



BENELUXA:

*First results of
multi-country
cooperation on
medicine price
negotiations*

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BENELUXA: FIRST RESULTS OF MULTI-COUNTRY COOPERATION ON MEDICINE PRICE NEGOTIATIONS

Executive summary

In 2015, the Dutch and Belgian Ministers of Health signed a historic declaration of intent to jointly negotiate with the pharmaceutical sector on the price and reimbursement of some medicines. Since then, the cooperation has been joined by Luxembourg and Austria, with several more governments expressing an interest. This intergovernmental cooperation on medicines is unprecedented in Europe. Until now, each national government negotiated with pharmaceutical companies on a bilateral basis.

The European Public Health Alliance (EPHA) has followed this development with great interest. The information asymmetry between the pharmaceutical industry as the vendor and national governments as buyers is assumed to have contributed to the rise in medicine prices to today's unsustainable levels. As a consequence, access to medicines is no longer only an issue for developing countries. High prices are now also a barrier to accessing medicines for patients and health systems in some of the richest countries in the world. Could the new cooperations between national governments - not only "Beneluxa" but also the Valletta Declaration and other country groupings - go some way to redressing the balance? This paper tells the story so far of this innovative cooperation and summarises the first results announced by the participating governments. ■

Sovaldi, the wake-up call

The brief history of this voluntary intergovernmental cooperation speaks volumes about the current state of play and how far the debate on access to medicines in

Europe has evolved over the past three years. Beneluxa was born after first discussions took place between Health Ministers Edith Schippers (Netherlands) and Maggie De Block (Belgium) in December 2014. That was almost a year after



the launch, by American manufacturer Gilead, of Sovaldi, a highly effective new treatment against Hepatitis C. Sovaldi's price tag made headlines around the world and put the issue of high medicine prices on the agenda of journalists and politicians in Europe. Ministers of health realised that Sovaldi was only the tip of the iceberg, and that many more products across therapeutic areas with equally high or even higher price tags than Sovaldi were on their way. A few months later, in April 2015 the two Ministers [signed](#)¹ a declaration of intent to jointly negotiate with the pharmaceutical sector on pricing and reimbursement, starting with "orphan" drugs i.e. treatments for rare diseases.

ORPHAN DRUGS: a pharmaceutical product that has been developed specifically to treat a rare medical condition. Manufacturers often receive incentives - such as patent protections and regulatory flexibilities and advantages - to encourage development of drugs for rare diseases.

Source: <http://www.eurordis.org/sites/default/files/>

The fact that orphan medicinal products were identified as a priority area is no coincidence. The [groundbreaking](#)² June 2016 EU Health Ministers' [Council Conclusions](#)³ reflect a suspicion among governments that financial and other incentives [put in place](#)⁴ by EU legislators in the early 2000s, are increasingly being abused by the pharmaceutical industry. These incentives mainly take the form of longer patent protection and lower evidentiary

requirements, meaning easier marketing authorization and faster time-to-market, to encourage research and development of new treatments for rare diseases.

THE COUNCIL CONCLUSIONS ON STRENGTHENING THE BALANCE IN THE PHARMACEUTICAL SYSTEMS IN THE EU AND ITS MEMBER STATES agreed in June 2016, among other initiatives, mandated the European Commission to conduct an evidence-based analysis of the impact of the IP incentives on innovation, availability, accessibility and affordability of new medicines and set out a road-map for the collaboration among EU countries who wish to jointly tackle the issue of expensive medicines.

Source: <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

These products have grabbed Ministers' attention as an increasing number of "orphan" drugs have become blockbuster products with disproportionately high volumes of sales, although they are supposed to be for rare diseases, and attract the highest prices on the market. Additionally, the pharmaceutical industry continues to lobby hard for further incentives and watering down of requirements in the name of accelerating access. Today, [almost half](#)⁵ of all new medicines approved by the U.S. Food and Drug Administration (FDA) or the [European Medicines Agency \(EMA\)](#)⁶ are presented as orphans. In other words, what was supposed to be the exception, and therefore requiring incentivisation, is becoming the unintended rule. The so-called "orphanisation"

