

TRANSCRIPTION:

International Cooperation for sustainable access to high-cost medicines

Presented by Francis Arickx and Marcus C. Guardian

**Social Protection and Health
Division Inter-American
Development Bank**

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International cooperation for sustainable access to high-cost medicines

August 25, 2022

Presented by Francis Arickx and Marcus C. Guardian

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PRESENTATION



Pricing & Reimbursement including joint negotiations

Presented by Francis Arickx

Introduction

Good afternoon ladies and gentlemen. I first want to thank the organizers of this meeting to give us the opportunity to share what we have learned and what we are doing here, very far away from you, in Belgium, the Netherlands, Luxemburg and Austria, in collaboration on the work we do on pricing and reimbursement of drugs.

I am going to be talking about the Beneluxa Initiative on pricing and reimbursement, including joint negotiations for drugs that is joint contracting between the different countries. Beneluxa started in 2015, so seven years ago more or less, between Belgium and the Netherlands. Then very quickly Luxemburg joined, and a little bit later Ireland and Austria also joined our initiative and since then we have developed a way of working in a number of domains all concerned with pricing and

reimbursement. I will be talking about this later. I am not going to concentrate on joint health technology assessment. I will be talking a little bit about it but not very much because Marcus Guardian is here, and he can explain you a lot more on what is happening in Europe on HTA. And I am not going to be talking about joint horizon scanning because, although we like to think that the international horizon scanning initiative is an offspring of the Beneluxa initiative, it has grown to its own maturity and is now a stand-alone, very solid organization and I will let Marcus tell you all about it.



The initiative

**Objective is
to create an overall 'win' situation**

- for patients: accelerated and affordable access
- for authorities: economy of scale (not only financially), knowledge building (joint registries), joining expertise
- for companies: faster access, lower administrative burden

Objective: to create an overall win-situation

I will be concentrating on the Beneluxa initiative. You have to remember that, first of all, this is a collaboration between countries. It started with a collaboration between administrations that have an authority on pricing and reimbursement in the different countries, but de facto there is a commitment of the governments of the different countries to actually work together. It is the governments, the ministers that have signed a form of an official agreement, without it being a convention, to work together, aiming at creating an overall win-situation, in the first place for patients to have a faster and affordable access to drugs they really need, valuable drugs, but also for authorities obviously the economy of scale (is important). If you negotiate for Belgium, which is a country of more or less 11 million people – Beneluxa has a potential of 42 million patients – so if you negotiate the price of a drug for 42 million patients that is obviously different than if you only negotiate for 11 million. But it is not only that, it is not financial, as I just explained. We are not trying to get the best or the lowest price possible. We are trying to create the best access possible for the most patients possible in our country. So, for authorities it is not only the economy of scale but also capacity building, joining expertise, joining knowledge or creating joint registries for orphan drugs, for instance. For companies there is also a benefit in it. As we work together, companies are not obliged to introduce claims for

reimbursement in the five different countries and do the work five times. They can do it once in a coordinated way in five countries at the same time. So, there is a benefit for the countries too.

**Proof of concept of a ‘coalition of the willing’..
to ensure access to innovative drugs at affordable cost**

Cooperation is part of the policy-mix

Information gathering on global markets benefits from joint approach

National context determines course of action

Joint negotiations only in select cases

What works?

Setting clear, common goals

Mutual benefit needs to be clear

Pragmatic approach - Focus on desired outcomes - Lean organisational structure

Proof of concept of a “coalition of the willing”

The Beneluxa initiative is, as I mentioned, a proof of concept of what we call the “coalition of the willing”. Those countries are a number of countries that are willing to work together to try to join forces to ensure access to innovative drugs as at an affordable cost. It is only a part of the policy mix cooperation. We do not collaborate on all our drugs and on all our claims for reimbursement for the sake of collaboration. We first look if there is a clear mutual benefit of just working together on the drug. We try to work as pragmatically as possible. If all the countries are not convinced (and believe) that for a certain file, claim or drug there would not be added value in collaboration, we do not work together. We focus very much, we use horizon scan, we use some form of horizon scan – not as sophisticated as what Mr. Guardian is going to explain you a little bit later. We use some horizon scan to try to detect those files and innovative drugs where collaboration could have an added value for the different countries.

We focus very much on desired outcomes (and) try to work with a very lean organizational structure, although in the meantime we do have terms of reference and a steering committee. We have a very well-structured – could be better – but well-structured organizational structure. But still we try to be as pragmatic and as fast as possible. Collaboration is also a question of coordination and a lot of logistics and it is not always simple to do that.

In practice: ‘coalition of the willing’ in 4 domains..

Health Technology Assessment

Horizon Scanning

Exchange of information on pharmaceutical markets, prices and disease specific cross border registries

Pricing and reimbursement including joint negotiation

In practice: “coalition of the willing” in 4 domains

In practice it is a collaboration in four domains. We call them also the main task forces.

We work together on health technology assessment and horizon scanning. We exchange information, for instance, on pharmaceutical markets but also on disease specific cross-border registries. And we do joint pricing and reimbursement processes and procedures, including joint negotiations for managed entry agreements.

I will be focusing basically on the last two and a little bit on health technology assessment, plus on one which is not on the list and which has shown, after a few years of practice, probably the most

important impact. I will be talking about that. It is the political or the policy development impact of the existence of a very narrow collaboration between five countries. The fact that by working together and having one voice we are able to influence policy and development of pharmaceutical policy in Europe – or if it is possible a little bit broader – that has also shown its value.



1

Joint Health Technology Assessment

 Beneluxa

Graslei, Gent (B)

Joint Health Technology Assessment

We are working together on five domains where the first one is the joint health technology assessment.

Based on previous experience/expertise with MEDEV, EUnetHTA, JA2, informal collaboration,...

Coherent and compatible with Joint Action 3, EUnetHTA2,..

‘testing’ models for implementation:

Mutual recognition of Assessments (operational)

Joint ‘writing’/editing (operational)

Sharing expertise (operational), eg. Dutch ‘Wetenschappelijke AdviesRaad’ of ZIN/Lux/Austria acts as external expert in Belgian reimbursement procedure

Basis of joint HTA

Actually, this is not new. In Europe there has been a collaboration for a long time in different countries on health technology assessment (HTA), and Marcus can explain that too, but I don't think he is going to focus on that. In Europe we have EUnetHTA and we have EUnetHAT2. There is the European Commission initiative now actually putting a system into place for joint health technology assessment that is going to be completely operational probably only in 2030 but will be showing its first results as from 2023/24 forward probably. So, this is not new. What we are doing in Beneluxa in joint HTA is where the Joint Action 3, EUnetHTA, MEDEV and the other joint initiatives and collaborations for HTA do not give us the information we need. EUnetHTA, the European system, is going to concentrate, in the first place, on oncology drugs. For all the rest have to do the work alone or by ourselves. If we have a claim for reimbursement we look there and if we can work together then we actually we work together.

