



UNIVERSAL ACCESS AND AFFORDABLE MEDICINES

BENELUXA et al.: **THE BEST** **IS YET TO COME**

ANALYSIS

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BY Yannis Natsis • Policy Manager, Universal Access and Affordable Medicines



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Regional intergovernmental cooperation initiatives such as Beneluxa have become a pragmatic and irreversible political choice for all parties involved.

Executive summary

The intergovernmental regional initiatives of collaboration around access to medicines policy are here to stay. Zooming in on the BeNeLuxA coalition, the most advanced of the regional European clusters (henceforth the regionals), this reflection paper analyses the multi-layered cooperation, looks at the progress achieved so far and tries to foresee the challenges and opportunities along the way for these alliances in Europe.

A new culture of cooperation is being fostered among the civil servants of the participating Member States who pool resources, build capacity and exchange information and expertise. Above all, they are learning to trust each other. In the face of excessive medicines' prices, the regionals are a pragmatic and irreversible political choice for all parties involved. Put simply, if they were to fail, there would be little else to fall back on.

The International Horizon Scanning Initiative (IHSI), a Beneluxa spinoff has created an additional, new platform of exchange for public authorities. Its primary objective is to mitigate the effects of the information asymmetry which undermines governments' leverage in the negotiations with pharmaceutical companies. This early warning system will provide public administrations with more and better information about what is in the companies' pipeline. Combined with a joint determination and upfront public announcement of the willingness to pay, public authorities hope to be able to break the "sky's the limit" pricing strategies of pharmaceutical manufacturers. This will have implications for transparency in prices and in medicines' pricing, the market and competition dynamics; as well as the future of biomedical innovation and investment decisions both for countries and pharmaceutical manufacturers.

Beneluxa is not just about lowering medicines' prices. In fact, it is not even about joint price negotiations per se. It prioritizes the optimization of the various preparatory building blocks that may or may not eventually lead to joint price negotiations. This is what perhaps makes it stand out compared to the other regionals. In the past four years, Beneluxa has created the conditions for a multi-layered, continuous cooperation and exchange of information amongst its members.

The paper concludes that when all parties share the same information, whether or not, in the end, multiple governments will carry out joint price negotiations becomes a secondary issue. They can negotiate individually should they decide to do so, but companies will in any case, expect to deal with a de facto united front, thanks to the same baseline of information, reinforced by the jointly

determined willingness to pay.

That said, willingness to pay does not mean, nor necessarily leads, to affordable prices. Someone might well be willing, prepared or able to pay two million euro per patient to cure cancer, but this might also equal rationing access due to lack of affordability, effectively denying access due to cost, which is the challenge faced by most in the current system. Also worth noting is that the proposed “solution” does not bring about a radical overhaul of the system. On the contrary, it may be considered to be a piecemeal solution which feeds into and maintains the status quo and the “innovation is expensive” narrative. Meaningful innovation should not have to be expensive, let alone unaffordable and unsustainable. Innovation needs to be efficient, available and accessible too.

Will Beneluxa as we know it today exist in five years? Probably not. Will the structures it set in place still be there and (better) used by a high number of countries? Undoubtedly, yes.

Preface

In recent years, BeNeLuxA¹ has become a household name for those involved in pharmaceutical policy-making in Europe. When the first signs of regional inter-governmental collaboration appeared in 2015, many thought that it would be a short-lived experiment. However, the launch of the International Horizon Scanning Initiative (IHSI) in late October 2019² has proved the naysayers wrong and has shown that regional intergovernmental cooperation initiatives such as Beneluxa have become a pragmatic and irreversible political choice for all parties involved. Additionally, its success, although modest so far, has prompted other EU national governments to follow in their footsteps and explore the possibility of joining forces to tackle the issue of affordable access to meaningful innovation for the benefit of all patients.³

The high prices of a growing number of medicines combined with the intransigence of pharmaceutical manufacturers has fueled the access to medicines debate in Europe. Pharmaceutical developers have increased their lobbying expenditure in Brussels and beyond in a desperate attempt to defend their reputation and regain control of this debate.⁴ On the other hand, governments in Europe do not seem to have ready solutions. Hence, they view these regional intergovernmental partnerships (henceforth the regionals), with Beneluxa being the most advanced, as one of the few tools at their disposal to counter-balance the “divide and conquer” strategies diachronically pursued by medicines’ developers.

1 Belgium and The Netherlands signed the first agreement in April 2015. Luxembourg joined in September 2015, Austria in June 2016 and since then this project has been named ‘Beneluxa’. Ireland joined the Beneluxa initiative in June 2018.

2 Press release by Belgian Minister of Health <https://www.maggiedeblock.be/fr/la-belgique-sas-socie-a-huit-autres-pays-pour-maintenir-les-medicaments-a-un-prix-abordable/> (accessed, 15 November 2019).

