World Health Organization

REGIONAL OFFICE FOR Europe

Report from technical working meeting on access to new medicines - joint horizon scanning and strategic negotiations opportunities

22 - 23 February 2017, Copenhagen, Denmark

Health Technologies and Pharmaceuticals Programme (HTP)
Division of Health Systems and Public Health
WHO Regional Office for Europe

ABSTRACT

This report, with a focus on horizon scanning and strategic procurement, reviews current options for collaboration between WHO Regional Office for Europe and Member States examining opportunities for facilitating introduction of new innovative medicines in a sustainable manner. The report summarises the presentations, discussions and action points from a technical meeting hosted by the Health Technologies and Pharmaceuticals Programme, WHO Regional Office for Europe, 22-23 February 2017.

Keywords

MEDICINES
DRUG COST
PHARMACEUTICAL POLICY
HORIZON SCANNING
HEALTH TECHNOLOGY
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Background

On 22- 23 September 2016 the Health Technologies and Pharmaceuticals Programme (HTP), WHO Regional Office for Europe, hosted the workshop "*Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region*". The report from this workshop is available online[1]. Forty-two Member States participated (Ministries of Health and public procurement medicines agencies) along with key partners (Austrian Public Health Institute, European Commission, London School of Economics and Political Science, Organisation for Economic Co-operation and Development and UNICEF). The workshop was the first of its kind organized by the WHO Regional Office for Europe to discuss the challenges of procuring pharmaceuticals in the Region. Voluntary collaboration on public procurement of high-price medicines and other relevant products is relatively new in Europe; it was confirmed that interest is growing in developing and expanding collaboration in areas of mutual benefit.

Creation of a strategic procurement working group – a medicines procurement practitioner's forum for the European Region – was a natural next step as well as potentially a pilot project on joint horizon scanning (HS) to identify new medicines and their potential budgetary impact on health systems. The Regional Office agreed to organize a smaller technical meeting in 2017 to ascertain country interest and willingness to continue this collaboration. In addition, in conjunction with the Government of The Netherlands, WHO Essential Medicines and Health Product (EMP) department in Geneva will convene a global dialogue among relevant stakeholders to explore strategies for establishing fair prices for medicines in May 2017. These streams of work are carefully coordinated and collaboration between WHO Headquarters in Geneva and the Regional Office will continue. Hence HTP in collaboration with EMP, and in consultation with an advisory group of technical experts, organized a two-day technical meeting 22-23 February 2017, to frame the discussions on next steps for possible Member State collaboration.

Purpose of the technical meeting

As a follow up on the 22- 23 September 2016 meeting organized by the Health Technologies and Pharmaceuticals Programme (HTP), WHO Regional Office on "*Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region*" the meeting sought:

- To clarify interest, and discuss participation as well as responsibilities for development of a pilot project on joint horizon scanning;

[1] See http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2016/challenges-and-opportunities-in-improving-access-to-medicines-through-efficient-public-procurement-in-the-who-european-region-2016

- To explore opportunities for a medicines procurement practitioner's forum for the European Region;
- To co-create an outline of the content of these particular collaboration initiatives to be taken forward jointly by Member States and WHO.

Expected outcomes of the technical consultation

- A shared understanding of the needs for and purpose of Member State collaboration;
- Agreement on the principles for collaboration;
- Collection of ideas for practical actions and concreate next steps.

Summary of Day 1: Joint horizon scanning opportunities in the European Region

Presentations on current and future planned horizon scanning systems were made as a background and to clarify the need for a pilot project on *joint* horizon scanning in the Region. Presentations were followed by a discussion.

BeNeLuxA initiative – Irina Cleemput (KCE)

A Letter of Intent was signed by Belgium, Netherlands, Luxembourg and Austria on collaboration, focusing on health technology assessment (HTA), horizon scanning, pricing and reimbursement, and information sharing. Some pilot projects on these topics are being conducted to start the voluntary collaboration. The population covered by this BeNeLuxA initiative is 37 million inhabitants.