1. <http://www.deblock.belgium.be/fr/remboursement-des-m%C3%A9dicaments-orphelins-les-pays-bas-et-la-belgique-n%C3%A9gociation-ensemble-avec-le>

2. <https://www.ip-watch.org/2016/07/05/the-dutch-pharma-policy-a-groundbreaking-presidency/>

3. <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

4. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:018:0001:0005:en:PDF>

5. <https://www.statnews.com/pharmalot/2017/02/10/grassley-orphan-drugs/>

6. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500185766.pdf





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What used to be the exception, and therefore requiring incentivisation, is now becoming the unintended rule.

of the pharmaceutical regulation goes hand in hand with the consolidation of the “niche-buster” pharmaceutical business model. As a result, the market is being flooded with so-called orphan drugs at unhealthily high prices, straining health systems. At the same time, the innovative value of these new medicines may be questionable, due to the very limited evidence required for their approval.

NICHE-BUSTER BUSINESS MODEL:
Drug prescription is combined with genetic testing to identify patients who might benefit from a particular course of treatment, developing the possibility for more personalised forms of treatment. At the heart of the nichebuster model lie lucrative incentives introduced to encourage the production of “orphan” drugs.

Source: <http://www.pharmavoice.com/article/2010-09-nichebusters-vs-blockbusters>

From BE-NE to BENELUXA

The announcement of the partnership between the Netherlands and Belgium was a historic step. It signaled that even the wealthiest EU member states felt they needed to increase their bargaining power in price negotiations with drug manufacturers. The Dutch-Belgian plan foresees [four areas of collaboration](#)⁷:

- a) joint horizon scanning,
- b) joint Health Technology Assessments (HTA),
- c) exchange of strategic information,
- d) joint price negotiations (though not joint procurement).

Luxembourg [joined](#)⁸ in September 2015 followed by the [addition of Austria](#)⁹, another

wealthy EU country not known for facing serious access to medicines challenges, in June 2016. While Beneluxa was evolving other groups of EU member states moved in similar ways; Bulgaria and Romania [signed](#)¹⁰ a cooperation agreement while Southern-Mediterranean member states moved in the same direction.

Why does this matter?

Some initial observations on the “birth” of Beneluxa:

- The proposal was conceived at the highest political level due to the realization that the pharmaceutical companies’ business strategies and pricing practices pose a serious threat to the sustainability and survival of their national health systems. It was not born of pressure from public opinion in these relatively wealthy countries where access to new medicines has not historically been a challenge. That said, it is noteworthy that the rationing of the most expensive treatments has also become reality in the richer countries;
- There is a notable contrast between Beneluxa countries, which at present face relatively minor access to medicines challenges, and other EU countries where fully-fledged access to medicines crises have been around for years.
- It is possible for other countries to join the group;
- The four areas of collaboration are broad and far-reaching;
- Whilst the cooperation prioritises orphan products due to their paralysing prices, the

7. <http://www.beneluxa.org/en/collaboration>

8. <http://www.deblock.belgium.be/fr/grand-duchy-luxemburg-joins-belgium-netherlands-initiative-orphan-drugs>

9. <http://www.chronicle.lu/categoriesluxembourgpolitics/item/17622-austria-joins-benelux-countries-collaboration-to-lower-orphan-drugs-prices>

10. <http://www.nineoclock.ro/romania-and-bulgaria-agreement-on-the-patients-access-to-medicines/>



collaboration is not limited to them.

How did the pharmaceutical industries react?

Drug companies are used to negotiating bilaterally with national governments. This puts them in a favourable position, having a panoramic overview of each of the 28 EU member states' pharmaceutical policies, purchasing power and willingness to pay. In contrast, their customers – the national governments - due to market fragmentation and the shroud of secrecy that covers pharmaceutical decision-making, are prevented from knowing what is happening in their neighbouring countries.

This information asymmetry is favoured by the industry, who are able to game the system and offer each government a “tailored” deal. The arrangement has been enabled by governments through national legislation which guarantees and consolidates this confidentiality through secrecy clauses and non-disclosure agreements. Presumably each government is assured that they are getting a preferential deal. The negotiating leverage a country might have – depending on its purchasing power, market size and GDP - is undercut and gives the seller the upper hand in the negotiations. Whilst this might work to the advantage of a big country with the purchasing power of Germany or France, smaller and poorer countries are most affected by this power imbalance.