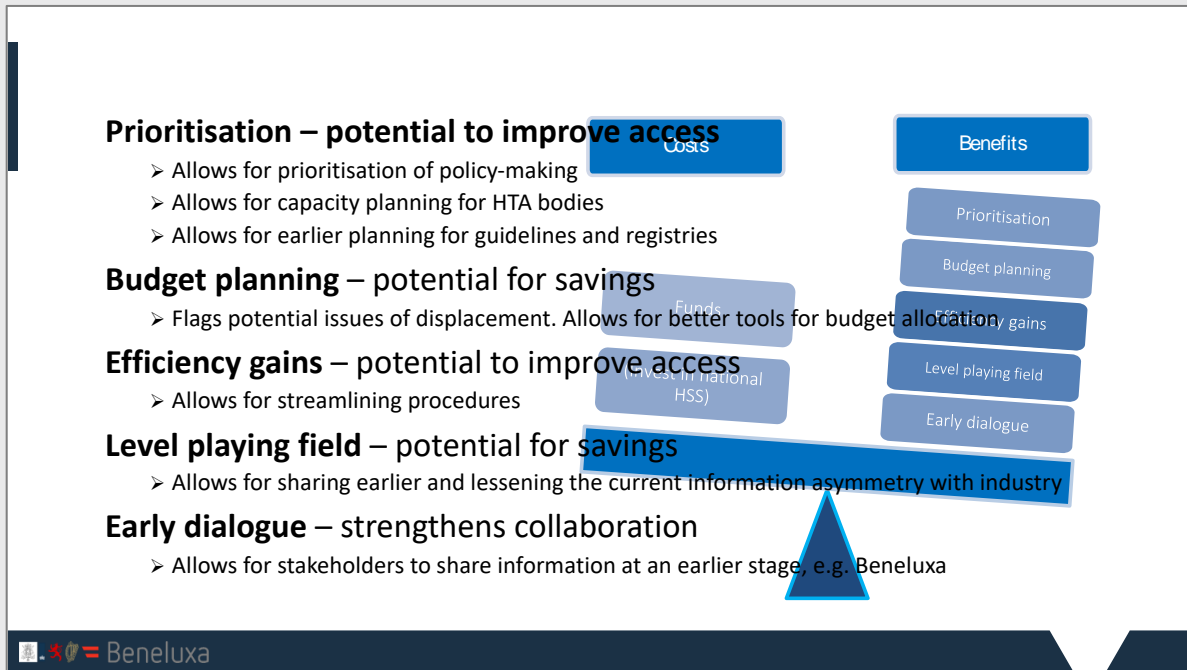
The second big difference between MEDEV, EUnetHTA and the European HTA system and the Beneluxa is that we test different models or other model for joint working, other than the joint writing and

editing of HTA reports that is the standard of EUnetHTA and the European HTA that is in development. We use techniques of mutual recognition of assessment reports. That means that if another country has already written a report we try to reuse what has been written or completely adopt the assessment report that has been written by another country. For Belgium, for instance, in our health technology assessment process we need to, and we are obliged to, consult external experts, so do some sort of peer reviewing with external experts here in Belgium, but with Beneluxa that gives us the opportunity to also consult scientific organizations in the other countries of the Beneluxa collaboration as external reviewers, or the Dutch Scientific Council can be an expert, Austria has acted as an external expert in Belgian reimbursement processes, and the other way around. So apart from doing the work that is not being done yet by the European HTA collaboration, apart from that we also try to test out other models of collaboration. That is a demonstration of trying to build capacity in HTA and build expertise and experience in doing that HTA.



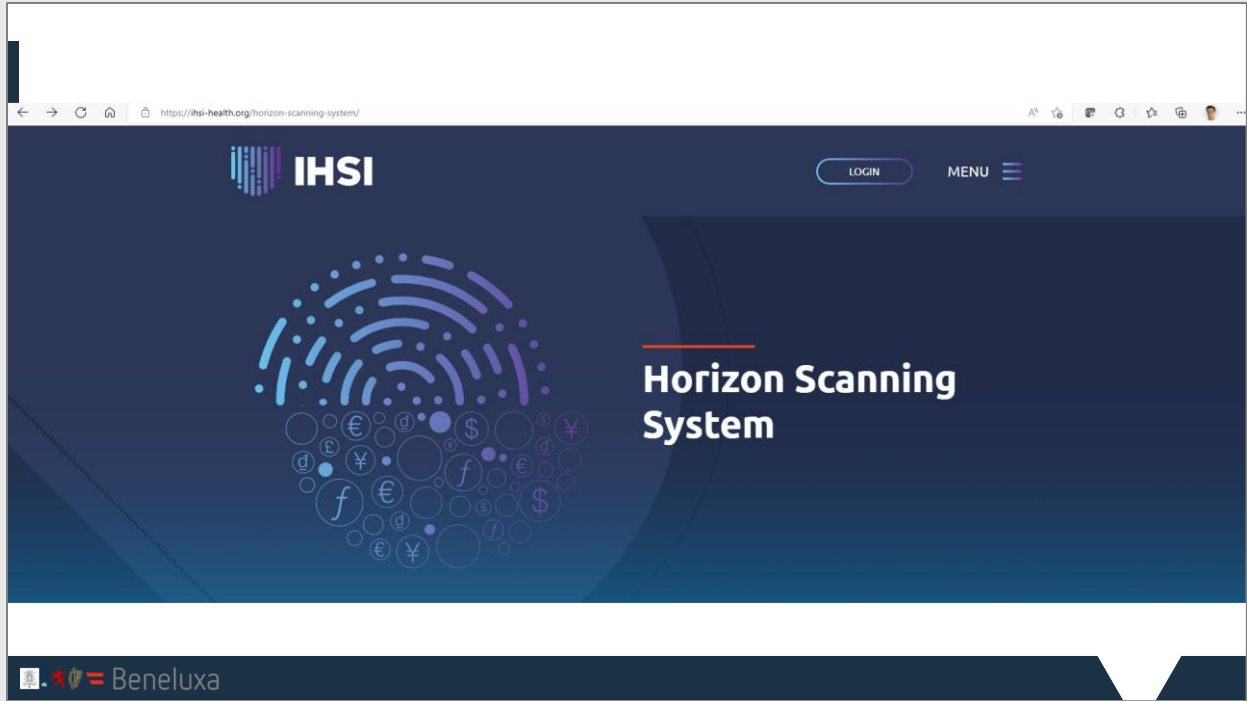
Joint Horizon Scanning

The second domain where we try to work together, or we work together, is the joint horizon scanning. Actually, we started doing that in 2015. From that grew the idea to make this a much bigger initiative.



Joint Horizon Scanning

That is what horizon scanning can do. Mr. Guardian is going to explain that a little bit too, so I am not going to go into detail. (This slide shows) what it can lead to, it has (information on) what the future can bring and it has the obvious added value for each system that has to prepare or be ready for what is coming and try to prioritize in giving access to these innovative drugs. You know what the benefit of that is.



Horizon Scanning System

Mr. Marcus Guardian is going to explain you a lot more and in detail what the International Horizon Scanning Initiative is.

3

Information Sharing

 Beneluxa

Keizersgracht, Amsterdam

Drug consumption

Prevalence and burden of disease

Best practices in (health budget) management (e.g. hep. C approach, reference pricing, generic policy, biosimilar policy,..)

Post marketing evidence gathering (e.g. **registries**)

Policy questions (e.g. KCE-ZIN Study 2013-03-HSR_on drug pricing scenarios)

 Beneluxa

Information Sharing

Another domain where we work together is information sharing on drug consumption, for instance, prevalence or burden of disease but also best practices, for example on health budgets, the approach

on Hepatitis C. We organize webinars where you are very welcome if you would like to join them, where we try to exchange information between the five countries and from time to time, when we want to have a much broader discussion, we open these internal webinars to external people. You would be very welcome to join us there just to learn from each other on best practices for instance for generic policy, biosimilar policy, pricing policy or managed entry agreements.

We have installed, and that is also part of the information sharing group, two international registries, one for multiple sclerosis and another one for spinal muscular atrophy, also as part of the information sharing group. And then the discussions on policy questions and communications and I will be coming back to this a little bit later.



Joint reimbursement and negotiations

Fourth, and probably the most spectacular part of the collaborative work, is the work on joint reimbursement and joint negotiations, where we try to work together on decisions for the reimbursement of certain drugs and on negotiating managed entry agreements for these drugs.

The Process – general information

- No joint 'BeNeLuxA' reimbursement regulation - **national regulation will be followed**
- In case of a successful joint assessment and negotiation, a **decision on reimbursement** will be made **simultaneously but separately in the participating countries**.
- A joint reimbursement negotiation without a joint HTA will not be accepted
- **Opt out possibility**
 - Any reached milestones, such as the result of the joint assessment will still stand, and both countries commit to upholding the projected timelines to the best of their abilities in separate procedures.
 - Day 0 of the joint procedure will still count as day 0 in both countries if the procedures are separated.
- In general, Luxembourg does not (yet) actively participate in any joint HTA & negotiations pilots. Luxembourg can act as an observer or an external expert opinion. Luxembourg does receive the joint assessment report (day 90).