3 The Valletta Declaration Group of was born with the signing of the respective Declaration in Malta in May 2017 initially by six countries. Four more have joined since bringing the total number of countries to ten (Italy, Greece, Cyprus, Spain, Malta, Portugal, Croatia, Slovenia, and Romania). Ireland signed the Valletta Declaration in May 2017 but also joined Beneluxa in June 2018 as stated above.

4 Corporate Europe Observatory (CEO). High prices, poor access: What is pharma fighting for in Brussels? Chapter 2. EFPIA and Big Pharma’s web of lobbying in Brussels <https://corporateeurope.org/sites/default/files/2019-05/High%20Prices%20Poor%20Access%20Chapter%202%20-%20CEO%20-%20May%202019.pdf> (accessed, 15 November 2019).

1. Building blocks of a success story

The regional collaborations offer significant advantages to the participating Member States:

1.1. Starting with the basics: Building trust, pooling resources

Ministries of Health are struggling with their own resources and expertise, particularly in the field of pharmaceutical policy-making. Often, the respective departments (especially those in charge of medicines' pricing and reimbursement) within Ministries of Health and other public agencies dealing with pharmaceuticals can count a handful of civil servants called to cope with an increasing and complex workload. Moreover, staff turnover exacerbates problems not only of capacity but also of continuity and consistency in the decision-making process. The regionals offer a solution out of this predicament. A new culture of collaboration is being fostered among the civil servants of EU Member States who pool resources and exchange information and expertise. Above all, they are learning to trust each other. Civil servants who regularly attend the technical meetings of Beneluxa et al. learn from each other, split tasks and understand how to work together. This is no small feat and requires considerable effort and energy. Health care systems are diverse while linguistic, legal and other barriers should not be under-estimated in the process of establishing these channels of collaboration. These elements are as essential for the success of these initiatives, as the political will and commitment to make them work.

1.2. Fighting information asymmetry: Foresight is key

Governments' leverage in the negotiations with pharma has always been undercut by all sorts of information and power asymmetries. Indeed, these asymmetries have had a blindfolding effect on governments. As Ruth Dreifuss, the former President and Health Minister of Switzerland recalls when she negotiated with companies she felt she had one arm tied behind her back as companies would have more information than her.⁵

One of the fundamental objectives of the regionals therefore is to shed light into the black box of pharmaceutical systems and the IHSI is an important step in this direction. After some delay, it kicked off in late October 2019 - the launch had been scheduled for the first half of 2019 - as it took longer than expected to finalize the financial and organizational commitments of contributing countries. It sets up an

The emphasis on publicly available information stems from the need to minimize any chances of data manipulation by companies who would like to see favourable impact assessments for their products coming out of the IHSI.

⁵ "The Swiss authorities should protect patients – not patents" event, 22 May 2018, Geneva Press Club, comment made at 01:02:00 https://www.youtube.com/watch?v=o-WB-EHieGI&index=9&list=PLEuneE-bMnuEb8vd8fj-rt09KKS7d_uOU.

early warning system and enables health care systems to better prepare for the reimbursement of expensive treatments.⁶

Thanks to the new joint Horizon Scanning System (HSS) central database, governments hope to have more and better information, earlier, about what is in the companies' pipeline. This is crucial as it offers insights not only on what is coming up, but also on how the competition landscape is shaping. The latter is an important component governments can use in their negotiations with the industry. In the world of pharma, where companies race to bring their products to the market first, governments will benefit from knowing in advance if additional, competing alternatives are on their way, also compared to the options already on the market. This way, they will be able to take informed decisions, plan more efficiently and eventually drive prices down. In addition, they will be able to identify unmet medical needs, -therapeutic needs, i.e. those areas where treatments are not currently available, guiding their own investment decisions.

As it is succinctly summed up on the IHSI website, "IHSI data enables healthcare systems to prepare for disruptive technologies through data insights that deliver the leverage required to confidently assess new products coming to market."⁷ The ambition of countries participating in the IHSI is to have an effective foresight of 5-10 years by scanning open source, publicly available data globally (pharma financial data, investors' reports, clinical studies, scientific literature, regulatory sources and others).⁸ It is noteworthy that the HSS database will not be completed by the producers of medicines or medical technologies. No confidential data from the industry will be collected but should the industry wish, they will be able to provide the IHSI with non-confidential information regarding future costs.⁹ The emphasis on publicly available information stems from the need to minimize any chances of data manipulation by companies who would like to see favourable impact assessments for their products coming out of the IHSI. By relying exclusively on transparent, non-confidential data, the information inserted in the HSS database will be verifiable, the outcomes will not be distorted and companies will have to be trustworthy. Simply put, the data transparency equals that companies will not be able to hide nor attack the assessments.