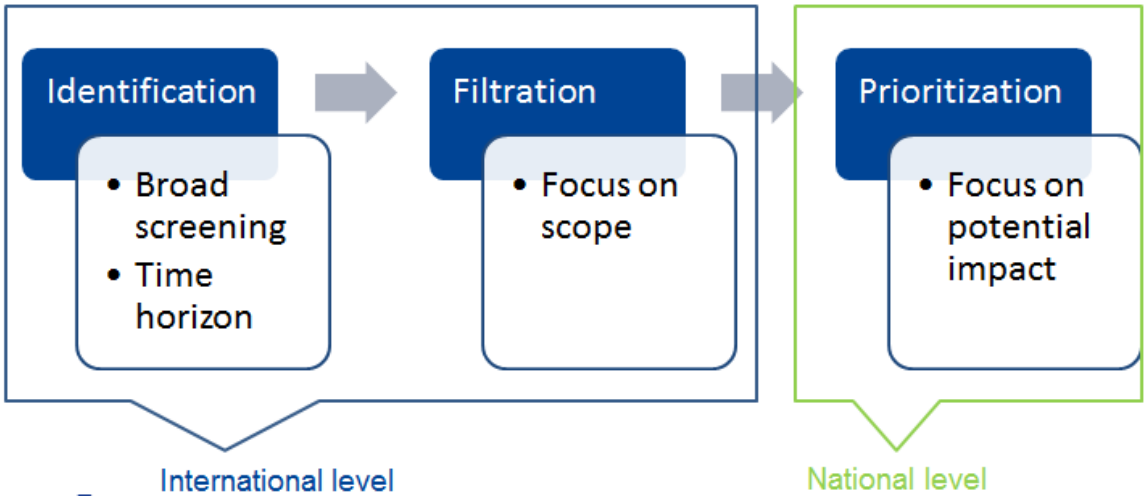
The role of the Belgian Health Centre Knowledge Centre (KCE) in the project was so far to develop a model and methodology for a joint horizon scanning system (HSS) for BeNeLuxA, with support by Panaxea (external consultancy). Panaxea performed an international comparison of eight existing HSSs and developed a draft proposal for a BeNeLuxA HSS.

The objectives of the proposed joint BeNeLuxA HSS are to:

- Help decision-makers through identification of upcoming opportunities, challenges for reimbursement, challenges in generating evidence pre- and post- marketing authorization (MA) evidence generation, and challenges for financing solutions;
- Enable collaborating countries to prepare their local decisions on the basis of jointly collected and validated information;
- Prepare for early dialogues, joint HTA and negotiations, and policy discussions.

The HS process is composed of 3 phases:
1. Identification (broad screening of current and new products, and defining time horizon to limit identification)
2. Filtration (focuses on scope, need to make HS manageable)
3. Prioritization (focus on potential impact, financial, organizational, clinical)
Identification and filtration are performed internationally while prioritization is performed at national level.

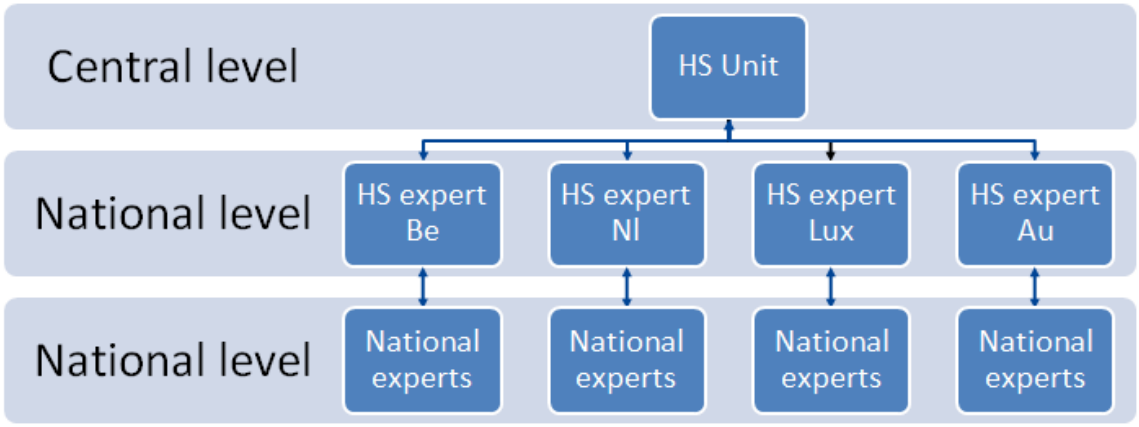
Figure 1: HS process (source KCE, Belgium)



The possible areas for sharing work are identification and filtration. There is a desire for restricted access to a secured database and the BeNeLuxA Proposal contains such a data base. The main data base will contain only information on new and emerging pharmaceuticals, first biosimilars, late phase II or early phase III trials. The data base does not include vaccines, medical devices or generic medicines.

The proposal for the organization of joint HSS is that at the central level there is one jointly financed HS unit; and at the national level, an HS expert in each of four countries (Belgium, Netherlands, Luxembourg and Austria). National experts are designated in each country. They are responsible for collecting national data required for national priority setting but also to feed into the central HS database. These experts will communicate outputs of central HS to national decision-makers, ensuring the outputs are used.