The process – general information

You have to be warned first that there is no such thing as a Beneluxa reimbursement regulation or process. We are still thinking if we want to install that or not. It is each time the national regulation that will be followed, but what we do in practice actually is that we prepare, very much in advance, the file in the way in which we will process it. And then we put together and synchronize all the processes in the different countries and coordinate all these processes and we do have one red line running in between that reports to all the different countries simultaneously.

There are a few or a number of conditions on that joint reimbursement and joint negotiation. One of those is some sort of political commitment and it is quite important actually, that (for) any decision on reimbursement, if there has been a successful joint assessment and negotiation, there is a joint decision on reimbursement or non-reimbursement simultaneously but separately in all the participating countries. And one of the pre-conditions is that before we start with the joint process on pricing and reimbursement we do a joint health technology assessment, because we have learned that it is completely impossible to have a joint decision or a joint negotiation on the reimbursement of a certain drug if we do not agree on the value or if the idea of perception of the value or the added value of that specific drug cannot be shared between the different countries. If we start with different

positionings between different countries it is impossible to reach a common result if you start negotiation. There is at all time an opt-out possibility. This is a voluntary collaboration between countries and also a voluntary collaboration for the participating companies, so at any point in time – which has only happened once – at any reached milestone, for example after the result of a joint assessment, the company can decide not to proceed with the joint process but continue in the five countries separately. That could be possible, for instance, if the result of the joint assessment is not very positive for the drug. So, the companies always have an opt-out possibility without losing the time since that the joint assessment is going to be repeated so there is no time lost for the company.

In general Luxemburg did not participate actively in any joint HTA negotiation because Luxemburg is a very small country they acted as an observer and as external experts and they do receive joint assessment reports. They just participated, and they are now just developing a system for managed entry agreements in Luxemburg.

The Process – general information

By structural exchange of information and testing through pilots of procedures or scenarios for joint negotiations that lead to financial arrangements and contracts

That are compatible with and respect national legislation and competence and responsibility of the different stakeholders in the decision making process

That respect confidentiality of the commonly negotiated financial details (..nothing changes compared with today..)

THIS IS NOT JOINT PROCUREMENT

THIS IS NOT LIMBO DANCE BARGAINING.. how low can you go..

The process – general information

What do we do? We exchange information and we test through pilots, procedures and scenarios for joint negotiations that lead to financial arrangements but that all respect two things: the national

legislation and the authority and responsibility of all the stakeholders in each decision process in each country. That requires a lot of coordination and synchronizing but it is doable, and it actually worked very well for negative decisions and for positive decisions, for instance for SPINRAZA for the spinal muscular atrophy and recently for the very expensive ZOLGENSMA drug. And we respect completely and work in complete respect with the terms of confidentiality that for managed entry agreements the contracts that we make with the companies are confidential, stay between the governments and the decision makers themselves and the company. That confidentiality is maintained. Obviously, the countries that are on the table in the process know the financial arrangements of the other countries, but members of the Beneluxa consortium that do not participate in negotiations for a certain drug are not informed about the results or the negotiated financial details. Nothing is shared. So that does not change anything, there is no difference between local negotiations and a Beneluxa negotiation. These are two things. This is not joined procurement. The procurement still happens in every country, officially in every country separately. This is joint negotiation on procurement and this is not – sorry for the terminology – trying to get the lowest price possible or going as low as you can. This is also something that Mr. Astorga has explained a little bit. We are not trying to get the lowest price possible, we are trying to get the fairest price possible and the largest, the broadest access possible for all our patients in the whole group of the five countries which are working together.

Eligibility for a joint procedure

- An assessment and if applicable, a negotiation should fit within the national legislations, eg:
 - > intramural (hospital) pharmaceuticals eligible for the “lock procedure” in the Netherlands
 - > pharmaceuticals submitted as Class 1 or orphan application in Belgium
 - > ..
- Pharmaceutical not explicitly reimbursed for that particular indication in a country of the collaborating HTA partners
- The Steering Committee needs to agree with the selection of the pharmaceutical

Positive elements in selection

- high unmet medical need
- recent date of EMA-registration/EMA-positive opinion
- expected added value
- satisfactory degree of evidence
- willingness of the manufacturer to submit a draft submission file
- ..

Negative elements in selection

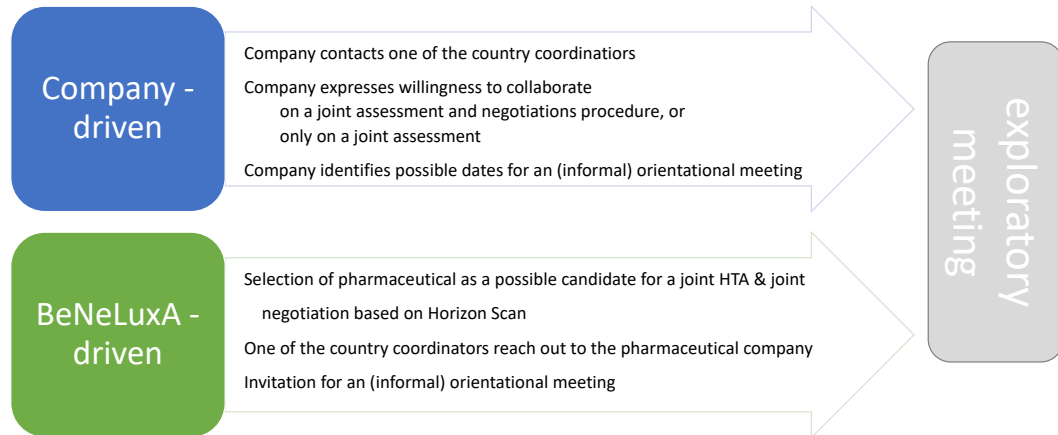
- previous refusal of reimbursement in a country of the collaborating HTA partners
- unwillingness of the manufacturer to commercialize the pharmaceutical in a country of the collaborating HTA partners after a positive decision on reimbursement
- ..

Eligibility for a joint procedure

As I explained before we do not accept all files to enter into this process. There is some sort of filtering for eligibility for the joint process. If a pharmaceutical is not reimbursed in a certain country or cannot be reimbursed in a certain country obviously it goes out. We have a steering committee that has to agree on the priorities that are proposed by the main task force that is doing the pricing reimbursement. And if an assessment is applicable a negotiation should fit within the national legislation. So, we are not aiming at orphan drugs, which are drugs with a very high medical need. If there has already been a `no` in a certain country, then the possibility of having a Beneluxa approach is very low. We work with drugs for which, based on horizon scanning, we expect some sort of added value and we try to see if there is a satisfactory degree of evidence, so a HTA that could lead to a quite solid assessment, a positive or a negative one, these enter into the eligibility criteria for a joint process.

Contact procedure

- Start of early dialogue on a possible joint HTA & joint negotiation - two scenario's



Contact procedure

It can be company-driven. Companies can contact us (saying): “We have a product for you. Would you be interested in doing this together?” And, as I explained before, there is an opt-out possibility for companies at any point in time. Or it can be Beneluxa-driven. We do a very fast, quick and long list of horizon scanning. Based on that we make a short list of possible candidates and then the steering committee decides on which candidates we contact to do joint HTA and then joint negotiations.

