

2018 Global Policy Forum

Facing the dynamics of future innovation: The role of HTA, industry and health system in scanning the horizon

"The future cannot be predicted, but futures can be invented"¹

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¹ Dennis Gabor (1963) "We Cannot Predict the Future, But We Can Invent It" Available via: <http://quoteinvestigator.com/2012/09/27/invent-the-future/> [Visited October 14, 2017].

Glossary

The definitions provided here are mainly derived from (glossaries^{2,3} of, and) relevant and recent reports on the subject, as well as the international HTA glossary.⁴

Early awareness and alert (EAA) system

A *system* that aims to identify, filter and prioritize new and emerging health technologies, or new uses of existing interventions; to assess or predict their impact on health, health services and/or society; and to inform decision-makers and research planners.

Note 1: 'Filter' is a process to remove technologies that are not relevant to the early awareness and alert system from the list of technologies originating from the identification process.

Note 2: 'Prioritize' is a process to determine the significance of, or order for dealing with, filtered technologies according to their relative importance to the aims of the early awareness and alert system.

Note 3: Synonyms of an EEA system include early warning system and horizon scanning system.

Horizon scanning

A *systematic examination of information* to identify new or emerging health technologies that could be potential threats, risks, emerging issues and opportunities, allowing for better preparedness of health systems and informing policymakers, purchasers, and health care providers (for health service research prioritization, financial or operational planning) or facilitate early access (by facilitating controlled diffusion of technologies).⁵ Furthermore, it may include health technologies that are becoming obsolete and that have the potential to effect health, health services and/or society.⁶

Forecasting

Evidence-based expectations on sales, budget requirements, demand, projected health gain/outcome and similar aspects.

Health technology

An intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize health care delivery.

Note 1: The intervention can be a test, device, medicine, vaccine, procedure, program or system.

Emerging technology

A health technology that has not yet been adopted within the health care system. Pharmaceuticals are in the Phase II or III clinical trial, or pre-launch stage; medical devices are in the pre-marketing stage.

2 Godman, B., Oortwijn, W., De Waure, C., Mosca, I., Puggina, A., Specchia, M.L., Campanell, P. Van der Tuin., J. Links between pharmaceutical R&D models and access to affordable medicines. European Parliament. Directorate General for Internal Policies. Policy Department a: economic and scientific Policy. European Union, PE 587.321 EN. IP/A/ENVI/2015-06, October 2016. Available via: [http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU\(2016\)587321](http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU(2016)587321)

3 WHO European Office. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. WHO: Copenhagen, May 2015. Available via: http://www.euro.who.int/__data/assets/pdf_file/0008/306179/Access-new-medicines-TR-PIO-collaboration-research.pdf?ua=1

4 HTA Glossary.net [Internet]. [Cited Sep 28 2017]. Available via: <http://htaglossary.net/HomePage>

5 EuroScan International Network. A Toolkit for the Identification and Assessment of New and Emerging Health Technologies. University of Birmingham: EuroScan International Network, October 2014. Available via: <https://www.euroscan.org/assets/Uploads/EuroScan-Methods-Toolkit-October-2014-FINAL-CC-added.pdf>

6 HTA Glossary.net [Internet]. [Cited Sep 28 2017]. Available via: <http://htaglossary.net/HomePage>

New health technology

A health technology that is in the launch, early post-marketing, or early diffusion stages.

Innovative health technology

A common definition of what constitutes an 'innovative health technology' is currently lacking. From a public health perspective, the level of innovativeness of a health technology is primarily defined by the benefits it generates for patients. These can be in the therapeutic, clinical or quality of life domains, but also in the socioeconomic domain.

Disruptive innovation

An innovation that improves a product or service in ways that the market does not expect, typically first by designing for a different set of consumers in a new market and later by lowering prices in the existing market.

Note: Disruptive technology is often used as synonym. Examples of disruptive health technologies could be cell and gene therapies, preventive therapies for Alzheimer disease.

Unmet need

A condition whose treatment or diagnosis is not adequately addressed by an available therapy or diagnostic.^{7,8,9} Addressing unmet need is defined as: If it (the intervention) has an effect on a serious outcome of the disease or condition that is not known to be influenced by available therapy; has a benefit for patients who are unable to tolerate the available therapy or whose disease has failed to respond to available therapy; provides effectiveness similar to available therapy, while avoiding serious harm that can occur with available therapy.¹⁰

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- 7 Definition used by AHRQ in their horizon scanning system. ECRI Institute, Presentation at ISPOR, 21st Annual Meeting, Washington D.C., May 24, 2016. Horizon Scanning – Identifying And Estimating Future Impact Of Emerging Innovations On U.S. Healthcare. AHRQ Healthcare Horizon Scanning System. See for more information Section 3.
 - 8 European Commission. Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation 726/2004 of the European Parliament and of the Council. Available via: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2006_507/reg_2006_507_en.pdf.
 - 9 Food and Drug Administration. Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review [Internet]. Available via: <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm> [Visited September 28, 2017].
 - 10 U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for Industry Expedited programs for serious conditions – Drugs and Biologics, May, 2014. Available via: <https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf>.

1. Introduction

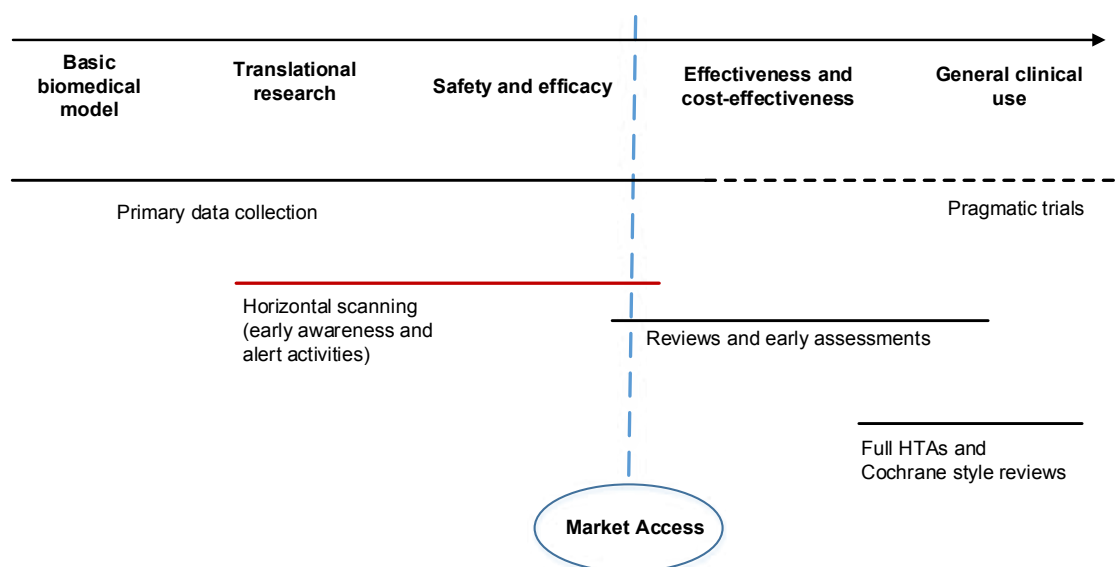
The subject of this paper, horizon scanning and horizon scanning systems is not a new phenomenon. Horizon scanning was originally introduced as the first step of the health technology assessment (HTA) process in order to systematically assess the potential impact of new and emerging health technologies to anticipate access to and provision of health services, as well as the development of health policy.¹¹ Horizon scanning systems can take either a short-term perspective (up to five years), or long-term perspective (>five years), which will influence the methods to be used.¹²

