take place in South Africa.

The third roundtable meeting of European Health Ministers, CEOs and Heads of Europe-based Pharmaceutical Companies took place in September, 2017.³⁵ The aim of the meeting was to agree on an aligned strategy for balanced healthcare costs and attractiveness for the industry to innovate and supply medicines.

The Horizon Scanning Initiative was launched in 2017 by the Dutch, Belgian and Luxembourgish health ministries aimed at "identifying, filtering, and prioritising new and emerging health technologies with a considerable predicted impact on health, costs, society, and the health care system" in order to, among other things, facilitate early access by enabling the controlled diffusion of technologies.³⁶

Pricing Policy (continued)

Multiple initiatives for collaborative medicines procurement within the Netherlands have been established (i.e., health insurer Achmea's 'Impact Collectieve Farmacie',³⁷ the joint procurement announcement of the eight university medical centres,³⁸ and a one-year deal reached by health insurers and about 70 hospitals with Novartis on immunosuppressants).³⁹

In 2017, a Medications Commission ('Geneesmiddelencommissie') existed at 97 percent of healthcare facilities.⁴⁰ These commissions are most often responsible for determining the position of new and existing medicines on internal formularies (often used to procure medicines), and the appropriate use of resources.

The Netherlands participates in the Euripid project, a voluntary non-profit collaboration of the European pricing and reimbursement authorities for the mutual sharing of price information of medicinal products.⁴¹

The Expensive Medicines Monitor ('monitor dure geneesmiddelen') is published twice a year by the Nederland Zorgautoriteit.⁴² The last edition retrievable online is from December, 2017.⁴³ These editions provide data on the type, number, and total costs by medicine, by patient, and by financing and purchasing agreement. It also describes patient access. In June 2016, the Monitor reported that that €13.9 million in savings were achieved in 2014 by negotiating prices with manufacturers for eight medicines, and that 16 deals were reached in 2015 (about which more information on savings would follow).⁴⁴ Information about the pharmacy purchase price is publicly available at www.medicijnkosten.nl.

The Preferential Policy ('preferentiebeleid') was continued. The policy permits health insurers to choose to reimburse only one medicine (listed in the GVS) when multiple versions are on the market. Preferential policy is, in general, only relevant for off-patent medicines and stimulates price competition.⁴⁵

Minister Bruins announced in 2018 that Germany will be replaced by Norway as a reference country in the WPG. Prices in reference countries are used to inform medicines prices in the Netherlands.^{46 47}

The Drug Price Negotiation Unit was legally implemented in the 'Besluit zorgverzekering' in April, 2018.⁴⁸ Since July, 2018, new medicines used in hospitals that cost more than €50,000 per treatment per year, or totalling over €40 million per year, are not automatically reimbursed by the basic reimbursement package ('Basispakket') and instead enter the 'sluis'.⁴⁹ This move allows the government to negotiate the reimbursement price without a time limit.^{50 51}

Ireland joined the Beneluxa Cooperation in June, 2018, as its fifth member.⁵² The Netherlands and Belgium successfully negotiated a price of the drug Spinraza in July, 2018.^{53 54} The Dutch government stated that the negotiations took place through a joint HTA, followed by a joint negotiation with the manufacturer, during which the two countries shared data and policies.⁵⁵

Minister Bruins spoke to the Association for Innovative Medicines on 6 September, 2018, where he said: "Als de geneesmiddelensector verantwoordelijkheid neemt, ben ik bereid mijn deel te nemen."⁵⁶ (In English, "If the medicines sector takes responsibility, then I am prepared to take mine.")

Reflections on Policy Actions

The Dutch government takes a three-pronged approach to balance the areas of 1) medicines regulation and IP incentives; 2) value determination and HTA; 3) market behaviour and competition.* From the perspective of one key informant, the government should take a holistic approach to 1) adopt coherent laws, 2) negotiate better prices; and 3) guide market behaviour.* Below, the authors consider to what extent the policy actions build political consensus, enhance transparency, and facilitate the implementation of these actions in each domain for access to innovative medicines.