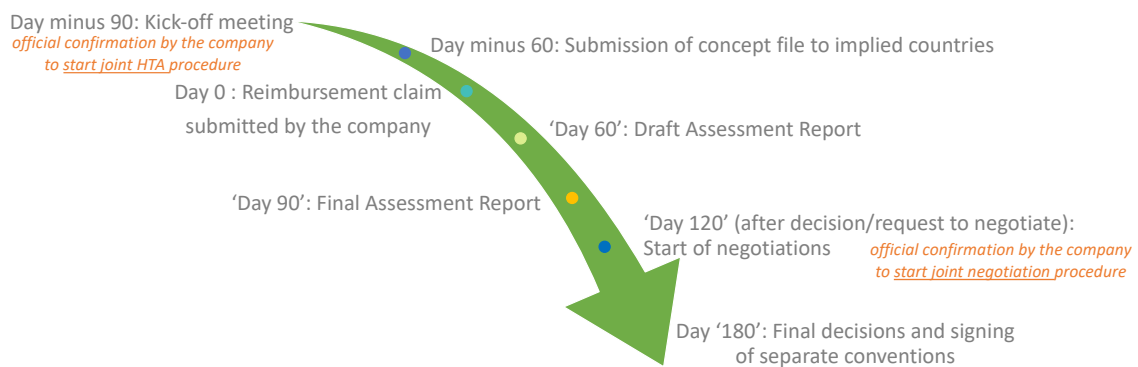
Requirements for joint reimbursement file

- Around time of CHMP opinion: **draft submission file** in all implied countries
- Day 0: (**simultaneous**) submission of the **identical** reimbursement claims in the implied countries
- The dossier must contain **all necessary documents** for participating countries according to national legislations
- In general:
 - A **country specific budget-impact analysis** is required in all cases.
 - The obligation of a **pharmaco-economic report depends on national legislation**. However, it is highly recommended to include one model split out using country specific data.

Contact procedure

Projected timing

- A timeline will be established taking into account national procedures and calendars of implied countries. 'Days' mentioned below act as an indication. Timing in all implied countries will be aligned.
- All parties commit to give maximum effort to reach on optimal timing.



Projected timing

I am going to skip a few slides and the organizers assured me that you will have access to all the slides, so you can read them at your ease.

In practice we start actually quite early in the process, long before marketing, to look at which drugs would be eligible for a joint negotiation. We contact the companies and we try to do kick-off meetings where we try to have confirmation from the company that they are interested in a collaborative approach. We try to fix a calendar where we take into account all the processes of the different companies and an agenda when the company can expect what kind of document from the Beneluxa initiative. So, if then, at day zero the reimbursement claim is issued and that is based on a concept file that is introduced at day 90 and at day 60, where we already have a first look if it is doable with the information that we have. If the process starts at day zero, there is a guarantee that at say 180, and this is a calendar day, the final decision and signing of the contracts will be done. So (this involves) synchronizing a lot of different processes and a lot of coordination between different companies, between the administration of different countries but an added value or benefit for the company because only one company will take the lead and will take the lead in the negotiation process. The other countries participating in this process will be around the table, but they will not speak out. This is done in preparatory work. There is a single point of contract and a single speaker who speaks on behalf of the two, three, four or five countries that are working together at that point in time.

the Negotiation framework of participating countries

- Negotiation framework is set up in close collaboration with all participating countries
 - All participating countries have **equal 'say'** in setting up negotiation framework
 - Target of framework = **same negotiation strategy /principles valid for all participating countries**
 - Framework leads most often to country specific net budget
 - **Not a bargaining** negotiation process
 - Arguments are given why deal is fair and defensible
 - **Implementation may differ** (eg in absolute number of discount or net budget)
- All participating negotiators ask for a “mandate” from their decision making authorities
- All participating countries give their agreement to written proposals sent to company and representatives of all participating countries are present in face to face meetings with company

➔ **Challenge on organization and coordination**

Projected timing

So, what is needed and what have we learned? It is a challenging negotiation and coordination. What is needed is a very solid negotiation framework and that is done in advance. It is actually a negotiation between the five countries of what position to take around the negotiation table where the company is present. Actually, the work of the negotiators is very well prepared between the different countries, so we are not surprised by the position of one of our colleagues in another country at a certain point in time. And all countries at each point in time have an equal say in setting up that negotiation framework. What we have to understand about the negotiation framework is, for instance, what the target population is, whom we want to provide access for, what the budgetary limits are that we have per country, and what the maximum price or the maximum cost is that we want to (accept), to what indications we want to restrict or in what way do we want to restrict access for certain patients and what is the maximum price or the maximum cost that we are willing to pay for one patient. In this negotiation framework we try to come to a consensus between the five countries and with that consensus we can go to the negotiation table. Also – and that is also on this slide showing on the second bullet – all participating negotiators ask for a mandate from their decision-making authorities. What does that mean? Actually, we are administration negotiators on behalf of our ministers. We ask

our ministers explicitly, we prepare the proposal that we will put on the table and then ask our ministers to agree on that proposal if we can defend that proposal. We ask for a guarantee that if we reach an agreement between the five countries and the company, within certain limits and a little bit of a margin for maneuverability, that the minister is not going to deviate from that agreement. And up to now we did get that mandate before we started negotiating.

Key learnings on joint P&R for both countries & companies

- Early alignment on local procedures
 - Timing of (joint) decision-making on mandate/WTP
 - Manage expectations
 - Communication 'rules'
- Early alignment on a joint framework for WTP
 - Early alignment on what elements to consider, e.g. cost-effectiveness, 'fairness'
- Early discussion on country-specific differences
 - Differences in local (reimbursement) policy or geographic differences may affect the WTP

Key learnings on joint P&R for both countries and companies

What are the key learnings for the joint process of pricing and reimbursement for the countries and the companies? You need to align very early your local procedures because there is a lot of work of coordination and synchronizing. It is also about managing expectations and it is also about being very clear on who can communicate, what and when. This is especially necessary if you have to communicate negative decisions.

Early alignment of the joint framework for a 'Willingness to Pay' (WTP), for instance, is very important. That is what I explained to you a little bit earlier. An early discussion on country specific differences is also important and the political mandate, the agreement of the ultimate decision maker, in our case it

is all ministers, on what we are going to negotiate for or trying to defend, is important too. So those were the four big topics we are working on.



Key Success Factors

Mutual and common understanding on value and appraisal assessments – early dialogues on ‘willingness to pay’.

Benefits must be clear for all partners (economies of scale and knowledge building; timely access;...).

Pragmatic approach, trust and mutual commitment.

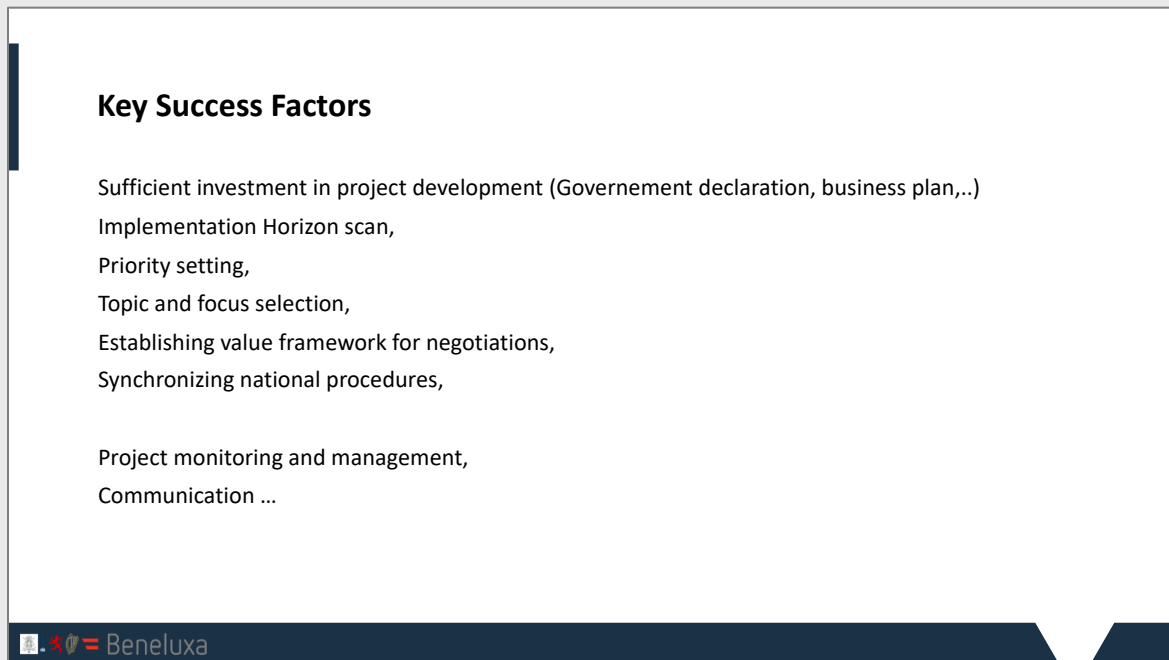
Political support (mandate, responsibility and accountability).