News of governments uniting to pursue better deals sent shockwaves through the

pharmaceutical sector. At first, industry voices tried to dismiss the cooperation, claiming that governments would never manage to set aside differences to collaborate on such a sensitive topic. As time progressed, they continued to play down the impact, highlighting the limited scope of the exercise and claiming that it would not change the overall *modus operandi*. Over the past two years, pharma sector representatives have made clear that they prefer to negotiate on a bilateral basis, implying that this sort of multilateral regional cooperation would never take off, and hinting that the best deals are made in the dark.

...and then this happened

On 23 May 2017, what has been happening behind the BENELUXA scenes was revealed. [Belgium](#)¹¹ and the [Netherlands](#)¹² announced that an agreement had not been reached for the cystic fibrosis (CF) drug Orkambi due to the excessive price asked by Vertex, its American manufacturer. Orkambi is indicated for the treatment of a specific form of CF, a rare inherited disease with severe effects on the lungs and the digestive system.

The two governments essentially told Vertex that Orkambi is not cost-effective as their HTA agencies concluded that, while it offers some improvement on the existing standard of care, the additional benefits for some patients do not justify the excessive asking price. The price set by Vertex is seen as unsustainable and unacceptable by both countries.

According to ZIN, the Dutch HTA body, the

11. <http://deblock.belgium.be/fr/n%C3%A9gociations-sur-le-prix-d%E2%80%99un-m%C3%A9dicament-contre-la-mucoviscidose-arr%C3%AAt%C3%A9es>

12. <https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport/nieuws/2017/05/23/prijsonderhandelingen-geneesmiddel-voor-cystische-fibrose-beeindigd>





Throughout the past two years, pharma representatives have made it clear that they prefer to negotiate on a bilateral basis, while implying that this sort of multilateral regional cooperation would never take off, hinting that the best deals are made in the dark.

drug was worth about 82 percent less than Vertex's asking price. Hence, until Vertex makes a fairer offer, the governments have decided not to reimburse the product. The Ministers highlighted their resource constraints and the fact that a decision to reimburse a very expensive drug would require cuts elsewhere in the health system. Even if Orkambi had been deemed to be cost-effective, it would not mean that it would be affordable or inexpensive.

The exact price discussed was not revealed but in a [letter](#)¹³ to the Dutch Parliament, State Secretary for Health, Welfare and Sport Martin van Rijn elaborated on the decision. He added that the budget impact for the 750 Dutch patients (500 in Belgium) would be between EUR84-125 million with an approximate cost per treatment of EUR170.000 per year. The two Ministers invited Vertex to return to the negotiating table with a reasonable offer. Until then, the CF patients in both countries are victims of Vertex's aggressive pricing strategy.

What does this first pilot tell us?

Above all, that the governments have demonstrated their serious commitment and belief in this new way of working. Whilst it has not yet led to an agreement in the case of Orkambi, there is reason for optimism that it will yield better results for patients and health systems in the near future. The ball is now clearly in the court of Vertex, which has been denied market access, with patients left without the drug because of the company's price setting policies.

Payers and governments across Europe are empowered by the solid, public and evidence-

based rejection of Vertex's offer.

The cooperation has already demonstrated some important advantages and key lessons:

- *Flexible*: It is not mandatory for all countries within a regional collaboration such as Beneluxa to move together at all times. In this case, it was only the Netherlands and Belgium which joined forces. Additionally, not all participating countries need to collaborate altogether across all four areas of collaboration (listed above) at all times either;
- *Surmountable obstacles*: Collaboration is possible, responsibility is shared and symbolism is strong when two or more health systems manage to work together and overcome their differences (ranging from language barriers to different working methods and priorities);
- *Groundbreaking*: This first attempt is undoubtedly a learning process for all involved. Over the past two years, there have been several other pilots but only Orkambi made it over the finish line. Negotiations are already underway regarding other products with various manufacturers;
- *Role of HTA reinforced*: The importance of the HTA process is once again highlighted as a gatekeeper for the system and as an enabler of genuine therapeutic advance. The respective agencies of the Netherlands and Belgium reached a common conclusion as to the limited added therapeutic value of the product. The Orkambi decision illustrates HTA's role as a tool to rationalise and not ration pharmaceutical expenditure;
- *Clearer signals, better value, increasing*