Intellectual Property and TRIPS Flexibilities

Consensus Building The 2016 EU Council Conclusions adopted during the Dutch Presidency of the Council of the EU questioned the suitability of IP incentives, instructed the European Commission to undergo an analysis of these incentives, and criticised the relevant EU legal measures. The significance of this adoption lies also in the fact that the final conclusions must be passed in accordance with the required voting threshold, traditionally done through unanimity. The Conclusions were followed up in the Maltese Presidency (January–June, 2017). In the Dutch government's view, the 2016 EU Council Conclusions advanced a debate that is renewed at each subsequent meeting of the Council of Ministers.*

Now, EU Member States that were not previously engaging with the issue of medicines prices, nor working together to address these challenges, are now doing so.* Therefore the issue of pharmaceutical development and pricing persists on the political agenda and has catalysed some intermediate results, such as building political understanding and cross-national cooperation.

Moreover, the Dutch government has proactively advocated the safeguarding of TRIPS flexibilities between the EU and third countries.

However, it is not clear how strong the current Dutch position on these issues is at the EU level despite statements by the Dutch government to explore the use of compulsory licensing in the Netherlands (consistent with 2016 RVS report). At the national level, Minister for Medical Care, Bruno Bruins, committed to the Dutch Parliament to “extensively explore” the use of compulsory licensing of patents on expensive medicines.

From the policy documents, it is unclear to what degree the positions of the various Dutch Ministries are aligned on IP and TRIPS flexibilities. The Dutch government indicates that better medicines prices, leading to lower pharmaceutical expenditure, will be welcomed by all ministries.*

Intellectual Property and TRIPS Flexibilities (continued)

Transparency

The 2018 Technopolis report, commissioned by the Dutch government, provides an important analysis of the effectiveness of the supplementary protection mechanisms. The report is publicly available. However, there is less transparency about how the Dutch government will act upon the report's conclusions.

It is unclear how the Dutch government applies its public commitments to safeguard TRIPS flexibilities in EU trade negotiations with third countries. There is less transparency about the Dutch government's IP enforcement policy objectives, which share equal footing with TRIPS flexibilities, according to a representative of the Dutch government.* The Dutch government confirms that ensuring IP is respected and enforced in trade agreements is a main policy priority despite not being affirmed publicly as a commitment.*

The Dutch government's approach to IP in international policy making (e.g., at the WHO) and in international trade seems to lack coherence.

Implementation

From the perspective of the Dutch government, there is neither a formal implementation plan for the 2016 Council Conclusions, nor a mid-level coordination mechanism to advance work in this area at the EU level.* Adding to the complexity of implementation is fragmentation between the areas of market authorisation, HTA, and market/competition issues.* A regular meeting of national pharmaceutical directors at the EU level has been initiated and can assist in co-ordinating national action.*

The Dutch government's commitments to "extensively explore" compulsory licensing in the national context have not (yet) been implemented in any tangible way. Representatives of the Dutch government explain that compulsory licensing is a mechanism that has never been applied in the Netherlands, and carries important implications that mean it should be a measure of last resort.*

This is a question that Bruno Bruins and Eric Wiebes will investigate with the advice of a commission to experts.*

In order to skillfully use compulsory licensing, it requires a 'proof of concept' study, which is not currently planned.* Points of consideration for applying a compulsory licence in the domestic context have previously been raised.⁵⁷

Alternative Innovation Models

Consensus Building In the development of the 2016 EU Council Conclusions, the Dutch Presidency championed a new narrative about the need for pharmaceutical effectiveness models among EU Member States. The Netherlands has also participated in the EMA's early projects on adaptive pathways thereby contributing to consensus about this 'early access' model, about which several concerns have been raised.⁵⁸

The Dutch government also reports that the Netherlands Federation of University Medical Centres' (NFU) Commission on Socially Responsible Licensing has a shared understanding about the benefits to patients of linking the public investment to university research and affordability of products.*

The Dutch government's engagement with the pharmaceutical industry aims to develop a mutual understanding in the short term of the causes of excessively high medicines prices. Future solutions can be built on this understanding.*

Transparency The Minister indicated that the NFU will establish a coalition of stakeholders to develop principles for, and exchange experience about, socially responsible licensing.⁵⁹ However, no information about this initiative was retrievable online. The Dutch government indicates that there has been limited action in this area.*

Implementation The Dutch government has invested millions of euros in two initiatives aiming to catalyse new models of innovation, namely Fair Medicine and the Oncode Institute. Both projects promote, in part, the repurposing of medicines. As both projects are new, it is not yet possible to judge whether their strategic plans will deliver innovative and affordable medicines. At the European level, the Dutch government participated in an adaptive pathways pilot study, which is currently stalled.*

The Dutch government has invested millions of euros in two initiatives aiming to catalyse new models of innovation, namely Fair Medicine and the Oncode Institute.