Solid founded and well documented framework.

The lessons learned - Key success factors

So, what are the lessons learned and what are the key success factors? It is a mutual, common understanding on value and on appraisal, both on willingness to pay and on the assessment. If you cannot agree on a common value for a certain drug you will not be able to jointly negotiate. The


benefits of the collaboration must be clear for all the partners. If there is no benefit in working together, don't do it - work alone. There is benefit in joining forces but not in all cases. Be pragmatic. Trust is a crucial element and the political support is obviously very important. A solid and well documented framework is also important. We are working in a lean structure and we are very flexible - a little bit too flexible - but some sort of a steering committee and organizational structure is quite important, and terms of reference are quite important.



Key Success Factors

- Sufficient investment in project development (Government declaration, business plan,..)
- Implementation Horizon scan,
- Priority setting,
- Topic and focus selection,
- Establishing value framework for negotiations,
- Synchronizing national procedures,

- Project monitoring and management,
- Communication ...

 Benelux

Key success factors

And sufficient investment in the project development (government declarations, business plans, implementing horizon scans, priority setting and communication) are very important.

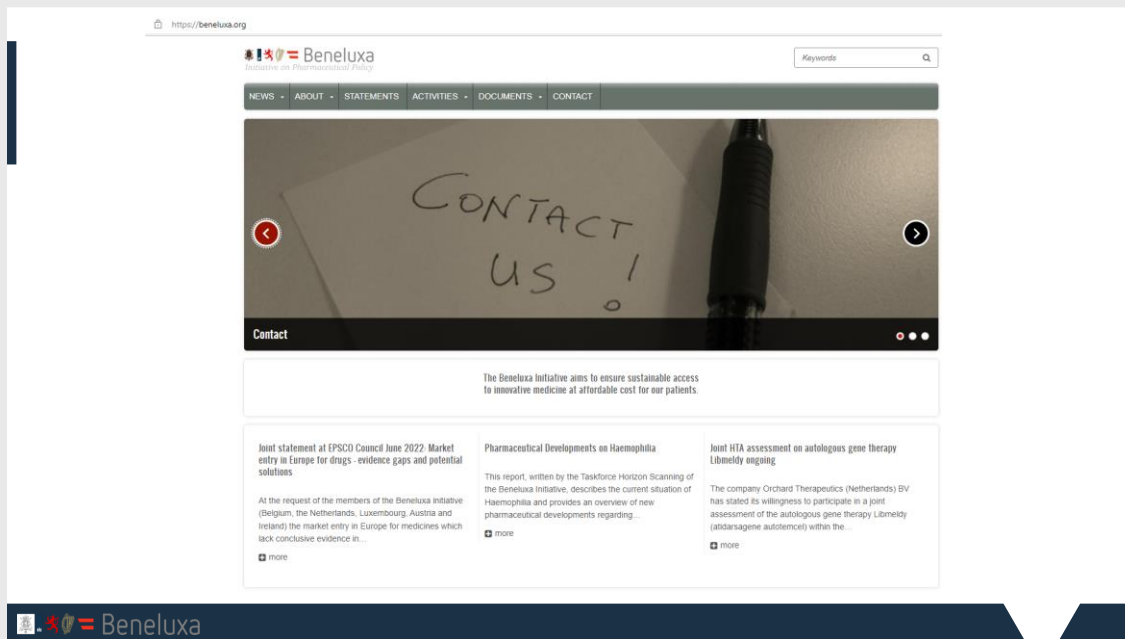
the Verdict

 Beneluxa

Rotterdam Central Station (NL)

The verdict

So, what is the verdict? It is a bit difficult to explain. It is an initiative we initiated, and it is a very big success. We consider it to be a success not only for operational domains.



Beneluxa website

There is a Beneluxa website: www.beneluxa.org. There you can find additional information. I would just like to mention two more things. Apart from the operational part of the joint HTA, joint horizon scanning, the joint pricing and reimbursement decisions and the managed entry agreements, there is also the political power. The five ministers are supporting each other when they have a message that they want to deliver to the world, to the WHO or to the European Commission. They can and do talk to each other in the Beneluxa contracts. They meet physically, and they speak to each other and they are able to make joint statements, for instance on the EPSCO Council - that is now on the website - but also on pharmaceuticals. You have the new Covid19 monoclonal antibodies that have been purchased by the European Commission recently and centrally. The five ministers were able to try to convince the European Commission that also for these monoclonal antibodies those new drugs some form of HTA is necessary before decisions are taken or before purchasing these drugs.

A little bit later we had the joint statement on the pharmaceutical forum. I just wanted to mention that and that is the last thing I wanted to say, that apart from operational benefits there is also the political benefits. Small countries working together have a louder voice if they work together.

International Horizon Scanning Initiative

Welcome



International Horizon Scanning Initiative | www.ihsi-health.org

International Horizon Scanning Initiative

Presented by Marcus Guardian

Introduction

Thank you so much and thank you for having me here today. My name is Marcus Guardian. I am aware of the time constraint. So, I will try to shorten my originally planned presentation. My normal strategy for that would be that I just talk much faster and try to go through the same amount of slides than I would do in a smaller period of time. The fact that this is translated, I don't want to put that burden on the translators, who are doing a fantastic job, and who I would really like to thank. So, I will skip a few slides and I will focus on certain elements that I feel complement what Francis already shared with you. And if you have any other questions or are interested in these topics and more details, specifically when it comes to technology underlying or any other elements, please feel free to contact me directly. Our contact details are at the end of this presentation.

This presentation will also be shared with everyone. I understand this is very kindly facilitated through Katherine. Thank you very much for that. And without further ado I will just go into the presentation.

IHSI – Members

1. Belgium
2. Ireland
3. Netherlands
4. Austria

BeNeLuxA

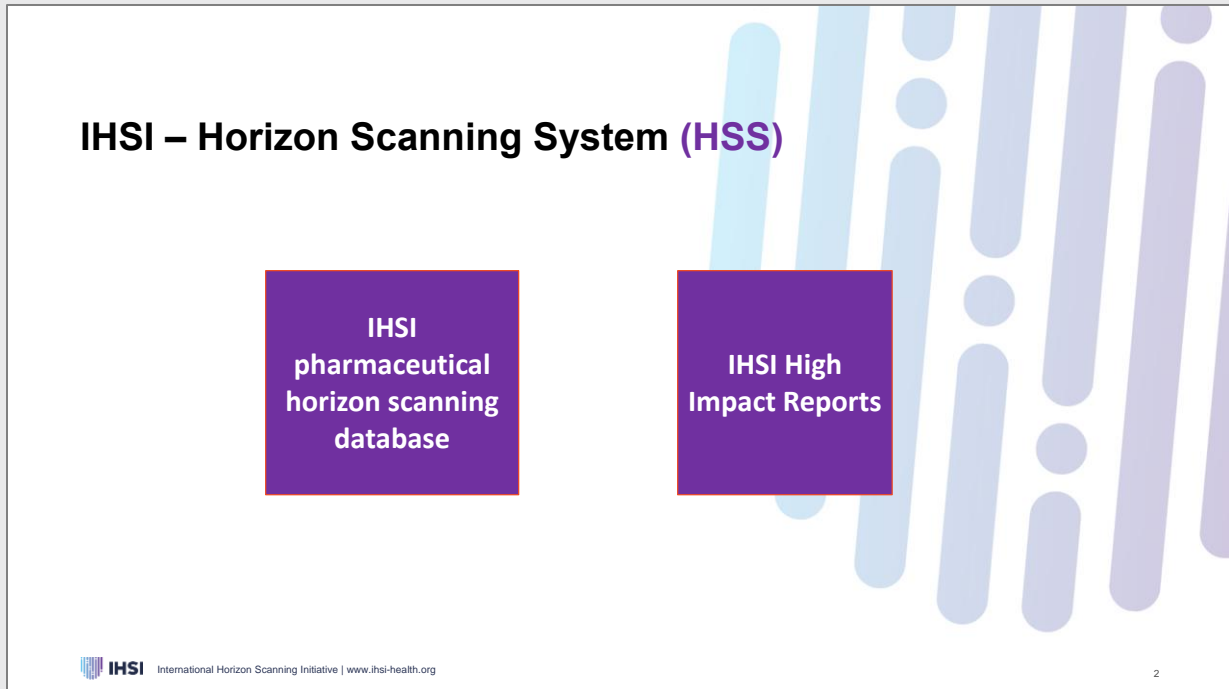
5. Sweden
6. Norway
7. Denmark
8. Portugal
9. Switzerland