6 Existing Horizon Scanning Systems (HSS) cover multiple objectives and goals: a) select products for HTA, b) inform reimbursement decisions, c) Inform for managed introduction and monitoring of drugs, d) Inform health care providers and managers, e) Inform budget forecasting, f) Plan services and g) Select for and inform price negotiations. KCE Report 283. Horizon scanning for pharmaceuticals: proposal for the BeNeLuxA collaboration, p. 24 https://beneluxa.org/sites/beneluxa.org/files/2017-07/Horizon%20scanning_ScientificReport_full.pdf (accessed, 15 November 2019).

7 International Horizon Scanning Initiative (IHSI) website <https://ihsi-health.org/>.

8 Ministry of Health, Welfare and Sport, The Netherlands. Horizon Scanning System – Report Open Market Consultation, https://beneluxa.org/sites/beneluxa.org/files/2019-03/Final%20190205%20Report%20HSS%20open%20market%20consultation_for%20website.pdf (accessed, 3 December 2019).

9 Idem.

A large part of the success of the joint horizon scanning exercise will depend on how individual countries actually use the wealth of information available to them via the IHSI. This information will help countries calculate their estimates and the budget impact of medical technologies as well as in setting their priorities. Not least, it will allow for negotiations with companies to start earlier than usual. This probably explains why pharmaceutical companies do not seem to object to such information being collected by Member States as they expect it to be conducive to business predictability which figures prominently on the sector's wish list. Truth be told, much of this information already exists. Yet, it is scattered across different sources and it is not user-friendly, nor readily available to those who need it most.¹⁰

Developers of medical technologies will not be the only ones to benefit from this early foresight. Insurance companies, public payers, hospitals, health care professionals and in general, all parties involved in delivering care will be able to improve their planning. Patients will be able to know in advance the stream of treatments coming their way and will have a preliminary idea of how effective these treatments are.

To sum up: Is this joint horizon-scanning exercise groundbreaking? Certainly not. Is it a significant step towards a more level-playing field, a sounder basis for (better) informed decisions and potentially lower prices? Definitely, yes.

1.3. Adaptability & flexibility

The IHSI, a Beneluxa spinoff showcases one of the core features of this initiative: its capacity to evolve and adapt to the needs of the collaboration. The fact that the IHSI is open to non-Beneluxa, but also to non-EU members speaks volumes about the needs-driven and adaptive spirit of the entire Beneluxa experiment. Nine countries are on board so far (Beneluxa member states minus Austria, plus Denmark, Norway, Portugal, Sweden and Switzerland)¹¹ while the tender for the HSS database will be published in Spring 2020. The fact that Canada has also expressed interest in joining the IHSI adds an interesting transatlantic touch¹² and

10 Problems with existing Horizon Scanning initiatives: a) there is no existing system meeting the requirements, 2) current initiatives are inconsistent and not comprehensive at EU level and 3) existing databases, including those at national level are not public (Open market consultation: Building a Horizon Scanning System (HSS), 12 December 2018 https://beneluxa.org/sites/beneluxa.org/files/2019-03/Presentation%20open%20market%20consultation%20Nov%2012th%202018_for%20website.pdf (accessed, 9 December 2019).

11 International Horizon Scanning Initiative: Une collaboration internationale autour des médicaments innovants <https://www.inami.fgov.be/fr/inami/collaborations-internationales/Pages/international-horizon-scanning-initiative.aspx> (accessed, 9 December 2019).

12 After Canada, Sweden Shows Interest In BeNeLuxA Joint Horizon Scanning, Pink Sheet, 6 September 2019, <https://pink.pharmaintelligence.informa.com/PS140799/After-Canada-Sweden-Shows-Interest-In-BeNeLuxA-Joint-Horizon-Scanning> (accessed, 9 December 2019).

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underlines its dynamic and global nature.

Interestingly, it is a fee for service scheme, set up as a not-for-profit legal entity (asbl), registered at the Belgian National Institute for Health Insurance (RIZIV/INAMI) in Brussels, with an independent from Beneluxa Secretariat hosted at the Dutch National Health Care Institute (ZIN).¹³ It is quite telling that even different types of membership are foreseen. The sort of membership (full, affiliate and joined members) with the corresponding fees and privileges determines the degree of database access.¹⁴ First horizon scanning results are expected by late 2020-early 2021. The information provided by the IHSI in the form of High Impact Reports on upcoming disruptive innovation will then be taken up by national competent authorities to conduct their own national planning.

It remains to be seen which company and/or consortium will win the tender as only few market operators have the combined IT and medical capabilities to submit a bid.¹⁵ The level of transparency of the HSS database is another issue to monitor. Furthermore, it will take a few years before a conclusion can be drawn on the impact of this foresight instrument on market and competition dynamics. Nonetheless, it is almost certain that its appeal will grow stronger when it takes off. It should not come as a surprise that more candidates will be compelled to join. The IHSI will be ready to welcome them.