For many years, governments and other stakeholders around the globe have been using (in) formal horizon scanning,^{13,14} but the topic has increasingly gained attention in the last few years. The renewed interest laid bare the limited evidence regarding the impact of the current horizon scanning systems on the awareness of and decisions towards new and emerging health technologies.¹⁵

As described in the 2017 Global Policy Forum Background Paper, disruptive health technologies (e.g. Hepatitis C drugs) and other innovative health technologies (including personalized medicines, molecular diagnostics, 3D bio printing, and cell/gene/regenerative therapies) are currently emerging.¹⁶ Coupled with discussions around financial sustainability of health systems and ensuring incentives for innovation, pro-active planning is needed to enhance financial and organizational access to these technologies.¹⁷ Pro-active planning needs to start before the health technology enters the market, and is often part of so-called horizon scanning activities.¹⁸ In Figure 1, the role of horizon scanning in the HTA process is depicted.

- 11 Velasco-Garrido, M., Busse, R. Health Technology Assessment. An Introduction to Objectives, Role of Evidence, and Structure in Europe. Brussels: European Observatory on Health Systems and Policies; 2005.
- 12 Robert, A., Stevens, A., Gabbay, J. "Early warning systems" for identifying new health care technologies. *Health Technology Assessment*, 1999; 3 (13).
- 13 Banta, H.D., Gelijs, A.C. An early system for the identification and assessment of future health care technology: The Dutch STG project. *International Journal of Technology Assessment in Health Care*, 1998; 14(4):607-612.
- 14 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxa collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.
- 15 OECD. *New Health Technologies: Managing Access, Value and Sustainability*, Paris: OECD Publishing, 16 January 2017; p. 71. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.
- 16 Oortwijn, W. on behalf of the HTAi Policy Forum. 2017 Background Paper. From Theory To Action: Developments In Value Frameworks To Inform The Allocation of Health Care Resources. Available via: http://www.htai.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1488956656&hash=7fdcbfd842e98dee4a18394d969eb9658eef3768&file=fileadmin/HTAi_Files/Policy_Forum/HTAi_Policy_Forum_2017_Background_Paper.pdf.
- 17 OECD. *New Health Technologies: Managing Access, Value and Sustainability*, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.
- 18 Godman, B., Oortwijn, W., De Waure, C., Mosca, I., Puggina, A., Specchia, M.L., Campanell, P. Van der Tuin, J. Links between pharmaceutical R&D models and access to affordable medicines. European Parliament. Directorate General for Internal Policies. Policy Department a: economic and scientific Policy. European Union, PE 587.321 EN. IP/A/ENVI/2015-06, October 2016. Available via: [http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU\(2016\)587321](http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU(2016)587321).

Figure 1. The role of horizon scanning in the HTA process



Source: Based on EuroScan (2014)¹⁹

The overall objective of the 2018 HTAi Global Policy Forum meeting is a) to explore how HTA as policy science may need to further evolve and adapt to inform decisions with regard to health technology adoption around the globe; and b) how current horizon scanning systems can be (further) optimized in order to become more effective in preparing health systems to adopt disruptive health technology with added value and that will change current health care paradigms. It will also explore how all relevant stakeholders can enhance their collaboration in order to better understand the needs and constraints of health care systems in promoting the development, diffusion and adoption of disruptive and/or emerging health technology, while ensuring financial sustainability of health care budgets. This might provide input to develop a shared agenda, outlining the demands and challenges for HTA and its stakeholders.

The purpose of this Background Paper is to present the policy context of the topic, provide an overview of selected horizon scanning systems (including the approaches to prioritize disruptive technologies to enter the health care system) and the key issues at stake (such as types and timing of multi-stakeholder interactions; collaborative development of evidence expectations; and potential for creating a shared agenda, focusing on the demands and challenges for different stakeholders). The information comes from scientific and grey literature mainly published in the last few years, identified by the author through an unstructured search in Google Scholar based on recent key publications,²⁰ reviewing websites of relevant organizations using horizon scanning (including EuroScan²¹ members), as well as input from the HTAi Global Policy Forum Organising Committee, HTAi Global Policy Forum members, HTAi Board members and the wider HTA community.²²

19 EuroScan International Network. A toolkit for the identification and assessment of new and emerging health technologies. Birmingham: EuroScan International Network, October 2014. Available via: <https://www.euroscan.org/assets/Uploads/EuroScan-Methods-Toolkit-October-2014-FINAL-CC-added.pdf>.

20 Lepage-Nefkens et al (2017), for example, provide an overview of 8 horizon scanning systems for pharmaceuticals, including England/Wales, Italy, Scotland, The Netherlands, Sweden, UK, US, Wales. In addition, the report from the OECD (2017) on new health technologies provides information on several horizon scanning systems (e.g., Korea, Italy, and Australia).

21 <https://www.euroscan.org/> [Visited October 5, 2017].

22 Through an online consultation of HTAi members, asking to provide feedback on the draft Background Paper.

Outline

Section 2 of this paper describes the background related to the topic, including an overview of past Policy Forum discussions also related to this topic. The subsequent Sections provide information with regard to:

- Governmental horizon scanning systems in a selection of countries, representing different continents and addressing different health technologies (e.g. drugs, devices, and diagnostics) (*Section 3*). We present a selection of most relevant/known systems, and do not strive for a comprehensive review;
- The relevance of stakeholder involvement throughout the process, illustrated by selected examples (*Section 4*);
- What kind of information and/or infrastructure can horizon scanning systems share/collaboratively collect and how, illustrated by a selection of recent initiatives (*Section 5*);

In *Section 6*, the use of horizon scanning in practice is presented, illustrating the key challenges related to the topic. The paper ends by summarizing the main issues that will feed into the 2018 HTAi Global Policy Forum meeting.