Figure 2: HS organization (source KCE, Belgium)

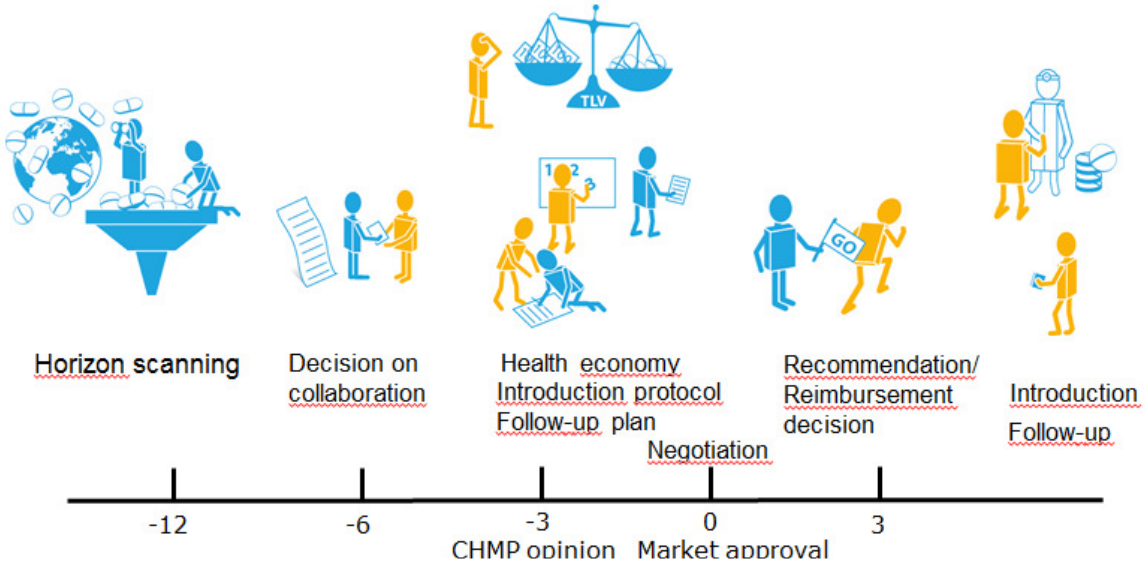


BeNeLuxA is willing to consider including other countries into their proposal and a steering committee will take this forward in the next few months, to determine how to share and how to collaborate with other groups/countries. In summary, the focus of the BeNeLuxA Proposal is collaboration on identification, filtration, data collection and impact estimation.

The Swedish process for horizon scanning and orderly introduction of new drugs – Mikael Svensson and Anna Bergkvist Christensen (Sveriges Kommuner og Landsting)

Two years ago a new project – a national strategy for introducing medicines in a safe, but faster and cost-effective way (the orderly introduction model) - was introduced in Sweden. Horizon scanning is the starting point activity of the project. Medicines are selected 12 months before the estimated marketing authorization (MA) is granted. At that time the decision process in the 21 counties in Sweden begins regarding potential introduction of new medicines. At MA, negotiation begins, followed by recommendation and reimbursement decision three months afterwards. This all relies on solid horizon scanning in order for best possible preparation for the introduction of relevant new medicines.

Figure 3: The Swedish orderly introduction model (Source: Sveriges Kommuner og Landsting)



The county council collaboration model has three levels of collaboration: Life cycle function, negotiation and market function, and each function has a working group. In the life cycle function, a HS working group coordinates horizon scanning for the county councils. Work involves different tools: Pipeline meetings with industry, coverage of European Medicines Agency (EMA) processes and newsletters. Deliverables include early assessment reports on medicines that are made available for all 21 county councils. These reports are available online (Stockholm country council website **janusinfo.se**) but are only available in Swedish. In addition, a newsletter is developed for county councils and contains a condensed list of new medicines, indications, and patient groups affected by the new medicines.

Sweden would like to further develop Nordic cooperation in the future and as first step to have better knowledge/overview of the medicines pipeline and patent expiry and to find ways of sharing information.

Horizon scanning in Denmark - Helle Bräuner (Amgros)

There have been changes in the Danish system, and since January 2017, the HS work in Denmark is conducted by a new team in the Regions' pharmaceutical organisation, Amgros. This work is in addition to work already carried out by the Danish Medicines Agency. The medicines covered by HS in Denmark are for in and out-patients. The Amgros goal is to identify all new medicines, doses, and dispensing forms at least two or three years prior to their arrival in the Danish market.

Monitoring capabilities will be built up in a step-by-step-process and it is planned that the HS team in 2017 will produce lists and summaries on all new medicines and indications. The lists will be available at least 120 days before marketing authorization for new medicines and at 90 days for new indications. High impact reports are available twice a year, for budgetary purposes. From 2018 the HS team will work on additional scanning of medicine patent expiry.

Deliverables from HS work will serve different purposes both internal for Amgros and external for the new Danish Medical Council, providing information to support national medicine use and quality of treatments, and for hospital drug committees.

Like Sweden, Denmark would like to further develop the Nordic cooperation in the future as well as cooperation beyond the Nordic countries, if feasible.