The IHSI shows that Beneluxa and perhaps other regionals too can be flexible in the way they collaborate, as countries which do not wish to be full members can take part in specific activities of the initiatives instead. This is a preview of the future modus operandi for the regionals.

1.4. Consolidation first

Whereas IHSI is keen on expanding and adding new members, Beneluxa per se is advancing cautiously. Ireland was last to join in June 2018 and the doors are closed to potential new members for the moment. Unfortunately, 2019 passed without a successful joint negotiation of a new medicine. The last one to be approved via the Beneluxa channel was Biogen's Spinraza (an orphan drug for Spinal Muscular Atrophy, SMA) in summer 2018. This was the first positive reimbursement decision by Beneluxa. The first negotiation attempt over Vertex's Orkambi resulted in a

13 <https://ihsi-health.org/contact/> (accessed, 9 December 2019).

14 <https://ihsi-health.org/get-involved/> (accessed, 9 December 2019).

15 Ministry of Health, Welfare and Sport, The Netherlands. Horizon Scanning System – Report Open Market Consultation, https://beneluxa.org/sites/beneluxa.org/files/2019-03/Final%20190205%20Report%20HSS%20open%20market%20consultation_for%20website.pdf (accessed, 9 December 2019).

negative reimbursement decision a year earlier.¹⁶ In both cases, joint negotiations took place between the pharma companies and only two of the five Beneluxa club Member States, namely Belgium and the Netherlands. That said, it is true that not all participating countries need to move together at all times. This has been the case since day one of this regional coalition. Moreover, the absence of publicly visible and palpable results in the form of headline-making successful joint negotiations does not mean there is no activity behind the scenes. Officials confirm that negotiations are ongoing with several pilots in the pipeline.

Negotiations take time for a multitude of reasons, one of them being that pharmaceutical companies are testing the waters.¹⁷ This is hardly surprising as it is as much a learning process for them as it is for those negotiating on behalf of health care systems. Some companies are also more willing to engage with clusters than others. Opinions may also vary within companies themselves. For instance, company executives more familiar with the national level processes may be more open to collaboration with the regionals than their supervisors at the company's international headquarters. Others initially embark on the path of joint negotiations for their products but eventually drop out and choose the conventional, more familiar option of bilateral negotiations at national level. Then there are those pharma executives who regard the regionals as uncharted territory and do not see the added value nor business case for them to go down that particular negotiations avenue. Those who are more sceptical go a step further still questioning governments' will, commitment and capacity to work together effectively. After all, the regionals are challenging the "business as usual" model which pushes not only civil servants but also companies and their executives out of their comfort zones. All conclude, though, that clarity and certainty, primarily but not limited to legal issues, are necessary prerequisites for companies to engage with the regionals. Otherwise, they risk turning into time and resource consuming exercises for them. This probably explains why there have not been many companies queuing to work with Beneluxa. They are almost unquestionably waiting to see if these initiatives survive and deliver in the mid and long run.

After all, the regionals are challenging the "business as usual" model which pushes not only civil servants but also companies and their executives out of their comfort zones.

16 European Public Health Alliance (EPHA). Beneluxa: First results of multi-country cooperation on medicine price negotiations. Reflection paper, September 2017 <https://epha.org/discussion-paper-beneluxa/> (accessed, 10 December 2019).

17 From Politico Pro Morning Health Care newsletter, 25 November 2019: "Pharma pull-outs: Five EU countries that have joined together in the Beneluxa group, as well as ten in the Valletta group, have tried to negotiate together prices for expensive medicines over the past few years. In the latter case, pharmaceutical companies have pulled out of talks in six different instances, Malta's Health Minister Chris Fearne said at the summit on Thursday. His country initiated the group, which is mostly made up of southern European countries, in 2017".

2. Chapter II: What does the future look like for the regionals?

Orphan drugs (medicines for rare diseases) will remain a high priority for the clusters of regional cooperation due to their paralyzing price tags and other specificities. Spinraza underwent all stages of the collaboration (i.e. joint Health Technology Assessment and appraisal by the Belgian and the Dutch HTA agencies, exchange of information, pricing and joint negotiations for reimbursement/procurement¹⁸). In the end, a confidential deal was signed between the company and the two governments, making the drug available and covered for patients.¹⁹ This should be viewed by companies as an approach that successfully addresses priorities close to their hearts, such as faster and simultaneous access to several markets at once avoiding the usual, time and resource-consuming national launches.