2. Background

In 1998, the International Network of Agencies for Health Technology Assessment (INAHTA) conducted a survey, which showed that 30 percent of its members were involved in horizon scanning activities. After an international workshop on the topic in the same year, a working group was set up. Their overall aim was to exchange information and expertise in the field of horizon scanning, especially around safety and efficacy of new health technologies. This led to the foundation of EuroScan in 1999.²³ The members of EuroScan (currently representing 14 countries around the globe)²⁴ differ in their approach towards horizon scanning, but share a common goal of informing decision-makers in health care about new and emerging health technologies that could have a significant impact on the health system ahead of their market entrance. In 2017, EuroScan became a legal entity, and refocused on scientific issues in horizon scanning, including strengthening the activities for the development of methodological approaches related to the identification, filtration and priority setting of new and emerging health technologies.²⁵ For more information on EuroScan, refer to *Section 5*, or their website.²⁶

The history of EuroScan shows that horizon scanning is not a new topic within the field of HTA. However, the issue has become more urgent due to discussions around optimizing access to care, especially with regard to access to medicines.²⁷ As stated in the 2017 HTAi Global Policy Forum Background Paper, health systems around the globe are challenged to achieve long-term financial sustainability of health care budgets, as well as assuring universal access to high quality and innovative care. This challenge is the result of a number of factors, including an ageing population, an increase in the prevalence of chronic diseases, the surge of new, emerging health technologies (some of them disruptive), as well as the necessity to address an increase in unmet need. Therefore, the development of and early access to these new, disruptive, often premium-priced health technologies needs to be balanced against issues of equity and financial sustainability of health systems.²⁸ This latter issue was also discussed during the 2016 HTAi Global Policy Forum meeting (see below) and the 2017 HTAi Global Policy Forum meeting.²⁹ The key issues with regard to early access have been further described in the 2015 HTAi Global Policy Forum Background Paper³⁰ and related journal paper.³¹

- 23 Banta, H. Jonnson, E. History of HTA: Introduction. *International Journal for Technology Assessment in Health Care*, 2009; (25): Supplement 1: 1-6.
- 24 Joppi, R. International Experiences of Horizon Scanning: An Introduction to Early Awareness and Alert Systems. Presentation. EuroScan Workshop. HTAi Annual Meeting, 18 June 2017.
- 25 EuroScan International Network. History of EuroScan. Cologne, 2017. [Internet]. Available via: <https://www.euroscan.org/assets/Uploads/History-of-EuroScan-Cologne-2017.pdf> [Visited October 5, 2017].
- 26 <https://www.euroscan.org/> [Visited October 5, 2017].
- 27 Godman, B., Oortwijn, W., De Waure, C., Mosca, I., Puggina, A., Specchia, M.L., Campanell, P. Van der Tuin, J. Links between pharmaceutical R&D models and access to affordable medicines. European Parliament. Directorate General for Internal Policies. Policy Department a: economic and scientific Policy. European Union, PE 587.321 EN. IP/A/ENVI/2015-06, October 2016. Available via: [http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU\(2016\)587321](http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU(2016)587321).
- 28 Iyengar, S., Tau-Teo, K., Vogler, S., Beyer, P., Wiktor, S., de Joncheere, K., Hill, S. Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis, *PLoS medicine*, 2016; 13(5): e1002032.
- 29 Oortwijn, W. on behalf of the HTAi Policy Forum. 2017 Background Paper. From Theory To Action: Developments In Value Frameworks To Inform The Allocation of Health Care Resources. Available via: http://www.htai.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1488956656&hash=7fdcbfd842e98dee4a18394d969eb9658eef3768&file=fileadmin/HTAi_Files/Policy_Forum/HTAi_Policy_Forum_2017_Background_Paper.pdf.
- 30 Facey, K. on behalf of the HTAi Policy Forum. 2015 Policy Forum Background Paper. Improving the effectiveness and efficiency of evidence production for HTA in the light of current trends in drug and device development, health system funding, regulation and HTA. 2015. Available via: https://www.htai.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1507133255&hash=8e0e2c2333a8ca5717230182ff51f9037ecc9aac&file=fileadmin/HTAi_Files/Policy_Forum_Publications/15019_HTAi_BackgroundWeb.pdf.
- 31 Facey, K., Henshall, C., Sampietro-Colom, L., Thomas, S. Improving the effectiveness and efficiency of evidence production for health technology assessment. *International Journal of Technology Assessment in Health Care*, 25; 31(4): 201-206.

In the 2017 report from the Organisation for Economic Co-operation and Development (OECD) on new health technologies,³² it is stated that the above-mentioned developments imply a “complex set of technical, ethical and financial challenges... that require new policies and approaches.” Horizon scanning is explicitly mentioned as an option as it can assist decision-makers in proactively planning for the adoption of disruptive health technologies and other innovative health technologies.^{33,34} Furthermore, to improve planning and resource allocation, forecasting the potential utilization and expenditure of a new health technology is essential.^{35,36}

This leads to the key questions related to the topic of this Background Paper:

1. how can horizon scanning systems (further) develop to effectively and efficiently identify which disruptive health technologies will emerge and which criteria (e.g. 'unmet need') should be used to prioritize and assess the most relevant and disruptive technologies for the health care system?;
2. how to enable interaction between all relevant stakeholders to facilitate both a) the proactive identification of and the uptake of possible disruptive (and potentially costly) technologies in health care systems in a sustainable fashion, and b) taking into account the organization of the health care system?

The topic of 'horizon scanning' has been highlighted during the last two HTAi Global Policy Forums; i.e. 2016 HTAi Global Policy Forum on “Changing HTA Paradigms” and the 2017 HTAi Global Policy Forum, “From Theory To Action: Developments In Value Frameworks To Inform The Allocation of Health Care Resources.” Below, the key elements from both HTAi Global Policy Forum meetings that are relevant for the 2018 HTAi Global Policy Forum meeting are presented.

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- 32 OECD. *New Health Technologies: Managing Access, Value and Sustainability*, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.
- 33 Miles, I. and Saritas, O, The depth of the horizon: searching, scanning and widening horizons, *Foresight*, 2012; 14(6): 530-545. <https://doi.org/10.1108/14636681211284953>.
- 34 Sun, F. and Schoelles, K., A systematic review of methods for health care technology horizon scanning, (Prepared by ECRI Institute under Contract No. 290-2010-00006-C.) AHRQ Publication No. 13-EHC104-EF. Rockville MD: Agency for Healthcare Research and Quality, August 2013. Available via: https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/horizon-scan_research-2013.pdf.
- 35 WHO European Office, *Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research*, 2015, WHO: Copenhagen, available via: <http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research>.
- 36 Wettermark, B., Persson, M.E., Wilking, N., Kalin, M., Korkmaz, S., Hjerdahl, P., Godman, B., Petzold, M., Gustafson, L.L. and the Regional Drug Expert Consortium in Stockholm County Council. Forecasting drug utilization and expenditure in a metropolitan health region, *BMC Health Services Research*, 2010; 10: 128.

