REPORT

CROSS-COUNTRY COOPERATION SCHEMES:

A fair-weather solution to the issue of access to medicines in Europe?

HAI HEALTH ACTION INTERNATIONAL

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EXECUTIVE SUMMARY

Over the past two decades, rising medicine prices have become an increasingly critical threat to the economic sustainability of health systems across the European Union (EU). To overcome this challenge Member States are seeking solutions outside the EU framework, exploring the possibilities of cross-country cooperation on medicines policy.

These governments are seeking a solution to the overpriced medicines and asymmetries of information in the pharmaceutical markets now typical all over the EU by collaborating with their neighbours on information sharing, health technology assessments (HTA), price negotiations and joint procurement.

In 2015, we saw the launch of the first formal cross-country cooperation scheme between EU Member States, the Beneluxa Initiative, which was welcomed by many as a defining moment in the quest for greater transparency and accountability in pharmaceutical markets. The Valletta Declaration Group (VDG) followed in 2017 and at the time of writing there are several formal and informal collaborations active in the EU. The European institutions have also made some moves towards supporting greater integration and collaboration on medicines policy, most tangibly by funding the European Integrated Price Information Database (EURIPID) scheme. This report aims to compare these different approaches to increased integration, determine their suitability for responding to health crises and assess which, if any, is key to the future of access to medicines in Europe.

In many ways, the Beneluxa Initiative, VDG and EURIPID share a lot in common. All are the products of a need for greater collaboration and transparency across Europe when it comes to medicines, and of a political desire to be shown to be taking action. All have the potential to contribute to a new healthcare world: one where decisions on medicines are made between equal players, with patient interests at the forefront. All, to some extent, focus on sharing information as a key step towards making that world a reality. All have had some success, to varying degrees. Beneluxa has the uneasy title of 'first positive reimbursement decision', VDG has made its mark on transparency on the global stage, and EURIPID is quietly facilitating greater price information sharing.

These cross-country collaboration initiatives are not simple success stories, however. The experience of Beneluxa shows that the coordination processes are complex and lengthy, that for greater collaboration reforms may be needed to make key national structures and agencies more cohesive, and that there is an acute need for greater transparency. The VDG urgently needs to speed up its processes, and push through some of the medicines the group repeatedly says are under scrutiny—it is difficult to assess the strengths and weaknesses of a group that has not yet delivered. Overall, these initiatives are not yet proving to be greater than the sum of their parts, and political will is needed to amplify them from experiments to a fundamental part of how healthcare works in the EU.

We must also acknowledge that in what could have been a seminal year for these groups, we have instead had to contend with a pandemic that has overhauled priorities, resources and political will. The urgency with which the Covid-19 crisis needs to be resolved has, crucially, presented reasons for countries to look beyond their existing alliances to secure vital therapeutics. And at the other end of the spectrum we could argue that the EU's proactive approach to negotiating on behalf of all Member States has made cross-country groups less relevant. This move towards greater EU-sanctioned collaboration looks set to continue and could determine the fact of these groups.

There is no argument that cross-country cooperation will be key to access to medicines going forward: but it remains to be seen whether that collaboration will continue outside the EU framework, or be absorbed as a reaction to the positive test that has been the Covid-19 crisis. Either way, we hope to see transparency protected and championed, and collaborative working, information sharing and joint negotiations heralded as the antidotes to the sky rocketing prices and information asymmetry that mean pharmaceutical companies are still in charge of the fate of Europe's health.

1 | INTRODUCTION

In 2015, we saw the launch of the first formal cross-country cooperation scheme between European Union (EU) Member States—the Beneluxa Initiative—in response to the rising medicine prices which are threatening the economic sustainability of health systems across the EU.

These initiatives differ in structure, number of partners and expected outcomes but share a common purpose: these governments are seeking a solution to the overpriced medicines and asymmetries of information in the pharmaceutical markets now typical all over the EU by collaborating with their neighbours on information sharing, health technology assessments (HTA), price negotiations and joint procurement.

Over the last few years, Beneluxa and its small number of peers have been finding their feet, slowly growing in strength, influence and success: Beneluxa was heralded by many as a defining moment in the quest for greater transparency and accountability in pharmaceutical markets, while the Valletta Declaration Group—which followed in 2017—has already garnered a reputation as 'disruptive', by focusing its efforts on reforming regional and global transparency policies.

At the beginning of 2020 we had expected the year to bring further progress for these cooperation schemes, certainly in terms of increased joint horizon scanning, but perhaps also in the form of successful joint procurement agreements. However, as with much else, any progress was put on hold by the Covid-19 pandemic and the associated fall out. We watched as the collaborative relationships built between these partners were swept aside in favour of much broader cooperation schemes, often beyond even the boundaries of the EU.

This needn't have been a foregone conclusion however: the countries making up the Beneluxa and Valletta groups could have used the pandemic as an opportunity to flex the muscles of the initiative, and could have seen the ongoing emergency as posing a problem to which their associations provided the solution. Instead, at the first sign of crisis, these schemes were, to the outside observer, placed firmly on the backburner. This poses the interesting question: are cross-country cooperation schemes only a fair-weather solution?