Norwegian horizon scanning unit - Vigdis Lauvrak (NIPH)

Norway has four regional health authorities (RHA), broken down into 29 public owned health trusts (HT), 19 of which are hospitals. There is one HT in charge of the procurement of medicines (Sykehus Innkjop (LIS)). The national system for the managed introduction of new health technologies – within Specialist Health Services – uses systematic HTA to inform decision-making. The goal is to improve patient safety, and promote timely and equitable access to new technologies shown to be effective, safe and cost-effective in Norway.
The main components of the system are horizon scanning (since 2015), HTA, priority setting decisions (made by four heads of regional authorities) and implementation.

Norway has three categories of HTA. They are done by different entities, have impact at regional or local level, and do not cover the same groups of products. The full HTA is done by the Norwegian Institute of Public Health and is covering all technologies. The single technology assessments (STA) are conducted by the Norwegian Medicines Agency (NoMA) and only covers pharmaceuticals. The pharmaceutical company submits an economic model provided by the company. The mini-HTA is done by individual hospitals and is restricted to non-pharmaceutical products.

The purpose of HS activity in Norway is to identify and track technologies and to propose what type of HTA is considered most useful. HS in Norway is based on a model where the main sources of information used are EMA public webpages and other public sources. New

pharmaceuticals are identified when they enter the EMA process and a draft alert is produced, published and companies are contacted if/when information on the substance and the anticipated indication is publicly available. A final alert is produced with recommendations for HTA and serves as a proposal to the system. An STA will be available 180 days after receipt of a company submission file. A full HTA may take until one year, and can be requested at any time for comparative analysis.

HS assessments are relatively quick and considered very efficient partly because the process already relies on reliable date from external sources and open access international early assessments.

In 2015, Norway used HS to produce 64 alerts (28 on pharmaceuticals); in 2016, 71 alerts were produced (51 on pharmaceuticals). The drafts of alerts are published online at NoMA. The Norwegian HS is part of a complete system for the introduction of new medicines. This activity has really had an impact on the process and has speeded up the introduction of new medicines.

Norway would like to collaborate with other countries in task sharing for identification, tracking of evidence, and tracking of obsolete technologies for disinvestment. They would like to have access to an open database with data on new technologies.

Public and patient involvement and engagement (PPIE) in horizon scanning activities: examples from Horizon Scanning Research & Intelligence Centre (HSRIC) – Sue Simpson (Birmingham University)

The NIHR Horizon Scanning Research & Intelligence Centre (NIHR HSRIC) was established as an independent research team at the University of Birmingham in 1998, and incorporated as a research programme within the National Institute for Health Research (NIHR) in 2006. The purpose of NIHR HSRIC has been to[2]:

- Provide advance notice to the Department of Health (England), health service policy-making bodies and research funders of significant new and emerging technologies - up to three years in advance of their launch in the National Health Service (NHS);
- Cover all health technologies (pharmaceuticals, devices, diagnostic tests etc.);

The Centre delivers three main outputs: briefings on emerging medicines, an early Medtech alert, and horizon scanning reviews which look across an entire disease area or set of technologies (e.g. artificial pancreas).

Public involvement is where members of the public are actively involved in research projects and in research organisations. Engagement is where information and knowledge about research is provided and disseminated. There has been very little public and patient involvement or engagement in horizon scanning. The first HSRIC PPIE strategy was produced in June 2013. The aim wass to identify areas in HS to build and strengthen relationships with patients and public, and professionals working within PPIE.

PPIE activities in HS have:

- Involved patients in the identification of technologies, prioritization and assessment;

[2] As of 2017 University of Newcastle upon Tyne will be taking over the role of providing advance notice to the Department of Health (England) and these functions will not be maintained any longer at Birmingham University

- Contributed to MedTech alerts – patient input on acceptability of an emerging technology (for example Reza Band for reduction of acid reflux into the throat and lungs). Initially there was uncertainty about it's potential impact, but patients were very keen and subsequently the topic was prioritized for an output ;
- Contributed to medicine briefing assessments. Patients comment on briefings, and have added to information in particular where the medicine has been for rare diseases.

All outouts have a lay summary that can be accessed by patients. In addition, there is an easy to search website where all outputs can be found.

The benefits of PPIE at the HSRIC are that it increases the accessibility of information on emerging health technologies for patients and carers; it supports identification of emerging technologies of relevance to patients and carers and increases the validity of HSRIC's work. The main challenges are to identify patients to participate to obtain representative input and the resource required.

From 1st April 2017, the horizon scanning contract for the NHS and NIHR research programmes will be held by Newcastle University. A new NIHR Innovation Observatory will continue the work of HSRIC..

EuroScan – current and future HS activities (Roberta Joppi, Clinical Research & Drug Assessment Unit, Verona)

EuroScan is a global collaborative network collecting and sharing information on both emerging and obsolete technologies. It has developed a tool-kit for different steps and areas relating to horizon scanning. EuroScan is committed to support the development of existing and new non-for-profit agencies in the HS field by providing tools and offering training initiatives on EAA activities. EuroScan has 17 members, in 14 different countries, in four continents.