2016 HTAi Global Policy Forum meeting

During the 2016 HTAi Global Policy Forum meeting (Changing HTA Paradigms),³⁷ horizon scanning was discussed in relation to financial sustainability of health systems and access of health technologies. In the journal article that reflects the discussion of the meeting, it was mentioned that "enhanced horizon scanning could play an important role in preparing for significant future investments"...for example in the case of Hepatitis C virus therapies...."taking into account multi-stakeholder engagement".... as well as "ongoing discussions from early in the technology development through to implementation." It was, however, questioned, "whether HTA bodies are the most appropriate placed organizations to convene such discussions or whether other institutions/bodies... might be better placed to do this". In addition, it was questioned, "what role industry can and should play in stimulating, convening or leading these activities."³⁸

2017 HTAi Global Policy Forum meeting

Horizon scanning was also discussed during the 2017 HTAi Global Policy Forum meeting (From Theory To Action: Developments In Value Frameworks To Inform The Allocation of Health Care Resources) concerning "how HTA may need to evolve and adapt to support the deliberations of decision-makers regarding strategies for coverage/pricing and technology adoption into the health care systems. Furthermore, it was mentioned that HTA agencies and industry could both benefit from deeper interactions that include discussion of a) health care system priorities in areas of unmet need, as well as b) limitations - either in science research or in the financial constraints a health system faces to the adoption of new health technologies - and the impact of these constraints on patients. This creates a potential to develop a shared agenda, outlining the demands and challenges for HTA and industry both in terms of capabilities and capacities."³⁹

Based on these discussions, horizon scanning was chosen as the topic for the 2018 HTAi Global Policy Forum meeting.

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- 37 D. Husereau on behalf of the HTAi Policy Forum, 2016 Policy Forum Background Paper. Changing HTA Paradigms, 8 January, 2016. Available via: https://www.htai.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1512579960&hash=9b0c3a74df04f0f7f6dcb0d81c491fd4d802d01d&file=fileadmin/HTAi_Files/Policy_Forum_Public/PF_Background_Paper_2016_FINAL.pdf.
- 38 Husereau, D., Henshall, C., Sampietro-Colom, L., Thomas, S. Changing health technology assessment paradigms? *International Journal of Technology Assessment in Health Care*, 25; 32(4): 191-199.
- 39 Oortwijn, W. on behalf of the HTAi Policy Forum. 2017 Background Paper. From Theory To Action: Developments In Value Frameworks To Inform The Allocation of Health Care Resources. Available via: http://www.htai.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1488956656&hash=7fdcbfd842e98dee4a18394d969eb9658eef3768&file=fileadmin/HTAi_Files/Policy_Forum/HTAi_Policy_Forum_2017_Background_Paper.pdf.

3. Overview of selected horizon scanning systems

In general, horizon scanning includes five related steps:

1. Identifying new health technologies and filtering them. The information can come from different sources, including companies, regulatory agencies, scientific literature, presentations, newspaper articles as well as online information/portals. The filtration is often based on population size, potential health benefits (health gain vs. current standards) and potential side effects;
2. Priority setting for health technologies to be assessed based on the level of unmet need, ability of new therapies to address this and potential budget impact;
3. Early assessment of the potential impact on health and health care, based on evidence, including findings from Phase II / III trials and expert opinion;⁴⁰
4. Dissemination of findings to key stakeholder groups;
5. Monitoring the information provided, including feedback from stakeholders and updates.⁴¹

A horizon scanning system must be clear about the end-users (e.g. health authorities, hospital managers), the time horizon⁴² taken into account, guarantee independence of the assessors, make sure that the information provided is relevant to the end users, and provide a clear dissemination strategy in order to reach them⁴³ (see Figure 2 below). EuroScan developed a toolkit for the identification and assessment of new and emerging health technologies, with practical guidance regarding steps 1-3 mentioned above.

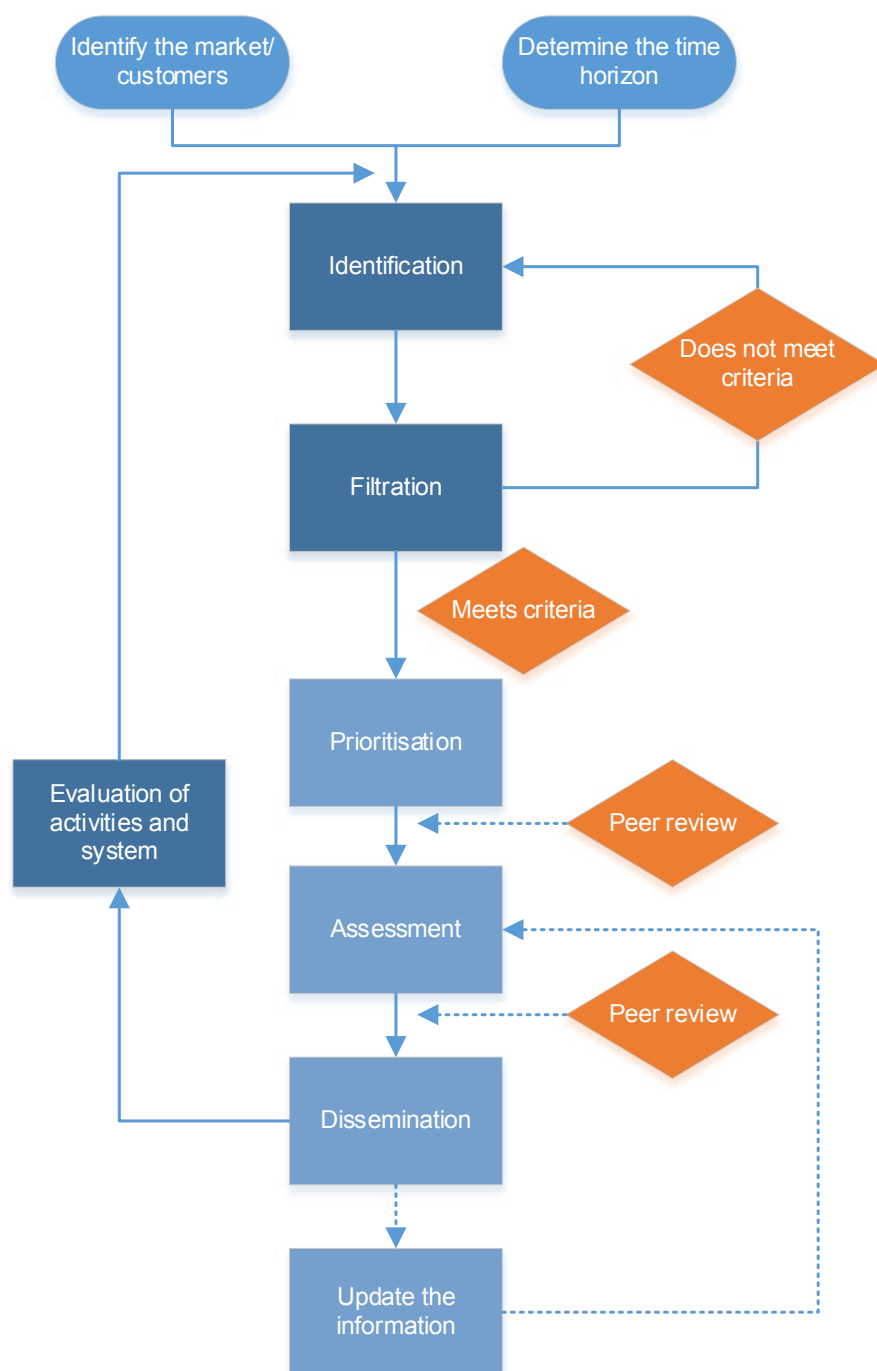
40 In the database of EuroScan it appears that most often results from Phase III trials are used. Ibarгойen-Roteta, N., Gutierrez-Ibarluzea, I., Benguria-Arrate, G., Galnares-Cordero, L., Asua, J. Differences in the identification process for new and emerging health technologies: analysis of the EuroScan database. *International Journal of Technology Assessment in Health Care* 2009; 25: 367-373.