13. <https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/kamerstukken/2017/05/23/kamerbrief-over-prijsonderhandelingen-orkambi/kamerbrief-over-prijsonderhandelingen-orkambi.pdf>



access: The primary objective of the Beneluxa collaboration is not lower prices per se, but meaningful and affordable innovation for the benefit of all patients, by tackling the power asymmetry between governments and the industries. Via this new cooperation, governments send clearer signals on their requirements for real added therapeutic value and possibly reshape the market through their joint horizon scanning and HTA work.

Into new territory - a new market called BENELUXA?

Whilst the first foray is promising, it may still be too early to say if this will become the new normal for the negotiation of drug prices with the pharmaceutical industries in Europe. It remains to be seen how vulnerable this intergovernmental collaboration might be to changes in the national political landscape. What is certain however is that the Orkambi case offers a glimpse of what the future could look like. More and more countries are seeking to work together.

VALLETTA DECLARATION: *An agreement between Malta, Cyprus, Greece, Italy, Spain, Portugal and Ireland to enhance cooperation and jointly negotiate with the pharmaceutical industry on drug pricing.*

Source: <https://www.euractiv.com/section/health-consumers/news/southern-eu-states-present-unified-front-in-drug-talks/>

The [Valletta Declaration](#)¹⁴ was signed in May 2017 by a group of six Southern-Mediterranean EU countries keen to follow in the footsteps of Beneluxa.

These cooperation initiatives should not be construed as an attack on the pharmaceutical sector. On the contrary, the industry also has much to gain from streamlining negotiations and economies of scale. Nevertheless, the pharmaceutical sector is certainly cautious towards these initiatives which challenge the status quo. There is a concern that companies might attempt to slow down or “boycott” these initiatives, so as not to set a new precedent. Governments might wish to respond by making the Beneluxa route the only available option for reimbursement of a company’s products or for some clusters of products.

DRUG PRICING SCENARIOS PROJECT: *A project initiated by the Belgian Healthcare Knowledge Centre (KCE) and Zorginstituut Nederland (Dutch Health Care Institute, ZIN) to explore new drug development and pricing models.*

Source: https://kce.fgov.be/sites/default/files/atoms/files/KCE_271_Drug__Pricing_Report_0.pdf

FAIR MEDICINE INITIATIVE: *An initiative from the Fair Medicines Foundation to develop new pharmaceuticals in a transparent manner, and provide everyone with access to safe, affordable and effective medication.*

Source: <http://www.fairmedicine.eu/>

Next steps: A fifth area of joint work?

Governments could consider adding the elaboration of alternative drug development models as a fifth area of cooperation. To this end, countries would pool resources and expertise and learn from initiatives already undertaken such as the [Drug Pricing Scenarios Project](#)¹⁵, the [Fair Medicine Initiative](#)¹⁶ and the

14. <https://www.euractiv.com/section/health-consumers/news/southern-eu-states-present-unified-front-in-drug-talks/>

15. https://kce.fgov.be/sites/default/files/atoms/files/KCE_271_Drug__Pricing_Report_1.pdf

16. <http://www.fairmedicine.eu/>



[Fair Pricing Forum](#)¹⁷.

Such an exercise would explore the feasibility and test the benefits of possible new models of funding for medical research and development (R&D) which are not built on patent-based monopolies and exclusivities.

In the face of today's unjustifiably and unsustainably high prices of medicines, national decision-makers understand they must show a more united front and reinforce

their leverage in the negotiations with the drug manufacturers. To this end, they organize themselves better by joining forces to increase their negotiating and purchasing power. This is exactly what Beneluxa and others such as the Valletta Declaration group of countries seek to achieve: sending new signals to the market and resetting the balance of power. ■



17. www.fairpricingforum2017.nl





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