EuroScan maintains a database of information on emerging technologies (not only medicines) provided by members of the network. The database also contains reports on obsolete technologies provided by members. EuroScan is currently also an important source on HS methodology and training. The EuroScan database is available for members but data can be shared with external partners at request.

Most EuroScan members are working on emerging technologies, but two members are currently also working on obsolete technologies - disinvestment (Australia and Basque country).

At the end of 2016, the EuroScan secretariat has been moved to the University of Düsseldorf, Cologne, Germany and Hans-Peter Dauben is the new head of the secretariat. The EuroScan network will change its statute and will become a legal entity. All the processes relating to this change are on-going. As a legal entity, EuroScan can provide services, not only to the members of the network but also to external partners interested in one or more activities/ initiatives performed by the network.

Discussion on collaboration on horizon scanning

- In the UK there is a source of intelligence on new medicines, indications and formulations in clinical development called UK PharmaScan. This is a database, not available publicly, but available to NHS horizon scanning organisations across the UK that is owned by the Department of Health and hosted by the National Institute for Health and Care Excellence. All pharmaceutical companies are invited to share information about their new pharmaceuticals, indications, formulations and in-licensed medicines in phase III clinical development or three years from UK launch, whichever is the earliest. UK PharmaScan allows companies to keep data up-to-date so that horizon scanning organisations have complete and accurate information available to them and do not have to get the information from alternative, less reliable sources. This would be a great model if it could be expanded upon beyond the UK with greater sharing of information instead of country-by-country approaches as a shared place for information rather than requiring individual sharing.
- What is the main obstacle in achieving a database with universal access? Is it financing, is it legal? Most of the information can be found publicly, the work of putting it into a database is the challenge. Is it a resource issue? What are the required funds and time?
- The EuroScan database is a voluntary database, where individual members are requested to add information about emerging technologies they have identified or produced reports on, however this doesn't always happen due to resource issues.
- One thing all countries struggle with is secondary patents. How can we identify these products and should one consider having patent lawyers involved in proposing a strategy to address this problem and to make it more feasible to identify patents in a better way? It was suggested to contact the University in Aachen, where a group is working at the university with the European Patent Office on issues related to this (HTP will take action on this).
- It was suggested that it be good to strengthen coordinate between BeNeLuxA and Nordic countries to work on prioritization issues, for example, to prepare summaries of drugs in the EMA filing process.
- Do we only need to make one type of impact assessment, or separate ones for Nordic, BeNeLuxA, etc.? The impacts on budget, work-load and resources will be different.
- How generalizable are impact assessments? The extent to which a new drug can impact the local or current treatments will be different.
- Our basic wish list for information to be brought about in a collaborative way for sharing and reliance is important. Once this is finalized it clarifies matters to be considered and it may serve basis for replacing repetitive, parallel national data gathering and identification of the data can be shared. Countries need to identify what they want from any information sharing activity, the basic requirement to work on joint HS.

Summary of working group discussion on the potential and scope of joint horizon scanning

Participants were divided in four groups, with the task of answering the four questions below. This is a brief summary of the discussion that followed.

Questions:

1- What could be the added value in a joint horizon scanning activity with the WHO Regional Office for Europe to prioritise medicines for access (public funding/reimbursement)?
2- What are the parameters of joint horizon scanning?

3- What is the scope for joint horizon scanning?
4- What are the basic minimum criteria that can help in prioritization?

The responses to the questions were as follows:

1. **What could be the added value in a joint horizon scanning activity with the WHO Regional Office for Europe to prioritize medicines for access (public funding/reimbursement)?**

Efficiency gains – Under the status quo, there is significant duplication of effort in horizon scanning (HS). In particular, the identification phase of horizon scanning is heavily resource intensive. Performing identification jointly would provide efficiency gains in terms of manpower, time, and money. This would reduce duplication and costs, and allow greater influence when discussing with manufacturers. It is important to have information at least six months ahead.

Expertise and capacity building - Collaborating on joint procurement planning offers the opportunity to bring together expertise and knowledge in order to develop high quality HS tools and robust methodologies. This is key for establishing best practices in HS. WHO has a convening power in a neutral environment and is already engaged in standard setting and methodology in other technical areas, so it would be useful if HS could also be included in WHO normative activities.

Consistency and data quality – The quality and completeness of data and databases varies widely across Member States in the Region. A joint horizon scanning initiative has the potential to deliver high quality and consistent data to all participating members. The problem is defining the common set of parameters that we need to set a prioritization list. Countries can participate in developing common standards and methodological quality standards.

Added value for small countries – Small countries with constrained resources have limited capacity to undertake horizon scanning. Joint horizon scanning would offer substantial value to small countries.

Added value for patients- Introduction of new medicines at the same time in different countries.