This question provides the context of this report, the purpose of which is to analyse cross-country cooperation schemes on new and affordable medicines in order to compare them to the work being instigated or supported by the European institutions, primarily the European Integrated Price Information Database (EURIPID) scheme. By looking at the actions and progress of the Beneluxa group and those countries that have signed the Valetta Agreement in comparison to the EU funded EURIPID, we can analyse whether cooperation within or outside the EU framework is more successful, and which model—if any—is key to the future of access to medicines in Europe. We will now also consider how these models can adapt to public health crises and the need for expedited research, development and access to medicines. We will discuss why, when a crisis did occur, these cross-country cooperation schemes did not take centre stage.

ACTIVE CROSS-COUNTRY COOPERATION INITIATIVES (INVOLVING 2+ COUNTRIES)

The Visegrad Group
- Also known as: The Visegrad 4, V4[1]
- Countries involved: Czechia, Poland, Hungary and Slovakia (other sources also include Croatia and Lithuania[2]
- Year active from: 1991 (across broad range of issues), and from 2004 as EU members

FINOSE
- Countries involved: Sweden, Norway, Finland[3]
- Year active from: 2017[4]

The Nordic Pharmaceuticals Forum
- Countries involved: Iceland, Norway, Sweden, Denmark[5]
- Year active from: 2015

Beneluxa
- Also known as: BeneluxaI
- Countries involved: Belgium, Netherlands, Luxembourg, Austria, Ireland
- Year active from: 2015

The Valletta Declaration Group
- Also known as: Valletta Group, VDG, La Valletta
- Countries involved: Malta, Cyprus, Greece, Italy, Spain, Portugal, Ireland, Slovenia and Romania. Observers: Croatia, France (Technical Committee only)
- Year active from: 2017

Our conclusions are three-fold: firstly, the fact that member states are having to organise themselves outside the EU framework is a damning indictment of the approach to collaboration that the EU founding treaties dictate. The EU institutions urgently need to step up, broaden current projects and commit to ensuring access to medicines. Funding EURIPID is not sufficient. Secondly, that while cross-country collaboration initiatives are taking positive steps towards their goals, and the impact they have had on transparency may be long lasting, they urgently need to secure more tangible successes to cement their position in European health policy. Finally, that the Covid-19 pandemic has completely changed the healthcare environment in the EU, challenging the place of previous collaboration initiatives, laying bare the contradictions and shortcomings of the current cooperation framework and offering the EU the need and opportunity to improve it. By whichever route progress is achieved, we hope that greater transparency and collaboration are embedded in the post-Covid-19 European health system.

2 | WHAT DO WE MEAN BY CROSS-COUNTRY COOPERATION INITIATIVES?

In the healthcare context, cross-country cooperation refers to the practice of countries working together to share data and information on medicines in order to better position themselves when negotiating with pharmaceutical companies.

These countries aim in particular to overcome challenges around procurement and price-setting, and to counter the lack of transparency that shape negotiations. This information asymmetry too often means pharmaceutical companies hold all the bargaining chips and countries are going in blind. 'Cross-country cooperation' also refers to less common higher-level cooperation, such as joint negotiating and reimbursing, when two or more countries approach a producer together.[6]

This phenomenon has come about organically as a response to the decades long push for market oriented medical innovation, which has contributed to sky-rocketing prices and powerful pharmaceutical companies. This push included regulations to extend monopolies and other market exclusivities for Orphan Medicinal Products and Supplementary Protection Certificates, to name just two examples.

Countries embarking on collaboration try to strike a balance between retaining independence of their national health care bodies, regulatory authorities and social security apparatus, and the sustainability of these systems. But many are driven to risk this independence in order to overcome access and 'affordability challenges' on behalf of patients they represent. While innovation is vital to the future of healthcare, many countries found that their internal systems

> 'Cross-border, voluntary collaboration is defined as a voluntary and organised cross-border activity between healthcare sector actors (often government and health agencies, providers, professional bodies, funders, educational institutions and others) that is designed to improve patient access to highly specialised, high-quality diagnosis and care in their own country.'[7]

were not structured in the way necessary to make the most of it: for example, single year healthcare budgets did not allow for the high up-front cost of drugs like Sovaldi (Sofosbuvir), launched in 2014.[8]

Unsurprisingly, smaller Member States have less to offer pharmaceutical companies in terms of market size, so they began to explore collaborative opportunities. In some cases, these opportunities emerged along already familiar lines—the Visegrad Group (Czechia, Poland and Hungary) formed in 1991 and looks at many different topics, and Belgium and the Netherlands have naturally worked together in the past given their partly shared language and geographical proximity—while others emerged simply for the purpose of jointly negotiating prices of medicines.[10]

At the time of writing there are several formal collaborations active in the EU, including Visegrad, FINOSE (Sweden, Norway, Finland) and the Nordic Pharmaceuticals Forum.[11] There are also standalone pairs of countries working together: Norway and Denmark who signed an agreement to work on joint pricing and reimbursement in September 2018, and Bulgaria and Romania who signed a similar agreement.[12] There are overlaps in membership—with Ireland joining both Valletta and Beneluxa, and Norway making agreements outside its FINOSE membership—which highlight the fact that these groups are not in direct competition. Overlaps are possible due to the slightly differing aims of each initiative and the different approaches these initiatives take to respond to the core issues of high prices and lack of transparency. It is generally expected that this flux in memberships will continue and that these groups will grow in size.[13] This report will focus on the two largest and most established cross-country cooperation initiatives: the Beneluxa Initiative and the Valletta Declaration Group.