A quick comparison between the two case studies (Orkambi and Spinraza) points to some interesting findings:

1. **A “no” can lead to a “yes”.** The example of Orkambi with the initial breakdown in the negotiations between the company and the two governments resulted in a positive reimbursement decision a few months later. A negotiation process goes through different stages and governments as well as companies use tricks to get to the desired outcome.
2. **Not all companies are the same.** Different companies mean different backgrounds, mindsets, interests and priorities. This diversity is something governments but also companies can use to their benefit.
3. **The pipeline is what matters.** The intransigence of Vertex is largely explained due to its own pipeline and the arrival of new more promising products against Cystic Fibrosis (CF), a rare, life-shortening genetic disease affecting several organs of the body. Vertex thus chose not to move an inch and ignore the public outcry and calls for price reductions. The stubbornness of the company triggered a tremendous public backlash in numerous EU Member States. Vertex,

18 Beneluxa Secretariat. Terms of reference, p. 3 <https://beneluxa.org/sites/beneluxa.org/files/2018-10/180622%20Terms%20of%20Reference%20Beneluxa%20Initiative.pdf> (accessed, 11 December 2019).

19 Beneluxa Secretariat. About BeNeLuxA – press releases. Positive outcome of joint reimbursement negotiations on Spinraza, 12 July 2018 <https://beneluxa.org/archive> (accessed, 11 December 2019).

Currently, companies are free to charge as much as they wish for the medicines they bring onto the market, with prices only increasing.

Public authorities find themselves presented with a “fait accompli,” and can only try to bring the prices down. Instead, if governments were to jointly set and publicly announce well in advance a range of their willingness to pay for a certain product(s), the roles may be reversed.

understandably, did not seem to care at all.²⁰ Had Vertex caved in, it would have set a dangerous precedent, undermining its own position in the negotiations over the prices of its forthcoming products. In holding firm, Vertex managed to weather the storm and safeguard its leading position –and high prices– in CF care. Put simply, Vertex’s unwavering stance over Orkambi’s excessive price paved the way for an even higher price for its new product, a triple combination therapy²¹ with the potential to treat the vast majority of patients with CF since it targets the most common CF mutation.²²

The pharma sector is a highly secretive private business but transparency and accountability are fundamental principles of good governance, especially when vast amounts of taxpayers’ money are involved and access to medicines and health care are in question.

2.1. Controlled transparency: A step towards genuine accountability

For society, the problem with the deal for Spinraza is that the final price was not disclosed to the public. Improved transparency is indispensable to protect the public interest. The pharma sector is a highly secretive private business but transparency and accountability are fundamental principles of good governance, especially when vast amounts of taxpayers’ money are involved and access to medicines and health care are in question. Nonetheless, there is reason for some optimism. Since the onset of the regionals, the exchange of meaningful and sensitive information between Member States has increased considerably. Again, this is no small feat and should not be taken for granted, given the previous situation where governments had limited or no information at all about what neighbouring countries were paying for pharmaceuticals. The natural flow of information between countries, inaugurated and nurtured through the regionals is contributing to what can be described as “controlled transparency.” It is indeed a significant step towards real and comprehensive transparency, but it will take time to reach this goal.

This gradual, controlled transparency is a tangible break from the past and it makes companies nervous. For a very long time, pharma executives would tour European capitals and talk public authorities into signing secret deals with confidentiality clauses in exchange for so-called discounts (which in turn would be hard to verify due to the exact same secrecy provisions). The usual response, an integral element of their “divide and conquer” tactics, was “don’t worry about the (high) prices, we will provide you with the tools and methods to pay us as long as you keep the final price confidential.” This offered decision-makers and their political

20 NHS England calls Vertex an ‘extreme outlier’ in conduct of Orkambi negotiations, <https://www.pharmaceutical-technology.com/news/nhs-england-calls-vertex-an-extreme-outlier-in-conduct-of-orkambi-negotiations/>.

21 Branded in the US as Trikafta with a price of \$311,000 for a year of treatment, higher than for the price of its existing therapy Symdeko http://www.pmlive.com/pharma_news/vertex_scores_fda_approval_of_cf_triple_therapy_trikafta_1314110 (accessed, 11 December 2019).

22 It was submitted to the EMA for marketing authorization through an accelerated pathway in October 2019.

supervisors with a seemingly easy way out. This “quick fix” allowed them to save face by reimbursing products and offering access to treatments for their patients.

Today, the same public officials have realized they have been shooting themselves in the foot. The access and affordability challenges all EU Member States face bring the limitations and innate problems of these secret deals to the surface. There is now recognition that the confidential contracts have reached their limits and outlived their purpose, not least as there is little evidence they guaranteed affordability to begin with.²³

Does this mean that we will see an end to confidential contracts tomorrow or that public payers have come up with alternative schemes? No. The system of secrecy in which companies thrive took time to build and will take just as long to unravel. However, it has been –finally- acknowledged that the confidentiality avenue is a dead-end and secondly, there is no doubt that transparency enforcement will require international coalitions.²⁴ A single country cannot do it alone because no government wants to be excluded nor be singled out and subsequently punished by the industry, but a new “country” called Beneluxa could.