Competition Policy

Consensus Building In line with the 2017 report by the RVS, the Dutch government's policy actions promote the role of ACM in addressing anti-competitive behaviour in the pharmaceutical sector and promoting collaborative procurement by purchasers (i.e., through guidelines aligned with competition law).

Transparency The ACM's online mission statement gives priority to prescription drug prices; its website lists the actions ACM is pursuing in the pharmaceutical sector.⁶⁰

Implementation This criteria is difficult to judge based on publicly available information about competition policy. For example, the ACM expenditures increased from 2015 to 2016, yet it is unclear if increased funding went to monitoring and acting in the pharmaceutical sector.⁶¹ From the perspective of pharmaceutical reimbursement, the 'preferential policy' aims to create a competitive market for generics, thereby enhancing the coherence of national competition and reimbursement policies.

Pricing Policy

Consensus Building Former Minister of Health, Edith Schippers, has been very outspoken in putting the issue of high drug prices on the national and European agendas. Significant political interest turned to the lack of price transparency and need for alternative innovation models (i.e., at meetings of the EU Ministers and the WHO Fair Pricing Forum). Her successor, Minister Bruno Bruins, continues the existing initiatives; however, the focus of the national policy agenda has transitioned to more decentralised initiatives, such as exploring pharmacy preparations and amendments to the reimbursement system. For example, the forthcoming second Fair Pricing Forum serves to achieve a broad understanding about the current challenges to the affordability of medicines around the world.*

The optimal outcome would be to raise awareness for this challenge that needs to be fixed in other health systems.* In addition, Minister Bruins has met with, and called for, the pharmaceutical industry to be more transparent about drug prices.^{62 63}

Pricing Policy (continued)

Transparency

Despite commitments from the Dutch government to “always strive to achieve a public price reduction or discount”, full transparency (i.e., publicly accessible information about medicines price-building and purchase prices) remains elusive. For example, the Expensive Medicines Monitor offers data about spending on medicines procurement. However, it offers no additional transparency about agreements—which medicines at what price—or on the costs of drug development. The Dutch government views transparency as a means to an end, which is to purchase the right medicines at the right price.*

Important questions remain, such as: How will the price information will be used?*

Greater transparency in pharmaceutical pricing helps to hold manufacturers accountable to the prices they are asking and, where necessary, to stimulate public and political inquiry into excessively high prices.* Within the Dutch government, both coordinated and uncoordinated approaches are taken to medicines price transparency.*

At the European level, the Beneluxai Cooperation shows continued commitment from the Dutch and other governments to engage in joint HTA and price negotiations. Yet, a joint negotiation that leads to a secret price agreement (i.e., in the case of Spinraza) is a short-term win without the long-term gains for greater transparency of R&D costs and prices.⁶⁴

The joint negotiations for the reimbursement of Orkambi demonstrated that the Dutch government has little power to force pharmaceutical companies to be more transparent in their price building and profitability. At the same time, these negotiations reinforced that national governments should not, and will not, pay an exorbitant price for a medicine.

Implementation

Under the leadership of Edith Schippers, multiple initiatives were launched to implement new pricing policies, such as the Expensive Medicines Procurement Platform, and the Drug Price Negotiation Unit (‘lock’ or ‘sluis’). The medicines ‘lock’ was created to find solutions to high-priced specialty medicines, meaning that the refusal to pay a high price does not indefinitely lead to rationing or non-availability of treatments that are important for patients. Recently the ACM has clarified uncertainties by publishing the rules for hospitals and insurers to collectively procure medicines.

At the European level, the Dutch government will participate in the Beneluxai joint horizon scanning initiative starting in 2019 to forecast upcoming innovations in industry’s pipeline.*

The core questions will be: Are these medicines really innovative? What is a reasonable price for them?*

CONCLUSIONS & RECOMMENDATIONS

Since 2016, the Dutch government has made numerous commitments for the development and marketing of new, affordable medicines. These commitments range from pharmaceutical pricing policies and mechanisms for IP management and TRIPS flexibilities (most commitments), to alternative models of innovation and domestic competition policy (least commitments). These commitments have been actioned to varying degrees.