The Regional Office as a neutral entity could coordinate and potentially initially be a secretariat for the new initiative of joint HS, but MS have to drive the process and preferably one Member State could host the Joint HS. The Pan American Health Organization (PAHO) is the Secretariat of RedETSA. PAHO Medicines and Health Technologies program (HSS/MT) has a larger human resource capacity (number of staff) and are also engaged in other activities than HTP, WHO Regional Office for Europe. Hence a direct comparison between these two Region and their medicines and health technology programme can not be made.

2. What are the parameters of joint horizon scanning?

Horizon scanning *collaboration* can be divided into five activities: Identification, filtration, prioritization, assessment, and dissemination. The extent to which joint horizon scanning can be done varies for the different activities.

Identification – Identification relates to clinical data collection including from regulatory sources and from industry but there are other identification sources. This involves broad screening and typically includes all main products. This task is the same across all settings and therefore presents the greatest opportunity for collaboration.

Filtration – Filtering defines the scope of horizon scanning; specifically which types of products are included. This narrows the data collected through broad screening to a shorter list. There is some potential for filtering at a supranational level with groups of countries that have set the same scope of interest. This is considered an intensive step in collaboration and hence collaboration will require that certain preconditions are met.

Prioritization – Prioritization involves defining the criteria of interest from a financial, clinical, and organizational standpoint. The potential impact of a product could depend on the disease prevalence, current standards of care, health system organization and other local factors such as patient perspectives. As such, there is limited potential for joint prioritization and this activity would be better placed at the national or local level.

Assessment – Following prioritization, the data that have been identified and filtered are assessed for potential impact according to the criteria defined in the local setting. There is limited potential for collaboration in assessing the impact unless the results of prioritization are the same across multiple countries.

Dissemination – The results of the horizon scanning process are then disseminated at a local level. This will be country specific. Among other things, horizon scanning could inform budgeting processes, organizational changes, or act as early warning for HTA processes.

Outside of these core activities, it was agreed that any joint horizon scanning initiative would likely benefit from a political mandate, funding, and a common agreed protocol. Agreement is also needed on the division of responsibilities and tasks and on whether the data are open access or closed. There would also be a need to harmonize the time horizon of interest between countries i.e when is information about an emerging technology required.

It was suggested that the focus should be on the creation of a commonly shared database – i.e. financed by members, rather than voluntary. It will be important that a joint HS initiative in the Region is self-sustaining and that Member States have influence on the design and output to ensure its suitability for the users.

It was agree that *Identification* is the HS activity where WHO engagement and collaboration between Member States could have the greatest impact.

3. What is the scope for joint horizon scanning?

There is a large range of potential targets for joint horizon scanning. The working groups highlighted the following types of products and information, which have potential clinical, financial, or organization impacts:

New medicines and indications

Biosimilars/generics
Regulatory data (EMA phase 3 initially and later phase 2 trials)
Patent data (secondary patents etc.)
Obsolete technologies
Therapeutic areas

While a focus has been placed on new medicines under development, it was noted that horizon scanning should not be limited to these products. Specifically, identifying and delisting obsolete technologies can have a substantial impact. Likewise, patent expiry is an important part of a product's life cycle as generic/biosimilar entry can generate substantial cost savings. Secondary patents and surrounding complications were also identified as a key issue.

Data management and development of the tool can be done jointly. Countries need to define basic requirements.

It was also suggested that one could undertake a HS exercise with pharmaceutical company focus – e.g. carry out company by company pipeline and asset assessments on an annual basis. This could be combined with a disease burden projection in terms of potential budget impact and help narrow where there can be optimal impact of collaboration between countries in relation to facilitating introduction of new medicines.

4. What are the basic minimum criteria that can help in prioritization?

A number of local factors will influence the potential impact of a product. Budget impact is a key consideration, and is captured through several factors including costs, indication, quality, patient group size, and off-label product use. Organizational impact is largely influenced through the innovative nature of the technology, as this may influence other parts of the healthcare system (e.g. eliminating the need for surgery, changes in staffing, training, etc.).

Overall the following criteria were mentioned as basic minimum criteria that can help in prioritization at the local level:

Costs
Safety
Quality
Indication
Degree of innovation (first in class, lack of alternatives, unmet needs, new formulation)
Patient group size
Off-label product use

Conclusion of Day 1

There was a general consensus and a widespread desire for some degree of joint horizon scanning with support from the Regional Office. An issues paper will be written by HTP with input from Member States, capturing the views of the working group and offering a set of alternative options for collaboration in the horizon scanning area.

Agreeing on a set of basic minimum criteria and requirements remain a challenge. Currently, the BeNeLuxA countries are set to meet and finalize a joint horizon scanning agreement (April 2017), the Nordic countries are set to meet and discuss joint horizon scanning (May 2017), and EuroScan has established methodologies and lists of criteria to support horizon scanning. The working group has agreed to discuss again minimum criteria and requirements at a later date, after the Regional Office have prepared the issues paper, in order to have time to reflect on these three initiatives.
Based on the WHO issues paper, the Regional Office will seek to organize a meeting or online virtual consultations at the end of June 2017 to take this collaborative work forward. This work will feed into the ongoing WHO Regional Office for Europe dialogue and collaboration with countries on Access to Medicines including the 67th Regional Committee meeting session *Strengthening Member State collaboration on improving access to medicines in the WHO European Region,* 13th September 2017.