> When more innovative treatments started to come through, patients had to fight for access and overcome affordability challenges.[9]

3 | THE BENELUXA INITIATIVE

The Beneluxa Initiative originated with the Health Ministers of Belgium and the Netherlands announcing in April 2015 their intention to explore collaboration on pharmaceutical policy including price negotiations for orphan medicinal products.

Luxembourg joined the pair a few months later, at which point the BeNeLux acronym formed. Austria became the fourth partner in 2016, followed by Ireland in 2018, creating BeNeLuxAI. (NB: Beneluxa is more commonly used and will be used in this report for ease of reading)

The initiative has thus far focused on reimbursement of orphan medicines—medicines for 'rare' diseases affecting fewer than 5 in 10,000 patients—although in the last year or so this focus has been expanded to include information sharing and horizon scanning.[14] The initiative's website explains that 'Beneluxa is a first collaborative step towards more balance in the pharmaceutical market. Our goal is to ensure timely access and affordability of medicines for our patients.'[15]

Information sharing and Health Technology Assessments

Two of the key pillars of the Beneluxa initiative's work are information sharing and horizon scanning. The countries work together to share information about medicines that will be on the market in the near future in order to prepare to handle the extremely high cost or to take steps to jointly negotiate. The countries also exchange information on medicine policies generally, including sharing templates for dossiers and HTA reports.

The Beneluxa group has also created a specialist horizon scanning tool—the International Horizon Scanning Initiative. This has already been lauded as a success, although it is not expected to be operationalised until late in 2020 (at the time of writing there has been no sign of it). In some ways this is a low bar for success, considering the simplicity of horizon scanning and the existence of other tools that do the same thing; however, it is an achievement in that it shapes the agenda and will force other organisations, like the European Commission and European Medicines Agency (EMA) to pay attention to the Beneluxa group as an proactive player whilst they continue to consolidate themselves.

The group also collaborates on HTA reports themselves, coming together to undertake technical reviews of new therapeutics.[18] This is one of the areas in which the group has been most productive. However, it also an area in which the group struggles: Beneluxa members have different and at times incompatible HTA systems. There are 'fundamental' differences between for example, intertemporal discounting, choice of perspective and the use of clear cost-effectiveness thresholds (Ireland is the only member with a clear threshold, while the Dutch employ a wide range).[19] Without clarifying these fundamental differences, joint negotiations are likely to continue to be extremely difficult.

Joint negotiations and reimbursements

The Beneluxa Initiative group, or more accurately, two of its members, has successfully negotiated the positive reimbursement of one drug since its conception. In July 2018 Belgium and the Netherlands reached an agreement with pharmaceutical company Biogen on the price of Spinraza, a drug for 5q Spinal Muscular Atrophy (SMA). The two countries agreed to reimburse the drug for specific groups of patients in both countries under similar conditions.[20]

> We believe that sharing information and collaboration between countries, over an extended period of time, will benefit policy initiatives on pricing and reimbursement of medicines.[16]

Spinraza had only been authorised for marketing for a year at the point of the agreement, and prior to its reimbursement there was no treatment for patients of SMA. While the joint pricing agreement is considered a first and key success for Beneluxa, that characterisation is over simplified. Both countries released the list price, which is a small step towards greater transparency, but the actual price remains confidential and could be up to 85% of the list price according to the Zorginstituut Nederland.[21] Just one year after the pricing decision Belgium joined Italy (a Valletta Declaration Group member) to challenge the agreed price point, and in particular the gap between the cost of development and the cost of reimbursement. This is due to lack of transparency, enshrined in the confidentiality clauses in procurement agreements, and information asymmetry around the final price of the product in Italy. The two countries are working together to allege Biogen's abuse of its dominant position.[22]

This brings the success of the Netherlands' and Belgium's joint pricing decision into stark relief: Spinraza remains one of the world's most expensive drugs, and patients who need it are still driven to desperate ends to get it. The most heart wrenching example being that of the Belgian infant Pia, who was the subject of a crowdfunding campaign to fund Spinraza at only nine months old, despite living in a country with a temporary reimbursement agreement.[23]

Following the European Commission's granting of conditional approval for Zolgensma, another treatment for Spinal Muscular Atrophy, in March 2020, Belgium, Ireland and the Netherlands announced their intention to undertake a joint HTA.[24] The manufacturer, AveXis/Novartis, has reportedly stated its 'willingess to collaborate on this joint assessment and dialogue on reimbursement.'[25] The joint HTA will determine whether there will be a joint price negotiation, but this is nonetheless a formative step towards a second jointly negotiated medicine for the group.