 **IHSI** International Horizon Scanning Initiative | www.ihsi-health.org

2

IHSI members

Let me come to a similar starting point as Francis did. The International Horizon Scanning Initiative is born out of regional collaboration and that is very important. That has a few relevant structural consequences, one of them being it is a member state-driven and owned separate legal entity. We created a separate legal entity. It takes the form of an international organization. Member states and member state ministries have come together and are the signatories to this organization. It is fundamentally important that member states are in the driving seat. You can see the four founding members or the four BeNeLuxA members of the organization. We have grown significantly beyond that. We will have three new members hopefully joining this year and we hope to continuously expand our membership. Here you have to keep in mind that at the moment it is looking very European-focused. This is simply born out of the fact that we started here. We are currently also talking to partners in Canada, Australia, and other countries and try to expand this field.

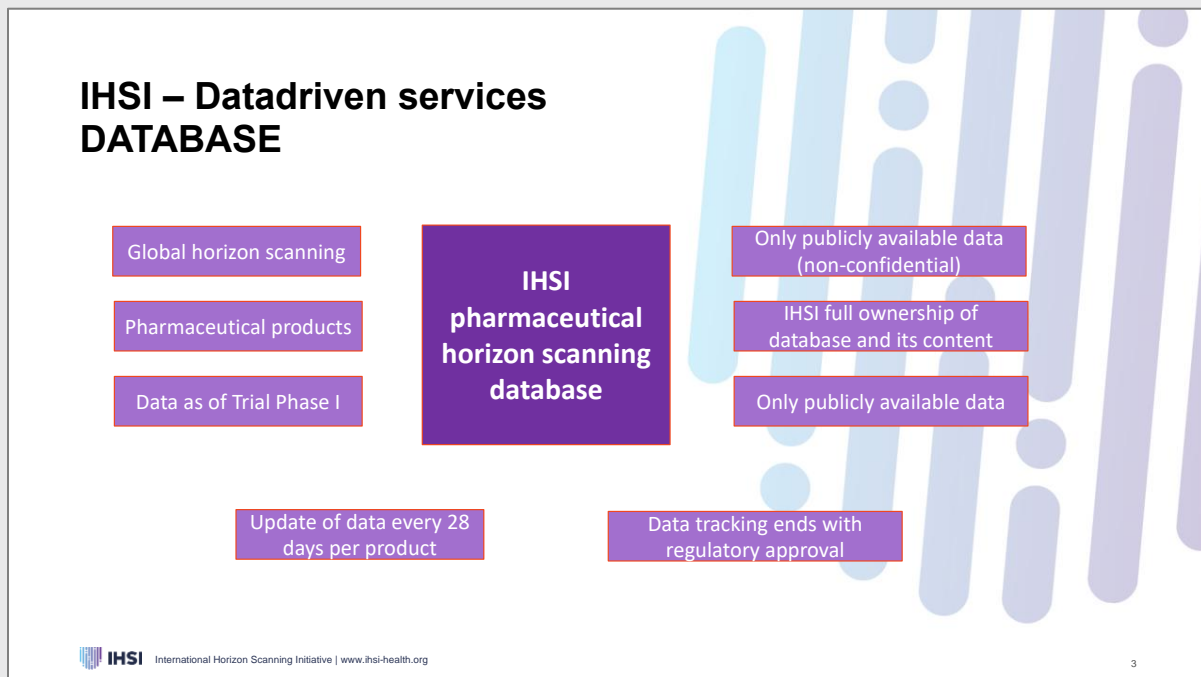


IHSI Horizon Scanning System (HSS)

And I would like to very briefly zoom into what IHSI is, what it does and what it does not do. IHSI as such, and that is important, is a data-driven and data-focused service provider. We provide a whole lot of information at a very high quality and speed to, for example, our decision makers in Beneluxa or in any decision-making organization within our member states. That is our purpose and our job. We try to provide data that allows decision makers to be significantly more informed, informed earlier, and thereby being able to negotiate prices better or more transparently, be aware of future trends and of health system changes and the full spectrum of things that our data provides. And we do this by two main service products. IHSI, as an organization, has created the first global pharmaceutical horizon scanning database. And I will come to that in a moment. But this is the backbone of everything we do. This database provides all the information you can dream of and we dreamt of when we started this.

And at the same time, based on this database, we very carefully analyzed the data that is put in there and we created what we call the IHSI High Impact Reports. So, for the entirety of our medical categories we screen them, we produce every year two reports per medical category which highlight specifically compounds that for one reason or another, be it price, be it mode of deliver or be it impact

for specific or larger patient groups, we consider as a high-impact compound that is coming our way. And we share this information with our members. And this allows them to prepare individually for member states, for organizations within our member states or jointly in policy decisions, as you saw maybe in Benelux, to prepare for them better and be ready for what is coming their way.



IHSI data-driven services database

I will zoom in, again very quickly, into the database. And after that I will go to the high-impact reports and from there I will build a bit more and I will try to finish in about six or seven minutes, so we have some time for questions.

The database and the underlying technique (are also explained on the slides) and I will not come to these slides in my presentation now, but they are part of the slides, so you will find that information later and if you want to look at it you are free to browse. I just provided them, but I will not talk about them now. However, the underlying technology is cutting-edge. We have been working on this database for a long time. We are working together with outstanding IT experts and teams around the world. We have poured significant resources into the establishment of this database and had a

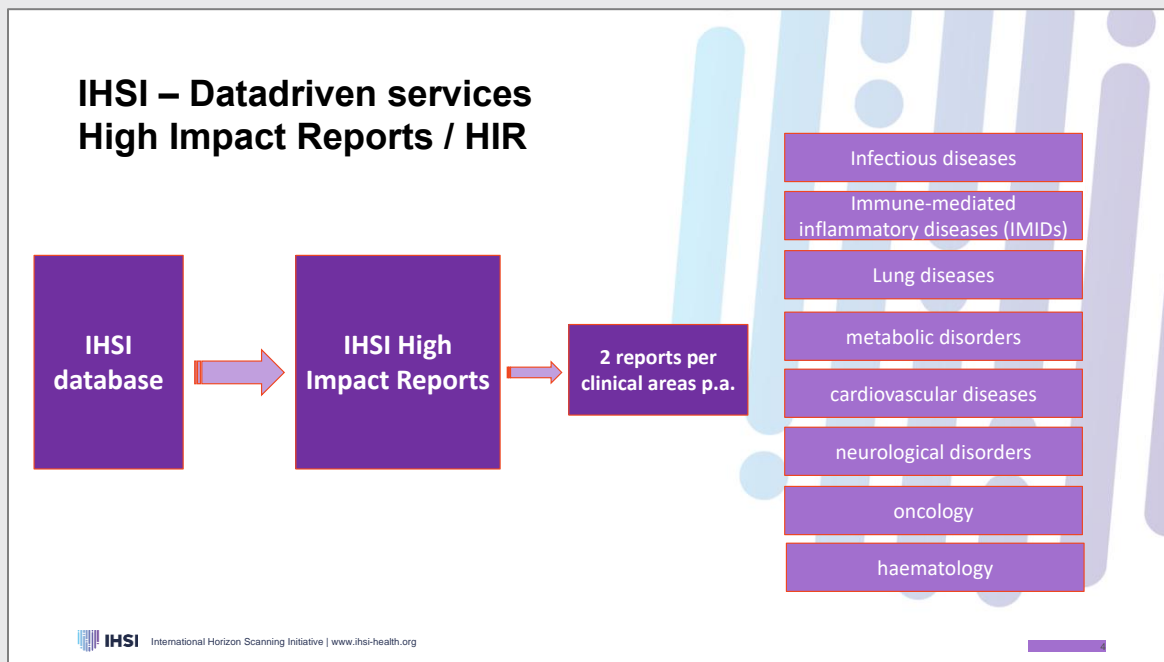
preparatory work phase of three years, so in designing and agreeing on which data needs to go in there, how the data is being collected and represented. All these decisions were done jointly among the member states and really show how strong such regional cooperation can form and transpire into something very concrete and very technical even and that allows us to create a very unique product. And we say it is very unique because you won't find this sort of database anywhere else.