How will companies adapt to this information exchange? How will their pricing and product launch strategies be affected? These are key questions and their answers will depend on how quickly the regionals progress. That is why it is imperative to see concrete results from negotiations of more products. Companies and patients need to consider these initiatives as reliable, efficient and permanent, not just as some ephemeral experiments, nor as more of the same.

2.2. Inter-regional collaboration: The regionals work together

The Valletta Group of countries²⁵ has different features bringing together a larger, heterogeneous formation of smaller and medium sized EU Member States with Spain and Italy being the most important markets in this particular alliance. There are similarities between the workings of the Valletta and the Beneluxa groups but progress has been slower than in the latter.

23 Wenzl, M. and S. Chapman (2019), “Performance-based managed entry agreements for new medicines in OECD countries and EU member states: How they work and possible improvements going forward”, OECD Health Working Papers, No. 115, OECD Publishing, Paris, <https://doi.org/10.1787/6e5e4c0f-en> (accessed, 13 December 2019).

24 Industry Pricing Tactics Are Driving Europe’s Cross-Country Backlash <https://pink.pharmaintelligence.informa.com/PS141240/Industry-Pricing-Tactics-Are-Driving-Europes-CrossCountry-Backlash> (accessed, 13 December 2019).

25 Presentation on the Valletta Declaration (Lisbon, 29 November 2018) https://www.infarmed.pt/documents/15786/2835945/Paola_Testori_Coggi.pdf/2388762b-7506-4a78-9533-7422ea480c55 (accessed, 13 December 2019).

One way forward would be increased collaboration between the various regional clusters. They share the same challenges and can learn from each other, even if in some cases, they have competing interests. One can safely say that there is more that unites than divides them and the IHSI example highlights possible ways of flexible collaboration between them.

If the southern-Mediterranean club of countries is to survive and build on the progress previously achieved, it would need to reconsider its course. It has thus far proven impossible for all ten members to move forward simultaneously. Consequently, one could anticipate closer collaboration among sub-groups of countries which are members of the Valletta coalition. It would also be useful if the Valletta partnership moved away from the viewpoint that large volumes automatically mean better prices because they do not. In addition, the process should be depoliticized in order for the technical-policy staff to be allowed to do their work and to continue learning how to cooperate with their colleagues from partner member states. It is worth remembering that political endorsement can not only act as a catalyst, but also as an impediment.

2.3. A spillover effect into new EU legislation

It is too early to say but one could not exclude the prospect of a spillover effect of the regionals into future EU legislation. The ways and areas of collaboration within the regional clusters may trigger or guide new pieces of EU-wide legislation. This should not come as a surprise as the regionals reveal gaps and identify opportunities and best practices at national level. Some have used the joint HTA assessments carried out by Beneluxa and the Valletta Group to downplay or discredit the need for European regulation in this area. They claim that the intergovernmental avenue is delivering and governments can do it on their own without central, EU-driven action. As much as this may be true on the specific matter, there are numerous other areas in medicines' policies which can only be addressed through new or existing European legislation. The regionals will certainly drive and/or benefit from such a development.

2.4. Payers become buyers - but is it enough?

The press release that followed the November 27, 2019 meeting of Beneluxa offers a glimpse of the next steps for these clusters of regional collaboration. Beneluxa members came together with their counterparts from the Nordic Pharmaceuticals Forum,²⁶ yet another cluster of regional cooperation which deserves monitoring.

26 The Nordic Pharmaceuticals Forum (NLF) was established by Amgro, the Danish pharmaceuticals organization, in 2015. The objective was to set up an informal space for Nordic collaboration with focus on identifying opportunities, knowledge sharing, and work towards common Nordic solu-

A joint determination of the price range of what governments are willing to pay will be a step towards fair pricing and in theory a serious blow to the “sky’s the limit” aggressive pricing model pharma companies are employing.

Such a convening demonstrates that Beneluxa does not unavoidably need to grow (by adding new members) as it can successfully function via international coalitions. Yet the most important element in this press release is the explicit reference to the “general and fruitful exchange of thoughts on methodological approaches including willingness to pay.”²⁷

Currently, companies are free to charge as much as they wish for the medicines they bring onto the market, with prices only increasing.²⁸ Public authorities find themselves presented with a “fait accompli,” and can only try to bring the prices down. Instead, if governments were to jointly set and publicly announce well in advance a range of their willingness to pay for a certain product(s), the roles may be reversed.

Pharma companies would be obliged to explain to patients, and everyone else, why the range offered by –more than one- government at the same time is not enough. A joint determination of the price range of what governments are willing to pay will be a step towards fair pricing and in theory a serious blow to the “sky’s the limit” aggressive pricing model pharma companies are employing.