Taking advocacy positions

The Beneluxa group has started to respond as one to key pharmaceutical policy developments, almost taking on the role of an advocacy organisation at times.

In early 2020, the Beneluxa group took issue with manufacturers AveXis/Novartis' plans to manage access to their aforementioned Zolgensma treatment for Spinal Muscular Atrophy.[26] The Health Ministers of the Beneluxa countries expressed their concerns and urged the companies 'to use objective medical criteria' when allowing early access to innovative medicines. The statement was strongly against the creation of a "human health lottery".

Only a couple of months later, the drug was given conditional approval by the EMA, thereby reducing the relevance of the issue of managed access. The Beneluxa group, however, had taken the opportunity to present a united front on managed access schemes which have in the past allowed pharmaceutical companies to make life and death decisions about who can use cutting edge medicines before they are reimbursed while securing market penetration. The ability of these countries to take a strong and united stance is likely to shape access to medicines debates in the years to come.

The negative reimbursement decision that Belgium and the Netherlands came to on Orkambi following joint negotiations with Vertex could be seen as an advocacy move too. The two countries came to the conclusion that the drug, for a type of cystic fibrosis (CF), added therapeutic value, but

not to the extent that it justified the excessively high price. Indeed, the Health Ministers of both countries stated that reimbursing Orkambi would force them to 'forego other innovative and more cost-efficient medicines.'[28] By ending these talks, and expressing hope that Vertex would return with a lower price point, the countries were taking a stand against excessive prices and indicating the strengthened negotiating position that pharmaceutical companies could expect from the Beneluxa group going forward.[29] Whilst valuable in some ways, this situation was still a failure, most critically for CF patients Belgium and the Netherlands who have missed out on a new, cutting edge drug.

Challenges and next steps?

The Beneluxa group has faced some enduring challenges since its inception: from language differences that meant choosing English as the working language, to the aforementioned incompatible HTA processes. Indeed, in general, the group has not proved to be greater than the sum of its parts. Whether a result of external or internal challenges, changing circumstances, or too little ambition, the initiative has not yet become the success story it was expected to be. Too many of its initiatives seem to be more theory exercises than practical ways of cooperating.

Perhaps this is because it was in part born of a political need to be seen to be doing something about high medicines prices, rather than an honest desire to work collaboratively.

The dominance of Belgium and the Netherlands in the group is also worth noting. Whilst this makes sense, given they were the founding partners and share a border, language, history and culture, this dominance means the other members are under used, making the bloc less powerful than it seems on paper.

An example of how the group's good intentions and initial first steps don't come to fruition is the 2019 World Health Assembly Resolution WHA72.8, known as the Transparency Resolution, aimed at increasing transparency at the supranational level. The group's website makes an effort to note that they discussed the resolution at a meeting, but that seems to be the extent of their group advocacy work on this issue, which is surprising given how closely it aligns with the aims of the group more broadly.[30] In fact the Netherlands and Belgium took different approaches to the resolution in the end, with Dutch officials playing a role in drafting it and then supporting it in a lukewarm fashion, while Belgium was much more supportive and

'First and foremost, the positive outcome is wonderful news for the young SMA patients and their families, both in the Netherlands and Belgium. It is also a very clear and promising example of the benefits of working together on price negotiations and pharmaceutical policy. Biogen's willingness to engage in a joint process and discover the benefits of gaining swift access in several markets at the same time is a positive development. Therefore I hope more companies will follow this example.'

Bruno Bruins, former Dutch Health Minister

> "The high level of uncertainty and the non-transparent approach is unacceptable. It proves no sincere commitment to patients and only increases the distress of the families concerned. They are given false hope. If one equals the fate of a patient to a lottery ballot, human dignity and moral values get out of sight. Lotteries are by their nature a form of gambling and this is absolutely the wrong model to bring to healthcare."[27]
>
> **Beneluxa Health Ministers joint statement, 30 January 2020**

engaged.[31] Overall this was a missed opportunity for the group to effect policy change, and a false start for them as a coherent influencing group rather than a negotiation partnership.

In spite of these challenges, the scheme's existence in general and the horizon scanning initiative and joint reimbursement in particular have led to greater transparency in pricing and terms, even in just a few years of activity.

It looks likely that Beneluxa will expand in the future. A November 2019 meeting between the group, Canada, Denmark, Finland, Iceland, Norway, Scotland and Sweden discussed opportunities for 'experts to interact' beyond existing initiatives. Reportedly the conversation 'spanned a variety of issues, such as the lack of evidence on the effectiveness of high-priced new medicines and the increasing pressure on pharmaceutical budgets.' While nothing has as yet come of this meeting explicitly, the way in which countries have reacted to the Covid-19 crisis have confirmed their interest in working beyond Beneluxa where necessary.[32]

Expansion is a cause for concern for some in the access to medicines world—with more members come more disparate systems that will complicate coordination and potentially dilute the mandate for further cooperation and harmonisation within the EU framework. Indeed, with already disparate health systems across the EU, the European Commission may well be concerned that giving Member States the space to make their own alliances will lead to reinforcement of existing disparities and inequalities: after all, the more successful collaboration initiatives are primarily led by wealthier, Northern Member States with greater sway on the political stage, only held back by their population sizes. We can only wait and see how the group evolves in the coming years, and beyond Covid-19.