41 Godman, B., Joppi, R., Bennie, M., Jan, S., Wettermark B. Managed introduction of new drugs. Chapter 20. In: Elsevier M, Wettermark, B., Almarsdóttir, A.B., Andersen, M., Benko, R., Bennie, M., Eriksson, I., Godman, B., Krska, J., Poluzzi, E., Taxis, K., Vlahovic-Palcevski, V., Vander Stichele, R. (Eds). *Drug Utilization Research: Methods and Applications*. Chichester: John Wiley & Sons, 2016: 210-221.

42 The time horizon is defined as the time before expected market authorization or market entry in which the health technologies are identified and information is collected regarding filtration, priority setting and assessment. Source: Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017: 20. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

43 Murphy, K, Packer, C., Stevens, A., Simpson, A. Effective early warning systems for new and emerging health technologies: developing an evaluation framework and an assessment of current systems, *International Journal of Technology Assessment in Health Care*, 2007; 23(3): 324-330.

Figure 2. Horizon scanning activities



Source: Based on EuroScan (2014)⁴⁴

In the OECD report on new health technologies (2017) it is mentioned that more than half of the 35 countries perform horizon-scanning activities, identifying health technologies that are relevant to the health care system. Most of these governmental horizon scanning systems take a two to three years' time horizon for scanning health technologies.⁴⁵

44 EuroScan International Network. A toolkit for the identification and assessment of new and emerging health technologies. Birmingham: EuroScan International Network, October 2014. Available via: <https://www.euroscan.org/assets/Uploads/EuroScan-Methods-Toolkit-October-2014-FINAL-CC-added.pdf>.

45 OECD. New Health Technologies: Managing Access, Value and Sustainability, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

A variety of aspects is considered in the process of horizon scanning. In the priority setting process, the criteria are often (potential) impact on:

- the care process, i.e., is it add-on or does it displace current treatment options and if it displaces, what happens to the technology that it displaces?⁴⁶
- health benefits, both at patient and population level;
- regulatory considerations;
- pricing and reimbursement considerations;
- factors that affect appropriate dissemination (e.g. acceptance by health care systems and society);
- utilization; some health technologies may affect the utilization of other health technologies. For example the advent of faster and cheaper next generation sequencing (molecular profiling) may expand the use of targeted medicines in cancer, Alzheimer's prevention could reduce the need for dementia care homes);
- unit cost or budget impact;
- ethical and legal considerations.⁴⁷

Below, we provide examples of (distinctive) horizon scanning systems from different continents that are addressing different technologies (i.e. pharmaceuticals⁴⁸, medical devices, diagnostics, procedures, combination therapies), with a focus on the following key issues:

- how (unmet medical) need is addressed in the horizon scanning systems (i.e. entry criteria for disruptive health technologies);
- the role of time horizon in the horizon scanning system, including link between horizon scanning and early dialogue/scientific advice and differences between type of technology;
- the impact of a new technology on current standard of care (implementation)/input to broader financial decisions.

A tabular overview of the horizon scanning systems described below can be found in Annex 1.

46 As input on the outline of the Background Paper, Policy Forum Members mentioned that this is a main implementation question in Canada that comes up repeatedly with respect to cancer drugs. It seems that the system is "hung up" on trying to address these questions, which delays access.

47 OECD. *New Health Technologies: Managing Access, Value and Sustainability*, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

48 Lepage-Nefkens et al (2017) provide an overview of 8 horizon scanning systems for pharmaceuticals: England/Wales, Italy, Scotland, The Netherlands, Sweden, UK, US, Wales.

Description of a selection of horizon scanning systems from different continents

Australia

HealthPACT (the Health Policy Advisory Committee on Technology) was established by the Medical Services Advisory Committee (MSAC) in 2003 and is Australia's (and New Zealand's) national horizon scanning body for new and emerging health technologies.⁴⁹ HealthPACT is a sub-committee of the Australian Health Ministers' Advisory Council, which is the advisory and support body to the Council of Australian Governments Health Council (i.e., HealthPACT ultimately reports to all health ministers in Australia). The Australian Commonwealth Government, the six state governments and the two territory governments fund HealthPACT.

HealthPACT members represent all Australian State and Territory health departments, the Commonwealth Government's Department of Health, Department of Veterans Affairs and Therapeutic Goods Administration, MSAC and New Zealand's Ministry of Health and District Health Boards. These members play a role in the priority setting of new and emerging health technologies for more detailed assessment⁵⁰ (see below). HealthPACT is a member of EuroScan and INAHTA and has a confined purpose as stated on its website: "to provide advance notice of significant new and emerging technologies to health departments in Australia and New Zealand to exchange information on and evaluate the potential impact of emerging technologies on their respective health systems. HealthPACT provides its health jurisdictions with evidence-based advice on emerging technologies. This information is used to inform financing decisions and to assist in the managed introduction of new technologies."⁵¹