Among the most notable are the Dutch government's initiatives to:

- Take steps to cultivate a shared understanding among pharmaceutical policy stakeholders at the EU and national levels. The Dutch government has also successfully advanced European cross-national dialogue and cooperation on the affordability of medicines.
- Raise awareness of its many policy commitments and actions in this field. Nevertheless, the significant transparency of R&D costs and public medicines prices—a key policy commitment—has not yet been achieved.
- Introduce several pilot programmes and pricing policies to implement and incentivise the development and marketing of affordable medicines; however, implementation plans are still lacking in certain areas (i.e., socially responsible licensing, compulsory licensing, protection of TRIPS flexibilities in trade relations with third countries).

These conclusions yield the following recommendations:

In the Netherlands

- Complement the recent decentralised pharmaceutical pricing policies with systemic interventions that also leverage IP and competition policy options to lead to more affordable medicines.

- Build greater coherence between the Dutch government's health and economic policies where health considerations take primacy over trade and IP concerns, in line with international law.
- This greater coherence is required for the Dutch government to play a leadership role in safeguarding TRIPS flexibilities in the EU's trade relations with third countries.
- Generate or leverage expertise for applying other new innovation models and kick-start national commissions exploring the use of socially responsible licensing and compulsory licensing in the domestic context.
- Finance and launch incentives for 'proof of concept' and pilot projects on new models of pharmaceutical innovation and IP management (i.e., delinkage, socially responsible licensing and compulsory licensing).
- Conduct and publish a robust evaluation of the R&D costs and affordability of products resulting from the Fair Medicine and OncoCode Institute initiatives over the long term. Develop a plan to apply the lessons learned from these initiatives to systemic changes in Dutch pharmaceutical policy.
- Defend the public interest by continuing to investigate potential cases of anti-competitive behaviour in the pharmaceutical market and widely publicise the outcomes.
- Develop an implementation plan to realise full transparency of R&D costs, price structures, and (public) prices. This plan should outline how this information will be used by the government in pursuit of more affordable medicines.

At the EU level

- Continue spearheading the debate on the affordability of medicines in national, European, and international fora. One area of focus is the proposed EC Regulation on HTA.
- Support the recalibration of incentives to bring affordable new medicines to the market through the anticipated revision of the EU Pharmaceutical, EU Paediatric, and Orphan Drug Regulations, and follow up the conclusions of the Technopolis report through a critical review of the SPC Regulation. The Dutch government should mobilise other EU Member States to elaborate comprehensive and coherent IP reforms in these Regulations to promote public health interests.
- Call for mechanisms to coordinate the implementation of the 2016 Council Conclusions among EU Member States and follow up the request for the Directorate-General for Competition to produce a report on recent competition cases or potential cases of market abuse, excessive pricing, and other market restrictions impacting negatively on consumers (article 48).
- Continue to participate in joint horizon scanning, particularly in the fields of (price) information sharing, joint price negotiations, and approaches to unavailable medicines, through EU initiatives, such as Beneluxai Cooperation, EUnetHTA, EUripid, and others.

ANNEX 1

Detailed Methodology for Document Review

Defining a Government Commitment

Commitments are written or oral statements made by government institutions (i.e., ministries, agencies) or government representatives in their official capacity (i.e., kamerbrieven) concerning the Netherlands' domestic pharmaceutical policy and, specifically, the price and affordability of medicines. Statements made by an individual in a private capacity are not considered commitments (i.e., personal statement by the former President of the Dutch Authority for Consumers and Markets).

Statements made in national and international (i.e., EU, UN/WHO) policy fora may be considered commitments.

Considering the structure and functions within the Dutch government, commitments towards medicines pricing and affordability on the national market may be made by:

- Ministry of Public Health, Welfare and Sport / Volksgezondheid, Welzijn en Sport.
- Ministry of Economic Affairs and Climate Policy / Economische Zaken en Klimaat.
- Dutch Authority for Consumers and Markets / Autoriteit Consument en Markt.