Summary of Day 2: Negotiation skills training for medicines procurement agencies

The objective of the session was to discuss the possibility of creating a forum for strategic procurement similar to other existing networks like the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. A strategic procurement forum could provide a platform for countries to share their achievements and lessons learned etc. Through these mechanisms best practices can be built over time. In the longer term capacity development in strategic procurement could be facilitated and country collaboration further explored.

Overall, the participants expressed a widespread interest and desire in developing a workshop and forum designed to improve negotiation capacity and provide a setting for sharing of experiences and best practices. In particular, the workshop/forum would aim to leverage the course in negotiation skills already offered at the WHO collaborating centre, LSE Health, along with the experiences of key stakeholders involved in negotiation for pharmaceuticals and health technologies. The possibility of a webinar or e-course was discussed, but due to costs, it was determined that a face-to-face meeting would be best for the first course. Participants agreed to share some real cases/experiences to help develop the course material. Workshop/forum participants would need to finance their participation themselves.

There are already several courses available on negotiation skills in this context but the added value of the WHO strategic procurement forum and training is to hear experiences of senior individuals that have gone through negotiations before and to identify what works and what does not work. Bringing together a number of individuals to share experiences would be important.

A range of scenarios will be explored as there is not a one-size-fits-all approach in negotiation. Different situations will call for different strategies.

Conclusion of Day 2

Participants agreed that a forum to share experiences in procurement is needed and participants are willing to share their own experiences in procurement in order to develop course material that can be used in collaboration with the WHO collaborating centre LSE Health negotiation course and the aim is then to develop a specific workshop for 2017/18 to share experiences and discuss negation and procurement planning strategies.

Suggested next steps and follow to Day 1 and 2 after this consultation

Horizon scanning collaboration:

- There is consensus and a widespread desire for some degree of joint horizon scanning collaboration with support from the Regional Office;
- The participants identified a potential role for WHO as a neutral agency to take forward reflections on how this collaboration could come about;
- Countries interested need to agree on a set of basic minimum criteria and requirements for a joint HS;
- Currently, the BeNeLuxA countries are set to meet and finalize a joint horizon scanning agreement (April 2017), the Nordic countries are set to meet and discuss joint horizon scanning (May 2017), and EuroScan has established methodologies and lists of criteria for HS. The Regional office will make a comparison of criteria listed and methodologies suggested by these three collaborative groups and present these back to Member States. The working group has agreed to reflect on these minimum criteria and requirements and discuss at a later date in order to make final agreement on this;
- An issues paper will be prepared by the Regional Office, capturing the views of the working group and proposing options for joint horizon scanning work in the Region;
- A meeting in June 2017 could be a next step to take country agreements forward and the Regional Office will explore this further;
- In relation to strategic procurement and negotiations skills development a forum to exchange information may be developed by the Regional Office, in which countries share their strategic procurement work, lessons learned etc. One can also explore the option to have some specific sessions on procurement during the PPRI meetings – although it was recognized that will lead to/require an expansions of the PPRI network. This will considered further in the issues paper;
- The Regional Office jointly with LSE Health will explore the development of a negotiation skills training course for public procurement agencies of medicines. Countries willing to collaborate will share their experiences/case studies;
- First negotiation skills training for the public procurement agencies of medicines to take place in second half 2017 or early 2018. It will be a face to face course. Participants will support their own participation;
- Online courses could be considered for future but will require substantial funding for their development.
- The Regional Office will be sharing their HS issues paper along with proposal for strategic procurement and negotiations skills development in June 2017. Input from member States will be sought either through on-line consultations and a face to face meeting towards the end on June 2017.