And I just want to go through the cornerstones here. So, we look at all new pharmaceutical products that are in development as of trial phase one. That is very important. And globally we try to really capture any development in the Americas, Europe, Asia or anywhere else in the world. At the same time we focus on pharmaceutical products. We are currently discussing whether we will expand horizon scanning activities for medical devices in the future. So, that decision would probably be made next year. But at the moment it is pharmaceutical products. (It is) important (that) as of trial phase one all data that we can find will be visible in the database. It is crucially important for us that we only use data and information that we scour across the globe that is publicly available, that is not only trial data, that is not only public regulatory information, that it is not only information that is shared in nature and science publications but also SEC filings or any other information that we can get our hands on and can produce liable information. And it is not that we sit there, or our team sits there and go through books over and over again. Of course, there is a lot of NLP programming behind it. There is a lot of machine learning involved and we have created a mixture of exactly that – actual thematical experts reviewing the work of machine learning AI and NLP products that we have put together, creating a database that with every iteration increases in quality, increases in precision and we are quite proud of what we have achieved there. So, you see me here making a little bit the case for it but it was quite a piece of work and we are quite happy about what we have achieved.

Equally important, since it is publicly available data, IHSI and its members have full ownership of over its content. It is important for our members so that they can cite freely any information of the database in their own publications, in their negotiations, strategies, their annual papers - be it for ministries of health or be it for university for academics – so this is really important. We want to be able to give data without any constraints to our members so that they can freely analyze, build models and create the best data structure for their own national, regional or individual settings. And the public availability, I mentioned it twice, but it is a focal point for us.

We start with trail phase one, we end our database, so we stop the tracking of a product once it hits maturity and receives regulatory approval. But just for your information, the only technical update here would be that every product is reviewed every 28 days. So, every compound that gets into the database with its first mentioning is rechecked for very specific information fields every 28 days. So, no compound has information in the database older than 28 days. With that we really capture all new developments for each new product and we keep these updates for the entirety up to regulatory approval.

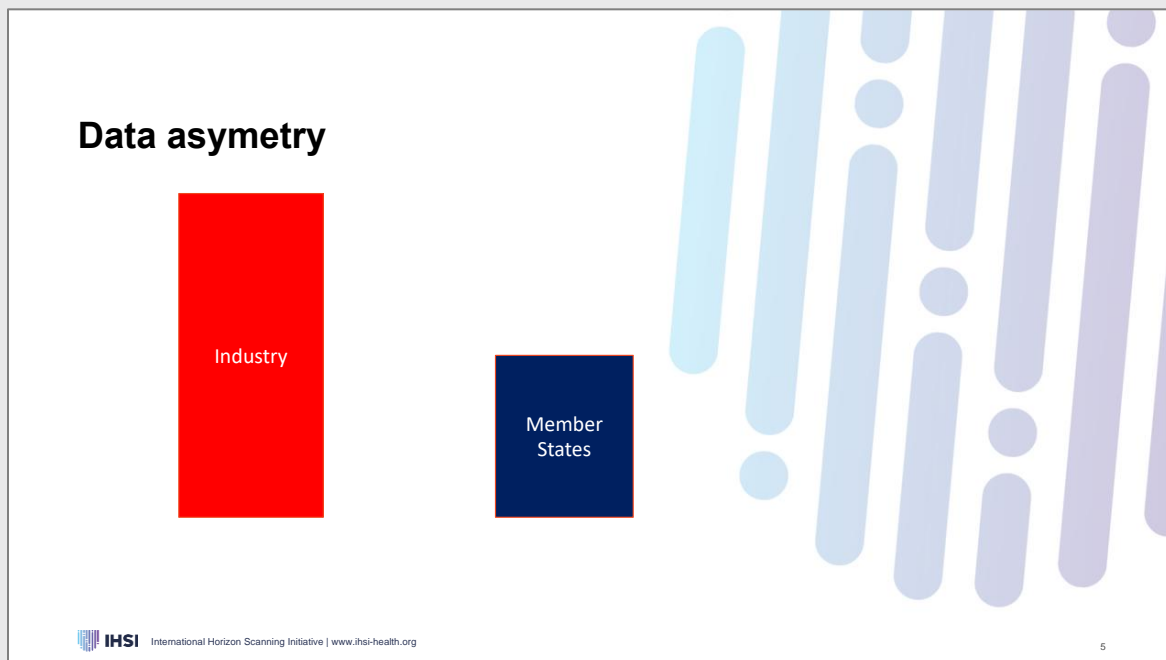
So this is the database. And the database is quite a large undertaking. You can imagine we have hundreds and thousands of data sets in there and this, of course, grows over time and we try to push it forward to a situation where we will be able to inform with a history that we are currently developing, meaning you will be able to not only see all the products that have come into our database since last year when we started, but we of course try to go a little bit backwards to capture previous compounds and of course all those that come in the future.



IHSI data-driven services - HIR

The second large product and service that we provide to our members, the governments and their affiliates, is what we call the high-impact reports (HIR). These reports really drill down to important