HealthPACT scans scientific literature, websites of regulatory agencies and other HTA agencies, databases with clinical trials, and news sites for potential technologies, including medical and surgical devices, diagnostic tests and procedures, and other non-pharmaceutical interventions. It uses the following classification for new health technologies: experimental, investigational, nearly established, established, established but changed indication or modification of technique and should be taken out of use.⁵² The filtering takes place via the following pre-defined criteria: i) It is associated with obvious efficacy, safety or ethical issues or controversies; ii) It has not been assessed and is rapidly diffusing throughout the Australian health system; iii) It is applicable to a large proportion of the Australian population and may have considerable clinical or cost impact; or iv) It is applicable to a small proportion of the population but has obvious and far-reaching benefits (clinical need). The time horizon taken is up to three years before entering into the Australian health system. In the assessment, efficacy and safety issues, estimated speed, geographic and practitioner use, existing comparators, estimated clinical impact, estimated cost impact, clinical need and burden of disease, ethical issues and religious considerations are taken into account, and summarized in a technology brief (up to 10 pages). The briefs are submitted to HealthPACT for decision-making, which includes monitoring the health technology for another 12-24 months, commissioning a full HTA (noting that no HTA has been commissioned to date), or take no further action (see Figure 3 below). HealthPACT advice articulated in each of its outputs reflects its position on whether the health technology is suitable, or not, for ongoing review or public sector investment.

HealthPACT reports are then disseminated throughout the jurisdictions, including to public hospitals, and these inform policy, investment, or disinvestment decisions by governments and health providers.⁵³

49 <http://www.inahta.org/members/healthpact/> [Visited October 5, 2017].

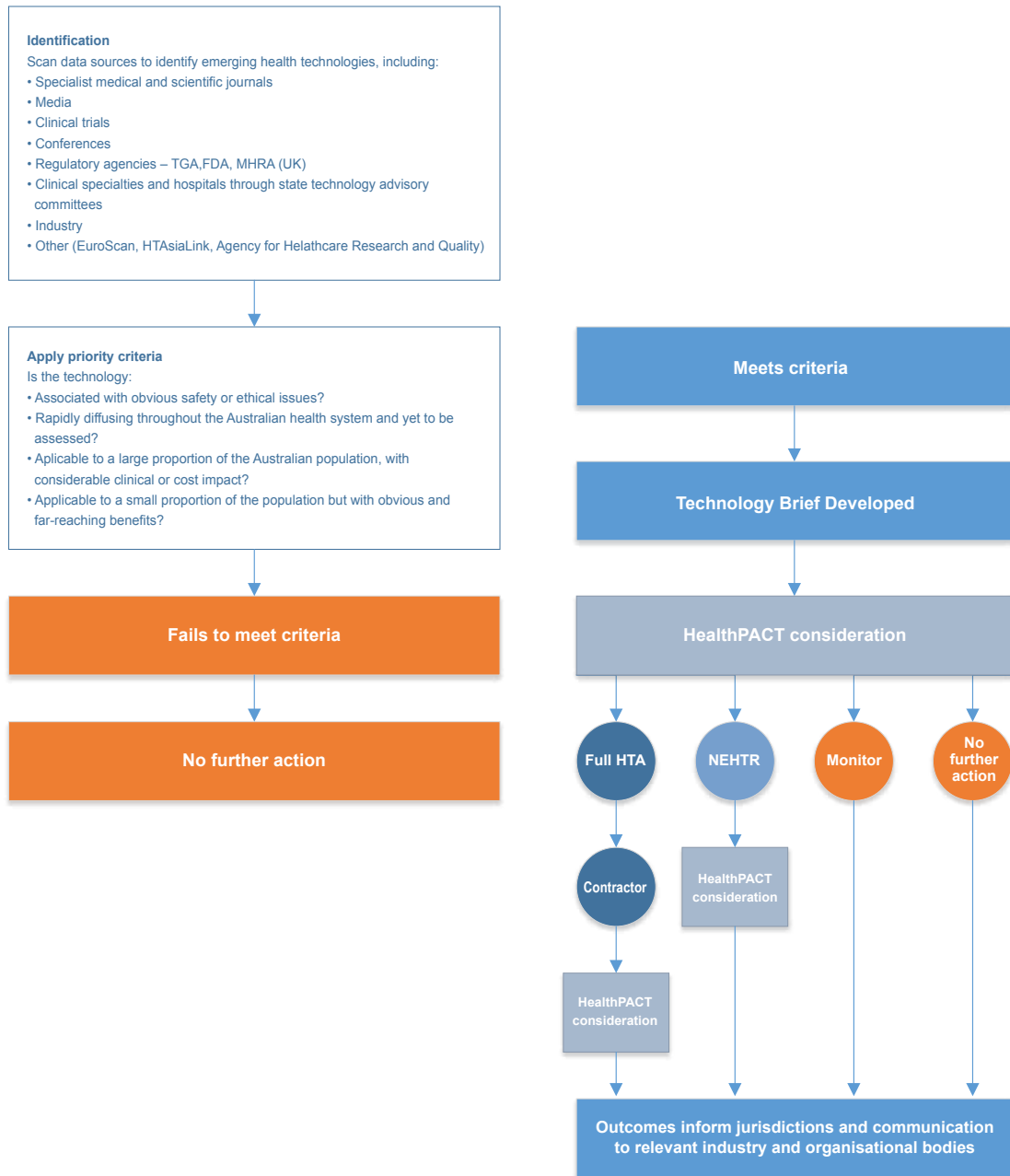
50 South Australian Policy Advisory Committee on Technology Information Sheet (15-02). Horizon scanning for clinicians and decision-makers. Available via: <http://www.sahealth.sa.gov.au/wps/wcm/connect/f24e7b004c45fde3a205fbb3172da4a1/SAPACT+Horizon+Scanning+for+New+Technologies.pdf?MOD=AJPERES>.

51 <https://www.health.qld.gov.au/healthpact> [Visited October 5, 2017].

52 Kearney, B. The role of HTA for innovative and emerging technologies. Presentation on behalf of the EuroScan International Network at the World Health Organization First Global Forum on Medical Devices. Bangkok, 9-11 September 2010.

53 <http://www.inahta.org/members/healthpact/> [Visited October 5, 2017].

Figure 3. HealthPACT horizon scanning process



Source: Based on SAPACT (2015)⁵⁴

In Australia, the challenges arising from disruptive technologies include the need to adapt the existing health care system to accommodate the new technology once a decision is made to publicly fund the technology.⁵⁵

54 South Australian Policy Advisory Committee on Technology Information Sheet (15-02). Horizon scanning for clinicians and decision-makers. Available via: <http://www.sahealth.sa.gov.au/wps/wcm/connect/f24e7b004c45fde3a205fbb3172da4a1/SAPACT+Horizon+Scanning+for+New+Technologies.pdf?MOD=AJPERES>.