If successful, national social insurance schemes and sick funds will stop being passive payers and will start behaving more like buyers who proactively set the scene in medicines procurement. To give an example, if thanks to the joint horizon scanning information, a group of national buyers announces publicly and early on in the drug development process that for a said product they are willing to pay between 100.000-500,000 euro and the company presents a price tag of 1 or 1.5 million euros, the latter will have to explain and not the other way around. The aspiration is that the starting point of the negotiation at the regional or the national level will no longer be the excessive price demanded by the company but the range offered by governments through their clearly and jointly stated willingness to pay. Pharma’s position will be further weakened as they will get (more or less) the same response from multiple markets/governments at the same time. In other words, pharma will no longer be able to play governments off against each other. Meanwhile, Health Ministers’ negotiating stance will be strengthened as they will not be alone in challenging the unreasonable prices charged by companies.

tions. At present, representatives from Iceland, Norway, Sweden and Denmark are taking part in the Forum <https://amgros.dk/en/about-amgros/cooperation-partners/international-cooperation/> (accessed, 11 December 2019).

27 Beneluxa Secretariat. About BeNeLuxA – press releases. Cross-collaboration meeting on strategic decisions for pricing and reimbursement, 4 December 2019 <https://beneluxa.org/news1> (accessed, 11 December 2019).

28 BioMarin Explores Pricing Experimental Gene Therapy at \$2 Million to \$3 Million, World Street Journal <https://www.wsj.com/articles/biomarin-explores-pricing-experimental-gene-therapy-at-2-million-to-3-million-11579190318> (accessed, 17 January 2020).

Unsurprisingly medicines developers will seek to influence and preempt the definition and range of the willingness to pay. Others will appreciate the clarity and predictability this change will bring, even if it comes with smaller profit margins. Some will not be happy with such a prospect and will play hard ball. In practice, they will delay or threaten not to launch their products in the markets concerned; although this would be a high-risk endeavour. Nonetheless, if they were to choose this approach, they would be held accountable and suffer the consequences to their public image. Governments and public payers will no longer be the first ones to blame.

Another often overlooked, yet crucial element is that by stating governments' willingness to pay openly and before the start of the negotiations, the negotiations inevitably become more transparent. This is public information, not limited by the confidential provisions usually enshrined in the final deals. This is a fundamental shift compared to the status quo, and surely makes companies unhappy.

What's in it for the pharmaceutical companies? They will be able to see the end of the game and the whole package deal from the very start, not currently the case. Is it compelling enough, though, for all companies? Smaller pharmaceuticals should have more to gain as the regional avenue of negotiations saves them time and money while acting as a one-stop shop. That is not the case for the pharmaceutical giants for various reasons - not least the competition between their own sales offices. Big pharma is not ready for this avenue (yet) and it should not come as a surprise if they attempt to boycott the regionals, as it is safer for them to follow the unadventurous path of traditional bilateral negotiations.

Conclusion: It is not (just) about lower prices

All of the above points to the fact that Beneluxa is not just about lowering prices. In fact, one sees that the partnership is not even about joint price negotiations per se. Its emphasis is on optimizing the various preparatory building blocks that may or may not eventually lead to joint price negotiations. This is what perhaps makes it stand out compared to the other regionals. In the past four years, Beneluxa has created the conditions for a multi-layered, continuous cooperation and exchange of information amongst its members. The multi-faceted sharing of information worries companies. They have also had a hard time influencing these voluntary intergovernmental alliances,²⁹ which are still uncharted territory for them. Above all, they do not favour all these exchanges amongst governments as they erode the shroud of secrecy and pharma's information monopoly, which to this day, provides them with substantial comparative advantage in the negotiations.

The IHSI is a new additional platform of exchange. When all parties share the same information, whether or not multiple governments will conduct joint price negotiations in the end becomes a secondary issue. They can negotiate individually should they decide to do so but companies will in any case, expect to deal with a de facto united front thanks to the same baseline of information, reinforced by the jointly determined willingness to pay. Besides, joint negotiations and procurement are not impossible, nor a panacea; and experience so far points to several legal uncertainties and barriers in conducting them. That said, willingness to pay does not mean nor necessarily leads to affordable prices. Someone might well be willing, prepared or able to pay two million euro per patient to cure cancer, but this might also equal rationing access due to lack of affordability, effectively denying access due to cost, which is the challenge faced by most in the current system. Also worth noting is that the proposed way forward does not bring about a radical overhaul of the system. On the contrary, it may be considered to be a piecemeal solution which feeds into and maintains the status quo and the "innovation is expensive" narrative. Meaningful innovation should not have to be expensive - let alone, unaffordable and unsustainable. Innovation needs to be efficient, available and accessible too.