4 | THE VALLETTA DECLARATION GROUP

The Valletta Declaration Group (VDG) was formed in May 2017 by the Health Ministers of Malta, Cyprus, Greece, Italy, Spain and Portugal. This originally solely southern European group was joined by Ireland, Slovenia and Romania in January 2018, along with Croatia, which holds observer status.[33]

Together these ten countries have a population of over 160 million.[34] Interestingly, in early 2018, France, one of the EU's larger nations (both in population and GDP) also expressed interest in the group and is currently following its Technical Committee.[35]

The VDG prioritises protecting innovation and ensuring access to new medicines without undermining sustainability.[36] Early analyses of the difference between VDG and Beneluxa explained that VDG was primarily focused on sharing information about drug prices—the kind of information that pharmaceutical companies forced countries to, by contract, keep private until the group began to look into how the information can be shared practically—rather than joint negotiations. However, more recent analysis indicates that the group is indeed interested in joint negotiations at the moment and in the near future. The group wants to prioritise protecting innovation and ensuring access to new medicines without undermining sustainability of healthcare systems.[37]

Some believe the VDG to be the most 'disruptive' of the collaboration initiatives, however this is thought to be a result of its impact on transparency and international collaboration, rather than its impact on specific reimbursements or the pharmaceutical industry: 'its ambitions for global reform of drug pricing could pose a far greater threat [than Beneluxa] to the pharmaceutical industry in the long term'.[38]

Information sharing, joint negotiations and HTAs

The group has met several times so far 'to explore ways of cooperation, particularly regarding information sharing, identification of good practices and mechanisms for negotiating medicine prices and joint procurement.'[39] They have set up a Technical Committee and begun to outline the processes for joint negotiations, including clinical, economic and price assessments. Beyond that, there has been little in the way of concrete progress. In comparison to Beneluxa, the group has no coherent online presence, which makes monitoring their progress more difficult. The paucity of information about tangible progress indicates that this group, while ambitious, is still finding its feet.

As of 2019, it is believed that six drugs have been prioritised for joint negotiations processes.[40] Other sources state that the group has two pilot joint negotiation projects underway, with one being for an orphan drug and the other for a drug with two non-orphan indications.[41] The Portuguese drug agency stated the 'endgame' was to negotiate a price for these drugs for their populations, which make up almost a third that of the EU.[42]

Taking advocacy positions and impact on transparency

One area in which the bloc has taken action is transparency. The Valletta Declaration Group

> "The objective of the Valletta Declaration is for the Ministers of Health of the participating countries to collaborate to improve patients' access to new and innovative medicines and therapies and to support the sustainability of their national health systems for the mutual benefit of all the different players, particularly the citizens of the countries concerned. This in the light of the fact that many innovative medicines coming on the market are extremely expensive."
>
> **Maltese Ministry of Health**

was a driving force before the 2019 WHO transparency resolution, discussed and adopted by the 72nd World Health Assembly in 2019. In March that year Italy had presented other members of the group with the draft resolution that it planned to submit. The resolution aimed to increase transparency in pricing, research and development costs, clinical trial data and patent information. Greece, Portugal, Slovenia and Spain sponsored the resolution, along with its drafter Italy, and Malta supported it.

Despite weakening of the resolution as it went through the adoption process, this was a clear win for transparency and a tangible output of the Valletta Group.[43] It is also in stark contrast to the lack of united front posed by the Beneluxa group, which as we have seen, has focused more on negotiations than increasing transparency more generally. This begs the question, which route will have a greater, and longer-term impact on transparency in access to medicines?

Challenges and next steps?

The VDG's Technical Committee has itself highlighted several challenges including which type of price to negotiate (range, maximum, fixed price), how joint outcomes would be implemented nationally, and how to guarantee confidentiality.[44] Without ironing out these critical questions, the group is unlikely to see progress in the near future. The group has some existential issues to work out regarding membership too: 9 states, 9 health technology assessment systems, 9 economic statuses, numerous languages and political battles to fight makes for an unwieldy group.

The next steps will be for the prioritised drugs to continue to work their way through the VDG's systems, with the hope of positive first joint reimbursement; and for the questions about how to properly work collaboratively to be answered—and soon.

5 | EU-LED COLLABORATION: EURIPID

Whilst healthcare remains a national competency, as high prices and lack of transparency began to seriously threaten the health of European citizens, many looked to the EU institutions for solutions.