55 Information provided by a Policy Forum Member as input on the outline of the Background Paper.

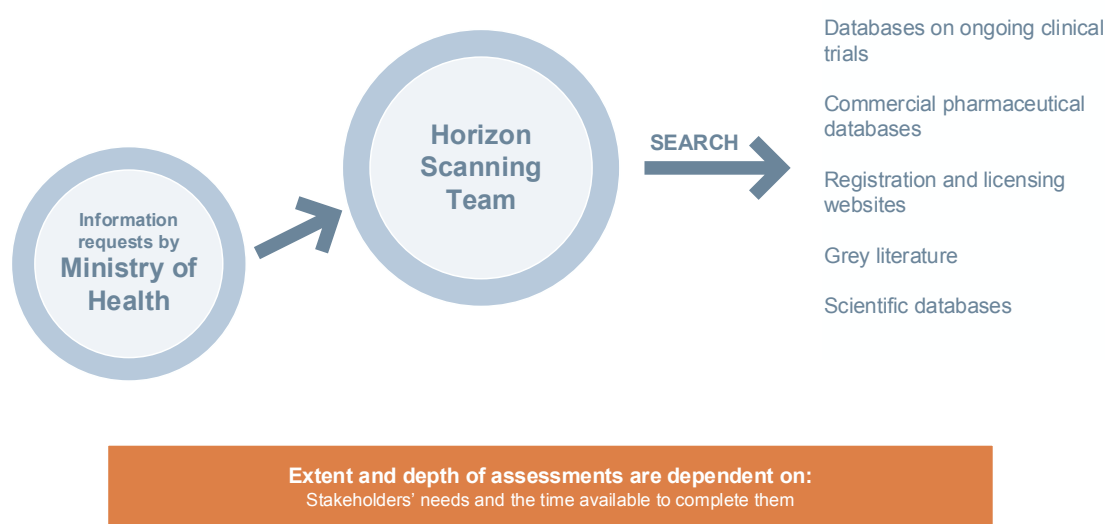
Brazil (CONITEC)

In Brazil, the National Committee for Health Technology Incorporation (CONITEC) is involved in horizon scanning. CONITEC is both a member of INAHTA as well as of the EuroScan International Network (since October 2016).⁵⁶

Members of EuroScan supported CONITEC in the set-up of their horizon scanning program, making use of the EuroScan Toolkit. The objective is to predict which technologies have the potential to impact on health care in the Public Health System of Brazil, in order to inform stakeholders and the public.

The horizon scanning team of CONITEC undertakes the identification of new technologies. The sources for the identification of new technologies include databases, both clinical trial databases as well as commercial pharmaceutical databases, websites (registrations and licensing), scientific and grey literature. The nature and depth of the assessment is currently dependent on the needs of the stakeholders and the time available, but priority is given to health technologies that can be introduced at affordable cost for the health system, but also have a favorable impact on clinical practice, on service organization and on the social and ethical aspects related to their use⁵⁷ (see Figure 4).

Figure 4. CONITEC horizon scanning process



Source: Based on Gomes et al (2017)⁵⁸

The information of the horizon scanning can provide input to support the decision-making process for the reimbursement of new technologies in the system, for defining which pharmaceuticals would be entitled for further development using public-private partnerships and to support the Ministry of Health in court cases regarding the right to health.⁵⁹ Furthermore, the information can be useful for the public. CONITEC produces so-called Alerts (concise information on a single technology in 6-8 pages) and Briefs (deeper analysis of a theme, consisting of 20-40 pages). In addition, the Brazilian Ministry of Health sees horizon scanning as a potential tool for proactively identifying health technologies for re-assessment in the context of disinvestment, and for the HTA process in general, by avoiding the evaluation of a health technology that could be replaced in the short-term.⁶⁰

56 EuroScan International Network. EuroScan Newsletter. Member profile: CONITEC. Issue 21, December 2016: p.2. Available via: <https://www.euroscan.org/assets/Uploads/EuroScan-newsletter-issue-21-Dec-2016.pdf>.

57 <http://conitec.gov.br/en/horizon-scanning> [Visited October 5, 2017]

58 Gomes, P.T.C., Souza, A.B., Petramale, C.A., Santos, V.C.C. Horizon scanning for information providing in Brazilian Ministry of Health. Poster presentation at the HTAi annual meeting in Rome. June, 2017.

59 Gomes, P.T.C., Souza, A.B., Petramale, C.A., Santos, V.C.C. Horizon scanning for information providing in Brazilian Ministry of Health. Poster presentation at the HTAi annual meeting in Rome. June, 2017.

60 IHS Markit. Brazil's CONITEC publishes guidelines for HTA evaluation. News item. Same-Day analysis. Published 8 December 2016. Available via: <https://www.ihs.com/country-industry-forecasting.html?ID=10659121852>.

Canada

In Canada, the Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec is a member of the EuroScan International Network.⁶¹ In this paper, we focus on the Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH, which is a member of INAHTA, has been actively involved in horizon scanning activities for quite some time. The horizon scanning process of CADTH is described in a report, which is publicly available.⁶²

The purpose of the Horizon Scanning Service of CADTH is twofold: a) to identify and evaluate the evidence on new or emerging health care technologies that may be important; and b) assess what their potential impact may be, both for patient care and for the health care system.

CADTH provides horizon scanning for any new or emerging health technologies, including drugs, devices, diagnostic tests or imaging, programs, medical interventions or surgical procedures. The definition used for 'new' is: "a health technology including drugs or medical devices, in the phase of adoption that has only been available for clinical use for as short period of time, and is generally in the launch or early post-marketing phases", while emerging is defined as "a technology that has not yet been adopted in a health care system. Emerging pharmaceuticals are usually in Phase II or Phase III clinical trials or pre-launch stage; Emerging medical devices are at the pre-marketing stage, or are within six months of being marketed, or have already been marketed, but are only in use a few centers. This may also include a new indication or use for an existing technology."⁶³

Staff of CADTH use different sources for the identification, including medical and technology media services, health care associations, networks and conferences, major medical journals, popular press and CADTH media monitoring, regulatory agency news, other HTA and HS networks and agency websites, CADTH rapid response, HTA or Optimal Use service queries. Several stakeholders, including decision-makers, CADTH staff, CADTH Board members and advisory committee members, as well as clinicians, patients and industry, may also suggest topics to CADTH's Product Development Team.

The Horizon Scanning Service summarizes the available evidence on technologies that are not yet in widespread use, i.e. 6-18 months from being licensed for use in Canada, not yet widely available, or not in routine clinical use.

The filtering of new and emerging health technologies for further evaluation is done by CADTH Product Development Team (separately teams for drugs and devices) on the basis of four criteria: i) what is the burden of disease, prevalence of the condition, or potential population impact of the technology in Canada; ii) is the technology within CADTH's horizon scanning time horizon; iii) does the technology have the potential to have a significant impact on patient outcomes or health care resources?; and iv) will the technology have an impact on health disparities?