Annex 1: List of participants

Austria	Vinzent Rest, Health and Pharma Economist, Federal Ministry of Health and Women Lukas Nigrowics, Main Association of Austrian Social Security Institutions
Belgium	Francis Arickx, Head of Directorate, Directorate Pharmaceutical Policy Health Care Department, National Institute Health and Disability Insurance (RIZIV-INAMI) Irina Cleemput, Senior Health Economist and Coordinator of the Domain Task Force for Horizon Scanning, Belgian Knowledge Centre for Health
Cyprus	Elena Panayiotopoulou, Pharmaceutical Services, Ministry of Health
Denmark	Dorthe Bartels, Head of Procurement; Lise Grove, Director, Strategic Procurement and Supply Management of Medicines; Helle Bräuner, Project Manager, Amgros
France	Claire Biot, Director, General Agency for Health Products and Equipment, Greater Paris University Hospitals
Greece	Chara Kani, Manager of the Department of Pharmaceutical Planning and Dispensing of Medicines, National Organization for the Provision of Healthcare Services (EOPYY)
Iceland	Einar Magnusson, Director of Pharmaceutical Affairs, Ministry of Welfare
Norway	Oyvind Melien, Chair of Secretariat for the Norwegian National System for Managed Introduction, Dept. of Medical Devices and Medicinal Products, Directorate of Health Vigdis Lauvrak, Head of the Norwegian Horizon Scanning Unit, The National Institute of Public Health Christina Sivertsen, Researcher, Norwegian Medicines Agency
Sweden	Mikael Svensson, Strategic Advisor, Lanstinget Ostergotland/ SKL Pontus Johansson, Senior Economist, Dental and Pharmaceutical Benefits Agency (TLV)
United Kingdom	Kevan Wind, Medicines Procurement Specialist, Pharmacy Dept, Southend Hospital, Westcliff on Sea, Essex, England Lindsay McClure, Pharmaceutical Adviser, NHS National Procurement, Scotland
EuroScan	Hans-Peter Dauben, Head of Secretariat, EuroScan Roberta Joppi, Clinical Research & Drug Assessment Unit, Local Health Authority of Verona – Veneto Region, Italy Susan Simpson, Associate Director, NIHR Horizon Scanning Research and Intelligence Centre, University of Birmingham

WHO collaborating centre, LSE Health	Panos Kanavos, Deputy Director, LSE Health, London School of Economics Mackenzie John Mills, LSE Health
WHO	Hanne Bak Pedersen, Programme Manager, HTP Melanie Bertram, Health Economist, WHO headquarters Guillaume Dedet, Technical Officer, HTP Tifenn Humbert, Technical Officer, HTP Kotoji Iwamoto, Technical Officer, HTP Andrew Rintoul, Scientist, WHO headquarters Olexandr Polishchuk, Technical Officer, HTP

Annex 2: Agenda

Technical working meeting on access to new medicines - joint horizon scanning and strategic negotiations opportunities
22 - 23 February 2017
UN City, Press Room, Copenhagen, Denmark
AGENDA

Day 1- Wednesday 22nd February 2017	
Session 1	**Welcome and Introduction**
10:00 - 10:30	Registration - Participants
10:30 – 10:45	Opening remarks (Hanne Bak Pedersen, HTP/WHO Regional Office for Europe) Self-introduction (All) Housekeeping announcements (Tifenn Humbert, HTP/WHO Regional Office for Europe)
Session 2	**Background and Objectives**
10:45- 11:00	WHO activities/updates in the area of sustainable access to medicines Background, objectives and expected outcomes of the meeting (Hanne Bak Pedersen, HTP/WHO Regional Office for Europe)
Session 3	**Horizon Scanning: what are the possibilities for creating a common horizon scanning mechanism in Europe? What is the role of WHO?** (Tifenn Humbert, HTP/WHO Regional Office for Europe)
11:00 - 13:00	Sharing of experiences (10 min per presentation): • The BeNeLuxA initiative and horizon scanning (Irina Cleemput, Belgian Knowledge Centre for Health (KCE) • Sweden – re-shaping the mechanism for horizon scanning (Mikael Svensson) • Denmark- mapping horizon scanning activities (Helle Bräuner, Amgros) • Norway- The Norvegian Horizon Scanning unit (Vigdis Lauvrak, The National Institute of Public Health) • Birmingham University – The patient perspective on prioritization of medicines (Susan Simpson) • EuroScan current and future horizon scanning activities (Roberta Joppi, Clinical Research & Drug Assessment Unit, Verona)

13:00 - 14:00 Lunch break

Session 4 **Discussion** (Panos Kanavos, LSE Health)
14:00 - 15:30 Lead questions:
1- What could be the added value in a joint horizon scanning activity with WHO Regional Office for Europe to prioritise medicines for access (public funding/reimbursement)?
2-What are the parameters of joint horizon scanning?
3-What is the scope for joint horizon scanning?
4-What are the basic minimum criteria that can help in prioritization?

15:30 - 16:00 Coffee break

Session 5 **Development of an outline of next steps for WHO horizon scanning activities**
16:00 - 17:00 Discussion

18:00 Joint dinner in town at participant's own expense

Day 2- Thursday 23rd February 2017

Session 6 **Strategic procurement working group and negotiation skills training for medicines procurement agencies (**Panos Kanavos,LSE)

09:00 - 09:30 Introduction of basic ideas for developing a Strategic Procurement working group including a training course on strategic negotiation related to introduction of new high-priced medicines.
How negotiations changed in Australia (Andrew Rintoul, EMP/ WHO headquarters)

09:30 - 11:00 Discussion: Lead questions:
1- Who is the target audience?
2- What content should be covered?
3- What resources can we build on?

10:30 - 11:00 Coffee break

Session 7
11:00 - 12:00 **Conclusions and next steps**
Summary of the working meeting: Conclusions and next steps
13:00 Closing

13:00 Lunch