In particular, there has long been a desire for the European Commission to facilitate information sharing and greater transparency—both of which are key to tackling rising prices and ensuring access to medicines. Thus far, the Commission has responded most concretely by funding the European Integrated Price Information Database (EURIPID), launched in 2010. 26 countries are listed as participating as of 2020—all of which make an annual contribution fee—meaning that it dwarfs Beneluxa and VDG in terms of participation and coverage.[45]

EURIPID aims to facilitate mutual sharing of information about medicines prices and is described as a 'voluntary non-profit collaboration' of 'mostly' European countries, and in particular pricing and reimbursement authorities. Its key output is a database: a 'technical tool to make prices more transparent via comprehensive, continuously maintained, easy-to-use online database of prices of reimbursed pharmaceuticals'. This database is populated with official prices of publicly reimbursed, mainly out-of-patent medicinal products that are published by national authorities in line with the Transparency Directive.[46]

The database is currently exclusively available for national competent authorities for pricing and reimbursement of medicinal products, providing them with the background information they need to set prices of medicinal products; an adequate interpretation of information related to pricing procedures of medicinal products is a precondition for external reference pricing (ERP), thus requiring up-to-date, easily accessible and unbiased information on the availability and prices of medicinal products. ERP is a dynamic tool employed by Member States to make the best reimbursement decisions for their needs, allowing them to make judgements based against other countries' decisions. But it is dependent on high-quality, up to date information. By building up and maintaining a database with information on national prices of medicinal products, EURIPID makes price setting of price-regulated medicinal products far more transparent and efficient. This transparency is essential for increasing openness and accountability of health systems in the EU and correcting the asymmetry of information that exists between payers and industry: EURIPID is therefore already making an important contribution.

Challenges and next steps?

One crucial challenge to the impact of EURIPID is that the database only contains publicly available data on reimbursement prices as published by national authorities. This means it brings little new content to the table and is at the mercy of national authorities' reporting habits, which

"Transparency about drug prices is coming like a tsunami - whether industry realises it or not."[49]

Dr Tim Reed, HAI Executive Director

may not always be timely or accurate. A truly groundbreaking database of pricing information would make more effort to source previously unpublished data and potentially net prices rather than just official list prices.

EURIPID is also exclusively available for the experts of the national competent authorities of its participating countries and for the services of the European Commission. Therefore, even though the patient perspective should inform decision-making, the processes and criteria behind pricing and reimbursement decisions are not transparent to patients or citizens. Without greater access to information on medicines prices, decision makers are less likely to be held accountable by those they represent, though we acknowledge that such a high level of transparency must be handled delicately.

Another factor undermining EURIPID's promise is the variety of ERP systems used internationally. In each country ERP is applied somewhat differently, due to continuing differences in institutional settings and the role of the respective institutions, like competent authorities. As a result, the information held in EURIPID is of variable use: because the prices are set within such specific parameters, using different references, they may be incomparable between countries. To get over this hurdle, EURIPID would benefit from carrying out a rigorous, independent evaluation of different ERP systems and attach this information to the prices, better allowing countries involved to coordinate their pricing policies.[47]

Health Action International and other NGOs, such as the Association of European Cancer Leagues, believe EURIPID holds huge potential to facilitate pricing collaboration among participating countries and thereby reinforce their negotiating capacity with Big Pharma: and it certainly has already had a positive impact on transparency over its first decade.[48]

However, as the furthest the European Commission has gone to facilitate cross-country collaboration, it has not gone far enough, as best evidenced by the growth of alternative collaboration initiatives.

6 | HOW HAVE THESE INITIATIVES IMPACTED EU-LED COLLABORATION?

In many ways, the Beneluxa initiative, the Valletta Group and EURIPID share a lot in common. All are the products of a need for greater collaboration and transparency across Europe when it comes to medicines, and of a political desire to be shown to be acting.

All have the potential to contribute to a new healthcare world: one where decisions on medicines are made between equal players, with patient interests at the forefront. All, to some extent, focus on sharing information as a key step towards making that world a reality. All have had some success, to varying degrees. Beneluxa has the uneasy title of 'first positive reimbursement decision'—though, as discussed, that has not been a simple journey. The Valletta Group has made its mark on transparency on the global stage. And EURIPID is quietly facilitating greater price information sharing.

Where they differ is in original backgrounds. It is not surprising that the European Commission funded EURIPID back in 2010 (and again since), given the desperate need for something to prevent the rocket-like trajectory of some medicine prices. What is striking is that Beneluxa, VDG, and their peers exist at all: that these cooperative initiatives emerged amongst EU Member States, despite the EU being theoretically well placed to defend smaller states against market vagaries that were putting the health of their citizens at risk. Instead of finding the support they needed in their supranational umbrella, they felt forced to cobble together at times uneasy partnerships with their neighbours. Their very existence is testament to the lack of ambition the shown by the EU in making EURIPID its main contribution to the issue of high prices and lack of transparency.

> "The EU healthcare agenda is becoming increasingly contradictory, with Member States wanting to keep their healthcare systems independent on the one hand and at the same time seeing the potential—and arguably ultimate—need to collaborate. Importantly, this development is happening and being driven forward by individuals and countries themselves, rather than from top-down mechanisms through the EU framework.[50]"

The other avenue down which the EU has gone on collaboration is joint HTA. This dossier, at the time of writing, is still stuck in political limbo at the Council of the European Union. Harmonising HTA processes is extremely difficult, given the fundamental differences in each country's approach—and this is something the Beneluxa initiative has also had to tackle—but its progress is still at a standstill following the European Commission's original proposal for reform and the European Parliament's comments in response.[51] It is likely that this dossier has been delayed even further by the combination of a lack of political will and the helpful cover of Covid-19. This unhappy pair of a functional but uninspiring database, and a stalled planned for joint HTA makes it clear why Member States aren't waiting for leadership from the EU institutions.