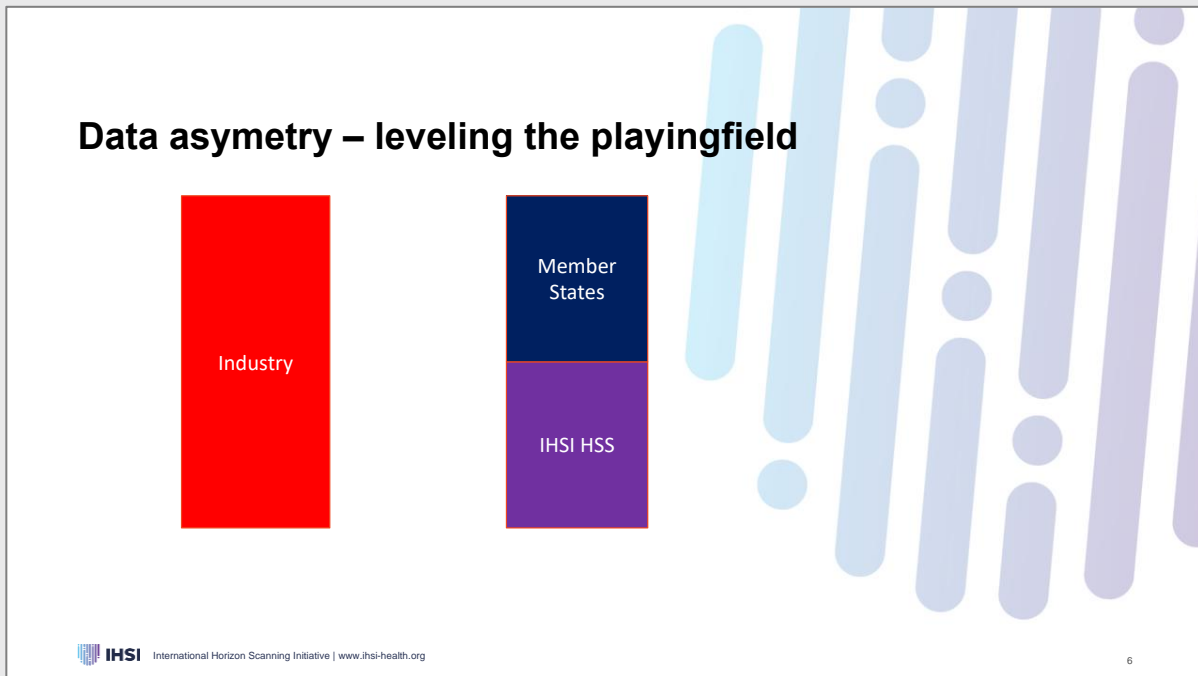
factors such as what is the cost impact of a drug, what is the mode of delivery or what are specific items to influence our health care systems or the way how we provide such a drug to the market and to the patients and does that maybe replace other drugs in the future or is this an improvement to development. And according to these factors and many others the high impact reports are designed to inform our decision makers and our policy members in the member states to take action or to prepare. And you see the categories that we have decided upon jointly to utilize. Within these categories all pharmaceutical products find their place, and again, we produce two reports per year per clinical area and we have started with those in June this year, so you see we are producing. The reports so far have been extremely helpful. We very practically started, of course, with infectious diseases given the overall global situation and our members found that specific report to be extremely helpful and we hope, of course, to continue with these in the future.



Data asymmetry

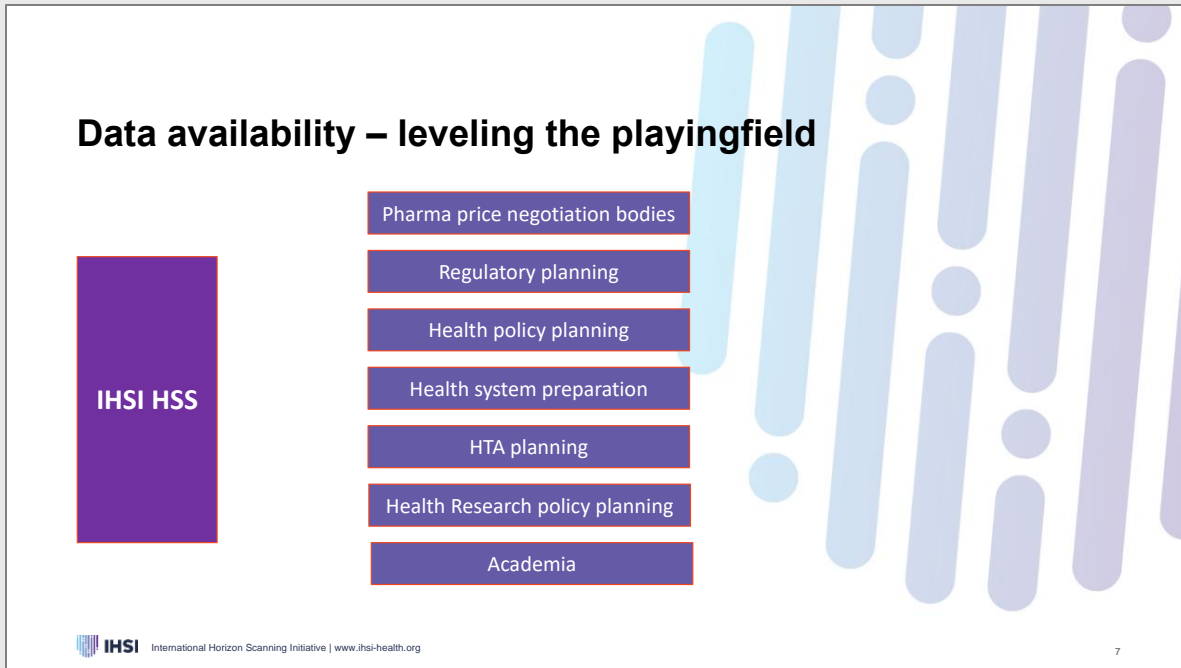
Here you see one of the key decision originators for why we wanted to go and build the database and why we wanted to provide this service. It is simply a data asymmetry in the negotiation structure that we have seen when we engaged with our colleagues in the industry. But in general, there was a data asymmetry in relevant fields when it came to new and upcoming pharmaceutical products that resulted

in previous existing data bases no longer being freely accessible or the closure of such databases for political reasons. We have seen that in the UK and in the US. Those databases were no longer available or actually closed down.



Data asymmetry – leveling the playing field

So to bridge and to counter this data asymmetry and to level the playing field - and this is one of the reasons that Francis also pointed out earlier - we created the data base and the horizon scanning system, as we call it, the database and the high impact reports to really support and provide our decision makers with robust, reliable, transparent and strong data to guide their decisions, to support their processes, and of course, as Francis also said, to allow collaboration. You can only engage joint activities if you have the same data underlying your actions and decision-making procedures. And this is something that we provide with the horizon scanning system.



Data availability

The data availability playing field goes far beyond price negotiations. It goes, of course, into regulatory planning procedures and health policy planning and health systems preparation, HTA planning, health research policy planning, academia and many more. We are at this very exciting stage where we get more and more requests from our member states to think jointly about use cases. How can we utilize this enormous wealth of data in the database and basically on a daily basis we receive new ideas on how to structure and analyze data, how to package it and sort of what to do with the data in the field. And this is what we are going to do in the next couple of years. And, of course, we invite everyone to join us and to come on board and see whether that data is relevant in other fields as well.

I will stop here for now. Again, there are I think 23 more slides in my presentation that you are more than welcome to look at offline.

Questions and answers

Katherine Del Salto: Thank you so much Marcus and Francis for such rich presentations. As you both mentioned the presentations and the video of this session will be on the Criteria Network website.

I think one of the questions that comes up very much, especially with an audience in Latin America is: are these initiatives doable in a context other than Europe? And although both of you have the experience of Europe, I would like to know if you have any tips for how to start because I also think that Europe didn't have it seven or nine years ago. How did you start this international cooperation? Maybe you can just expand a little bit on what Francis said and what you just mentioned about having clear objectives of what you want to do with this data.

Francis Arickx: We started from the bottom up. It is the administrations and the people who knew each other, for instance, through meetings like today. We talked to each other and just looked how far we could go in working together. And then we just demonstrated that there was added value in working together and then we managed to explain that to our governments and our leaders that it would be worthwhile to invest in that a little bit and to give us a bit of time to demonstrate that it could be going further. So actually, it grew from the bottom up. This is a voluntary collaboration but with political support. It is not an imposed collaboration coming from the top up. That is one thing. It is also – and that was one of the questions for IHSI, but I am going to let Marcus answer on that one – IHSI is a non-profit organization. This is also a collaboration between countries. Actually, there is a few countries investing quite a bit into it, into the further development of IHSI. But the same goes for Beneluxa. Each country pays its own expenses. It is some sort of (collaboration of) unique people who are enthusiastic, who know each other and who want to start working together and see how far you get. We made a lot of errors and we have learned that there is a lot of things that we can't do together and that do not work. But the results that you can get in the things that do work are very good. And why not? Why wouldn't it work in Latin America?

Marcus Guardian: There is so much more to say. I think one quality that this collaboration has is that it is a group that is driven by pragmatism with a heart. I think you have to have passion for it,

you have to be excitable about it and believe in what you do, and you have to be very pragmatic and open, not everything works. And you have to accept that. But then you focus on the things that do and it is a trial and error. And if you are ready to take the trial-and-error-approach, then yes it will work. But you have to be honest and open about it. And the political backing we got was, of course, extremely helpful as well.



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