Other statements of interest may come from the Raad voor Volksgezondheid en Samenleving (an independent advisory body to the government), and relevant meetings in the Dutch Parliament (i.e., 2017 hearing on the pharmaceutical industry).

International policy fora in which the Dutch government may make commitments in statements and presentations given at :

- World Health Assembly and Executive Board meetings.
- UN High Level Panel on Access to Medicines.

- Council of the EU, including the Council Conclusions adopted during the Dutch Presidency (January to June, 2016).
- European Commission Expert Group on Safe and Timely Access to Medicines for Patients.
- Related events in the European Parliament.
- The Fair Pricing Forum (co-hosted by the Dutch government and WHO).
- Beneluxai group and Valletta group.

Document collection

The document search was executed in August, 2018, in both English and Dutch. The search included:

1. A systematic search of government and multilateral institutions websites (see list below).

If a search engine was available on these websites, then the search terms specified below were used. If no search engine was available then a manual search was conducted of relevant documents.

The websites and search terms included:

- Dutch government www.rijksoverheid.nl/documenten (search terms: Geneesmiddelen and Geneesmiddelen Kamerbrief; 'Medicines Documents' on the English-language website.
- Dutch Council for Public Health and Society <https://www.raadrvs.nl> (search terms: Geneesmiddelen).
- Dutch Parliament.
- Dutch Authority for Consumers and Markets <https://www.acm.nl/en> (search terms: geneesmiddelen).
- World Health Organization iris, searched for: WHO recommendations on transparency and access to medicines; statements by the Netherlands.

World Health Assembly and Executive Board:

- Documentation for WHAs 69–70 and EB meetings 138–143.⁶⁵
- Official records for WHAs 69–70 and EB meetings 138–143.⁶⁶
- Resolutions, decisions and annexes from EB: EBSS4/2017/REC/1*; EB141/2017/REC/1; EB140/2017/REC/1; EB139/2016/REC/1; EB138/2016/REC/1; and WHA: WHA70/2017/REC/1; WHA69/2016/REC/1.
- Summary and verbatim records from EB: EB140/2017/REC/2; EB138/2016/REC/2; provi-sional summary records EB 142⁶⁷; WHA: WHA70/2017/REC/3; WHA69/2016/REC/3.
- UN High Level Panel on Access to Medicines, including the Submission by the Netherlands Ministry of Foreign Affairs⁶⁸ and the Report of the United Nation's Secretary-General's High-Level Panel on Access to Medicines.⁶⁹

Council of the European Union

- Council document register,⁷⁰ meeting minutes,⁷¹ and general search tool⁷²: 'medicine pricing'; 'medicines'; 'medicine'; 'drugs'; 'drug'; 'pharmaceutical'; 'pharmaceuticals'.
- Drafts of Council Conclusions and final versions adopted during the Dutch Presidency (January–June, 2016).
- European Commission Expert Group on Safe and Timely Access to Medicines for Patients,⁷³ meetings 4–9.
- European Parliament,⁷⁴ specifically the EP Workshop on EU Options for Improving Access to Medicines⁷⁵.

The Fair Pricing Forum:

- Speech by State Secretary Martin van Rijn at the 'Fair Pricing Forum' in Amsterdam.⁷⁶
- Report on the Fair Pricing Forum 2017.⁷⁷
- Informal advisory group meeting, WHO Geneva, 22–24 November 2016.⁷⁸
- 'Medicines Documents' of the website of the Government of the Netherlands.⁷⁹

2) A systematic search of academic literature in various databases, including:

PubMed using the search string:

- ((((((((((Transparen* OR pric* OR afford* OR "access to medicine*" OR "intellectual property" OR patent OR OR "government use" OR "compulsory licens*" OR "parallel import*" OR competition OR anti-competitive OR de-link* OR delink* OR "prize fund" OR "open innovat*" OR "reference pric*" OR negotiat* OR procurement OR "pric* control"))))))) AND ((pharmaceutical* OR medicine* OR drug*)) AND ("2016/01/01"[PDat] : "2018/12/31"[PDat]))) AND ("2016/01/01"[PDat] : "2018/12/31"[PDat]))) AND ("2016/01/01"[PDat] : "2018/12/31"[PDat]))) AND ((Netherland* or Dutch)) Filters: Publication date from 2016/01/01 to 2018/12/31.