It is difficult to assess whether the existence of these cross-country collaboration initiatives is reducing or complementing the EU's drive to make its own initiatives stronger or a reality. EURIPID was around for five years before the largest collaborations began to formalise their partnerships, arguably sufficient time to see what else the EU had to offer. However, there must be some correlation between the number and successes of these initiatives and how the EU institutions decide what needs to be prioritised. Perhaps their position will change as these groups evolve and potentially grow: will ever growing numbers of Member States negotiating for medicines prices together begin to undermine the European experiment? Will the Council and the Commission realise that patience is running out? Will more and more national governments begin to see these initiatives as critical to their healthcare systems? Or will these initiatives become so unwieldy, and so large, that they become victims of their own success? We shall have to wait and see. What is critical in the meantime, is that decision makers throughout the institutions begin to plan for and act on the closer collaboration on medicines policy that member states evidently desire, and most importantly begin to take much stronger action to increase transparency in medicines and to reduce the power of pharmaceutical companies.

7 | THE IMPACT OF COVID-19

The Covid-19 pandemic has impacted cross-country collaboration in two ways: firstly it has given the EU institutions, primarily the Commission, the necessity and opportunity to change how they lead and respond on healthcare issues; and secondly the emergency has led Member States in collaboration initiatives to look elsewhere for solutions.

Impact on the EU

The European Commission has, throughout the pandemic, been coordinating a 'common European response', taking action both to protect public health, and minimise the social and economic impact on the EU, but also to ensure the integrity of the Union is maintained (particularly in terms of coordination of changes to free movement between member states). The Commission drove the initial healthcare response, calling on member states to ensure Europeans have access to medicines, and injecting billions of euros into the response by activating the EU's Emergency Support Instrument.[52] At the end of April 2020, the Commission kickstarted a global pledging initiative—the Coronavirus Global Response—aimed at ensuring global coverage of therapeutics and vaccines, which raised €7,4 billion.[53]

This initiative is indicative of the more experimental side to the Commission's comprehensive pandemic response: it sees the Commission take on the position as a global leader in the fight against the coronavirus, and as chief negotiator, taking action to secure resources on behalf of Member States. The Commission has done this by employing rarely used legislative instruments. It has twice made use of the EU joint procurement instrument during the Covid-19 crisis: first 'to ensure participating countries had additional access to personal protective equipment (PPE), ventilators, testing supplies or ICU medicines', and secondly to secure 500,000 courses of Remdesivir from pharmaceutical company Gilead.[54] The Joint Procurement Agreement was signed by 36 countries—all EU Member States, plus European Economic Area countries, candidate countries and the UK.

"We need to bring the world, its leaders and people together against coronavirus. We will launch a global pledging effort. A real marathon. Beating the coronavirus requires a global response and sustained actions on many fronts. We need to develop a vaccine, to produce it and deploy it to every corner of the world."

Ursula von der Leyen, President of the European Commission, 24 April 2020

The EU has also made use of an Emergency Support Instrument to secure other doses of Remdesivir, and doses of potential vaccines. Shortly after the second batch of Remdesivir was secured, the WHO-led "Solidarity" clinical trial confirmed concerns that the drug was not as effective as initially thought, and in fact 'had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay'.[56] This highlights the way the Commission is expediting key processes: by negotiating terms and advanced purchase agreements while scientific studies are still underway. Nonetheless, several Member States appear to be satisfied to continue using it, given the paucity of other treatment options. The Commission has negotiated and agreed future purchase of potential vaccines from various pharmaceutical companies: the first agreement was made with AstraZeneca in August for an initial 300 million doses. This agreement was made whilst the vaccine candidate was in Phase II/III trials, and the press release expresses that the Commission planned to continue using 'existing flexibilities in the EU's regulatory framework to accelerate the authorisation and availability of successful vaccines.'[57]

In many ways the Covid-19 crisis has highlighted just how powerful and agile the EU can be when it comes to negotiating for access to medicines, and how valuable it is to be acting in a bloc of well over 530 million inhabitants when competing against the largest nations on earth.[58] However, while the EU's activities around Covid-19 have largely been successful—they have secured around 1.5 billion doses of various vaccines—these activities have signified a huge step back in transparency and equitable access to medicines.

By making advance purchase agreements of millions of doses and lobbying ruthlessly for the health of the European population, the Commission is at risk of fuelling the vaccine nationalism that they, on paper, are aware will scupper global efforts to bring the crisis to a swift conclusion. There is a lot of angst around the way that the President of the Commission has taken on a figurehead position, leaving Health Commissioner Stella Kyriakides and other senior representatives behind, and offering little in the way of transparency around decision-making. There is concern that other dossiers, like the long-awaited joint HTA file which would facilitate long term collaboration and cooperation on pharmaceutical policy and procurement, have been further delayed. Finally, the contracts being drawn up between the Commission and pharmaceutical companies for therapeutics and vaccines are being kept behind closed doors, even as Members of the European Parliament demand clarity on terms. It seems Ms Von der Leyen et al are delivering impressive results on Covid-19 solutions, but at the cost of future transparency and collaboration.