On the governments' side, there are three levels which have to be reconciled in order for these initiatives to deliver for society: a) technical, b) policy and c) political. For the regionals to grow and evolve, their success cannot depend on

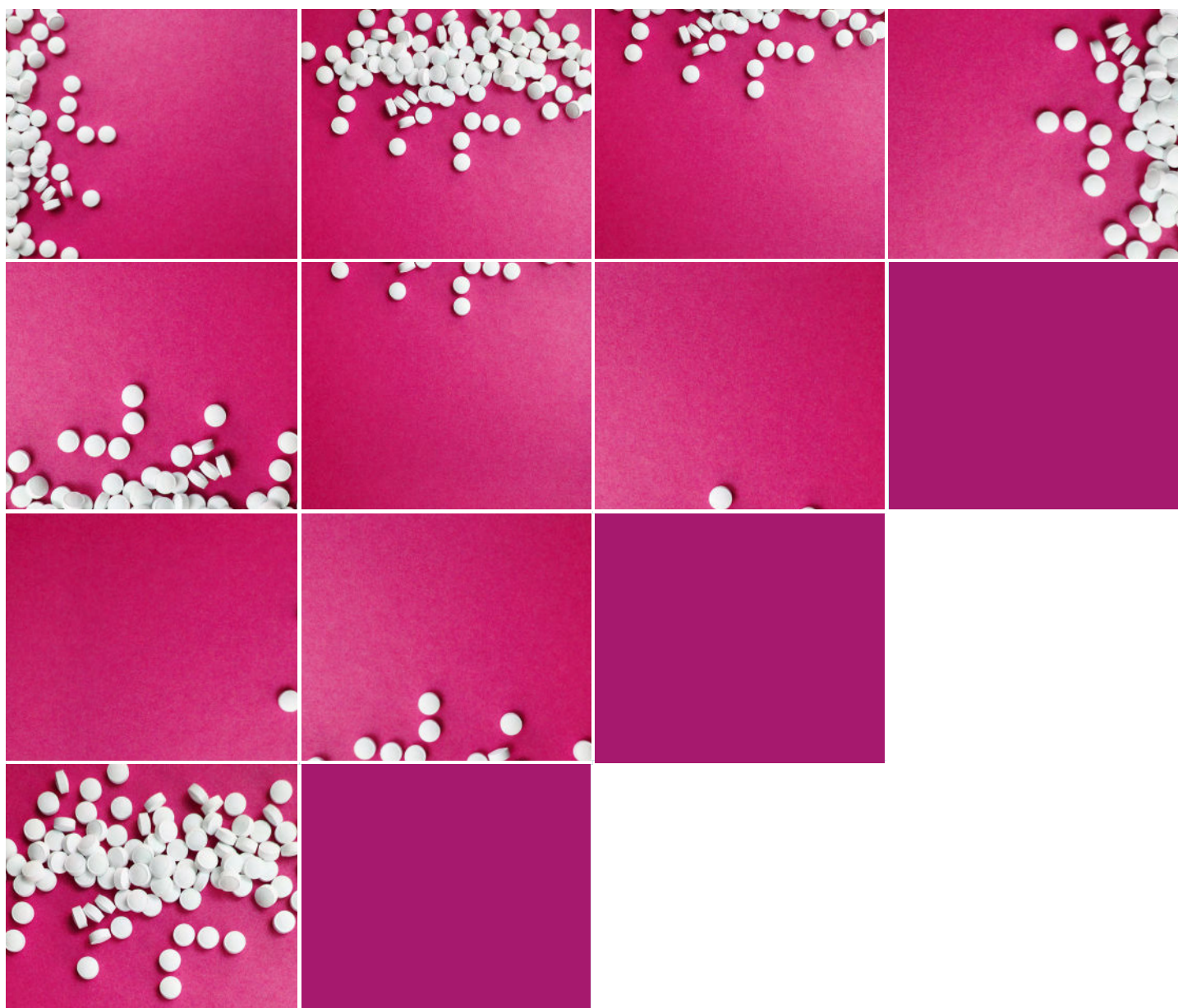
29 European Federation of Pharmaceutical Industries and Associations (EFPIA). Policy Principles on Cross-country Collaborations on Medicines' Pricing and Access by Nathalie Moll <https://www.efpia.eu/news-events/the-efpia-view/blog-articles/policy-principles-on-cross-country-collaborations-on-medicines-pricing-and-access/> (accessed, 17 January 2020).

the commitment of individual, visionary and hard-working civil servants in some capitals of the EU. Visionary individuals played an instrumental role in establishing and helping these partnerships take off, but permanent structures are required for their long-term survival and constructive impact. Benelux et al. need to be resistant and waterproof to political change and staff turnover. The three levels listed above should co-exist in harmony in order to seize the dynamics, translate the political momentum into concerted action and materialize the game-changing potential of these coalitions. If not, the regionals will become a victim of their own success.

Will Benelux as we know it today exist in five years? Probably not. Will the structures it set in place still be there and (better) used by a high number of countries? Undoubtedly, yes.

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EUROPEAN PUBLIC HEALTH ALLIANCE (EPHA)

Rue de Trèves 49-51 • 1040 Brussels (BELGIUM) • +32 (0) 2 230 30 56 • <https://epha.org/> • epha@epha.org