Google, PubMed, and LexisNexis, using the search string:

- "Netherlands" AND "pharmaceuticals" AND "transparency"; "Dutch" AND "pharmaceuticals" AND "transparency"; "Netherlands" AND "medicines" AND "transparency"; "Dutch" AND "medicines" AND "transparency"; Netherlands "trips+" provisions; "Netherlands" "trips+" trade agreements; "Netherlands" AND "Trade-Related Aspects of Intellectual Property Rights"; Netherlands "pharmaceuticals" AND "abuse"; "Netherlands" Truvada; "Netherlands" AND "SPC".

3) A systematic search of the Dutch Medical Journal (*Nederlands Tijdschrift voor Geneeskunde*) news section using the search term: geneesmiddelen.

4) A systematic search of grey literature on the IP Health and EU Alliance listservs for any document that constitutes a government commitment or action related to medicines pricing and affordability in the Netherlands.

We also 'crowdsourced' documents from non-governmental organisations actively advocating for lower medicines prices in the Netherlands.

Inclusion criteria for documents

Documents were included in our study if they met these inclusion criteria:

- Document expresses a government commitment to domestic policy measure or an action specifically related to the pricing and/or affordability of medicines in the Netherlands.

- Publication date after 1 January, 2016.
- Full text of the document was available.
- No newer version of the document was available.

Material that did not include specific commitments or actions were attributable to the Dutch government were excluded.

ANNEX 2

List of Source Documents

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ANNEX 3

Semi-structured Interview Guide

Key Informant's General Appreciation of the Commitments and Policy Actions

Do you agree the Dutch government has made the following commitments (selected from the draft report depending on the key informant's field of work)?

How have these commitments been implemented?

To what degree has the Dutch government implemented the commitments in the 2016 Council Conclusions? What are the key achievements? Which policy areas have key bottlenecks to achieving more affordable, new medicines?

Have the measures introduced since 2016 by the Dutch government to bring down excessively high medicines prices been successful? Based on what evidence?

Has the Dutch government's recent policies (since 2016) improved transparency of a) pricing b) cost of R&D, which is required for more affordable medicines?

Have the Dutch government's recent policies (since 2016) improved consensus about how to address excessive medicines prices i) both between EU member states, and ii) within the ministries of the Dutch government?

Questions in Relation to Specific Uncertainties Revealed in the Document Review

How have EU member states reacted to the Netherlands' position against TRIPS-plus measures in EU trade agreements with developing nations?

How does Minister Bruins plan to "extensively explore" the use of compulsory licences for high-priced medicines (in the Netherlands) (stated on November 22, 2017)?

Within the Dutch government, how aligned are the various ministries (foreign affairs, economic affairs) with Minister Bruins' position?

What is the mandate and action to date of the NFU's Commission on Socially Responsible Licensing? What does the government expect the outcome will be?

Does the government plan to take action on the results of the Technopolis report, specifically the conclusion that various protection mechanisms award the companies generously but that there is no evidence of their effect on innovation?

What action has Minister Bruins taken/plan to take to examine the funding and provision of pharmacy preparations?

What outcomes need to be achieved for Fair Medicine and OncoCode Institute to have been successful at delivering more affordable new medicines? If those are successful what are the plans for scaling up?

What is the Dutch government's long-term vision for sustaining affordable prices for new medicines? How will this vision be achieved (i.e., multiple coalition agreements a la Fair Medicine, other approaches)?

Is the ACM currently investigating other medicines? What is the impact of the ACM's guideline on cooperation for the procurement of medicines by Dutch insurers and hospitals?

Transparency of R&D costs has been called an essential starting point for policies aiming to deliver affordable medicines. This is affirmed in numerous documents. What action has the Dutch government planned?

One of Minister Bruin's commitments is to discuss the issue of high medicines prices and sustainability with the pharmaceutical industry. What does Minister Bruins want to achieve with these discussions?

What are the objectives of the second Fair Pricing Forum in South Africa? Which key issues are on the agenda and how will the Netherlands follow-up on the outcome?

What is the Dutch government's role in the various EU Collaborations (i.e., EUripid project, Benaluxai Cooperation, adaptive pathways)?

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