"Today we secure access to Remdesivir for the treatment of up to 500,000 patients in need. We are leaving no stone unturned in our efforts to ensure that safe and efficient therapeutics are available against COVID-19. Through our EU Joint Procurements, we are empowering countries across Europe to join forces and get access to vital equipment and medicines. We are always stronger together, and this is European solidarity in action against COVID-19."[55]

Stella Kyriakides, Commissioner for Health and Food Safety, 8 October 2020

Impact on cross-country collaboration initiatives

The urgency with which the Covid-19 crisis needs to be resolved has also driven countries previously involved in cross-county collaboration efforts to change their priorities and ways of working. Firstly, the crisis has dominated the schedules of politicians and civil servants across the EU. This greatly diminished capacity has led to stalling on progress of other work, including joint pricing and reimbursement decisions or information sharing within existing cross-country collaboration initiatives. With 2020 drawing to a close with no end to the Covid-19 crisis in our short-term future, it looks likely that progress will also be stalled in 2021.

Secondly, the Covid-19 crisis presented reasons for countries to look beyond their existing alliances to secure vital therapeutics. One is example is the Netherlands, which began working with the now dormant Inclusive Vaccine Alliance (Germany, France, Italy) to secure vaccines on their own, a move that was concerning to close partner Belgium, as well as to some in civil society in the Netherlands who saw this move as challenging the country's otherwise progressive stance on pharmaceutical policy.[59] It is striking that not only did the Netherlands not use the Beneluxa group in this scenario, but that they set up a new collaboration initiative. The more existential question posed by the Netherlands' move is, if Beneluxa is not sufficient when faced with a crisis like Covid-19, is it serving its purpose?

Perhaps these groups have become too unwieldy as they have grown, and smaller countries have tried to find a smaller number of potential partners with whom to approach pharmaceutical companies. At the other end of the spectrum we could argue that the EU's proactive approach to negotiating on behalf of all Member States has made cross-country groups redundant. Even the work of the Inclusive Vaccine Alliance has been co-opted by the European Commission. This move towards greater EU-sanctioned collaboration looks set to continue. A July 2020 European Parliament Research paper about the future of EU public health policy, states that 'the coronavirus crisis could act as a catalyst for a real 'Europeanisation' of HTA', and that the pandemic has shown that the joint procurement framework should be 'strengthened during emergencies and also expanded to use outside them.' The paper also suggests exploring a common EU public procurement agency, which would give an EU agency 'greater bargaining power'.[60] This could also be the result of a 'spill over' effect whereby the cross-country collaboration initiatives highlight to the EU areas ripe for new legislation.[61] Either way, if any of these policies were to come to fruition, they would signify that the EU institutions are making the kind of strong commitment to health policy collaboration that many states have been calling for, and may well signal the end of the need for collaboration outside the EU framework.

8 | CONCLUSION

The Beneluxa initiative, Valletta Declaration Group and their peers have made admirable strides towards their goals of creating fairer, more transparent health care systems, and ensuring medicines are affordable and accessible. The different initiatives have approached these shared goals in different ways—whether focusing more on reimbursements or advocating for transparency—and the landscape of health policy in Europe is healthier thanks to their existence.

They are not without fault, however. The experience of Beneluxa shows that the coordination processes are complex and lengthy, and that for greater collaboration reforms may be needed to make key national structures and agencies more cohesive. Furthermore, there remains an acute need for greater transparency, given the price points of the first positive reimbursement for the group remain hidden from the public. The VDG urgently needs to speed up its processes, and push through some of the medicines the group repeatedly says are under scrutiny—it is difficult to assess the strengths and weaknesses of a group that has not yet delivered. Overall, these initiatives are not proving to be greater than the sum of their parts at the moment, and political will is needed to amplify them from experiments to a fundamental part of how healthcare works in the EU.

But we must acknowledge that in what could have been a seminal year for these groups, we have instead had to contend with a pandemic that has overhauled priorities, resources and political will. This is particularly evident in the case of the Netherlands, who chose to team up with a whole different group of countries to engage in exclusive negotiations for potentially effective vaccines with pharmaceutical manufacturers. This step undermined not only Beneluxa's raison d'etre, but also basic EU solidarity principles. It is also evident in the U-turn the EU institutions have taken, going from the extent of their support for cross-country collaboration being funding the anemic EURIPID, to employing joint procurement instruments and acting as lead negotiator with pharmaceutical companies.

There is no argument that cross-country cooperation will be key to access to medicines going forward: but it remains to be seen whether that collaboration will continue outside the EU framework, or be absorbed as a reaction to the positive test that has been the Covid-19 crisis. Either way, we hope to see transparency protected and championed, and collaborative working, information sharing and joint negotiations heralded as the antidotes to the sky rocketing prices and information asymmetry that mean pharmaceutical companies are still in charge of the fate of Europe's health.

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