Health technologies that meet the initial filtering criteria are entered into a horizon scanning database, one for drugs and one for other health technologies. For each technology in the database, information is provided with regard to the name of the technology, approval and regulatory status, identified patient population, type of technology, medical specialty and clinical setting for use. Topics can be selected for more detailed assessment (i.e. priority setting), when they are likely to be of significant interest

61 EuroScan International Network. Current organizational members (clubs and association) [Internet]. Available via: <https://www.euroscan.org/members-and-membership/current-organizational-members-club-and-association/> [Visited October 14, 2017].

62 CADTH. CADTH Health Technology Management Program. Horizon Scanning Products and Services Processes. Version 1.0. September 2017. Available via: https://www.cadth.ca/sites/default/files/pdf/HS_Consolidated_Process_Final.pdf.

63 CADTH. CADTH Health Technology Management Program. Horizon Scanning Products and Services Processes. Version 1.0. September 2017. Available via: https://www.cadth.ca/sites/default/files/pdf/HS_Consolidated_Process_Final.pdf.

and relevance to CADTH stakeholders. Therefore, members of several pan-Canadian committees and networks assist in prioritizing topics for the evaluation of drugs. With regard to medical devices, topics are prioritized using a multi-criteria internal process (not further specified). The information provided by the Product Development Team includes a brief description of the technology, regulatory status in Canada or elsewhere, target population, the setting in which the technology is intended to be used, and recent clinical trial information. CADTH management gives the final approval to evaluate a certain health technology.

The horizon scanning publications include bulletins, newsletters and a compilation of reports from CADTH and other agencies (so-called Round-up).⁶⁴ The processes for each of these publications is described in more detail in the publicly available report.⁶⁵

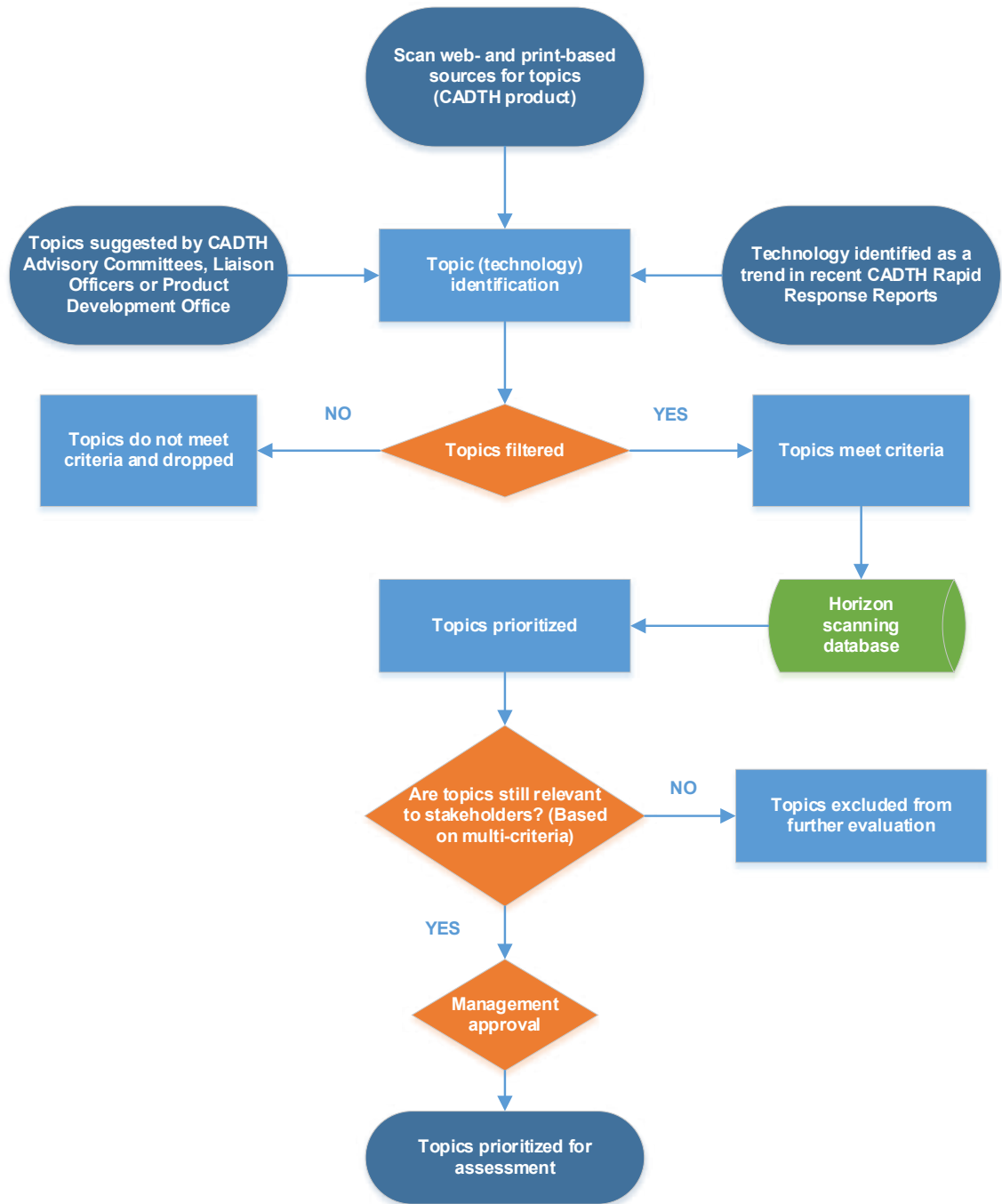
The main target audience of the Horizon Scanning Service are pan-Canadian health care decision-makers and health care providers across Canada. Furthermore, the information can be useful for other HTA agencies, horizon scanning programs, academic researchers, professional organizations, patients and patient groups, as well as the public and the media. Decision-makers can use this information for planning and priority setting purposes. It supports them to assess the evidence to better meet existing health challenges. Health care providers can use the information to facilitate the appropriate adoption and use of new and emerging health technologies, as well as to understand potential risks and benefits. For patients and caregivers, the outputs can be useful as they provide information about new and emerging health technologies that may affect them.

Figure 5 below depicts the process of CADTH.

64 <https://www.cadth.ca/about-cadth/what-we-do/products-services/horizon-scanning> [Visited November 28, 2017].

65 CADTH. CADTH Health Technology Management Program. Horizon Scanning Products and Services Processes. Version 1.0. September 2017. Available via: https://www.cadth.ca/sites/default/files/pdf/HS_Consolidated_Process_Final.pdf.

Figure 5. CADTH horizon scanning process



Source: Based on CADTH (2017)⁶⁶

66 CADTH. CADTH Health Technology Management Program. Horizon Scanning Products and Services Processes. Version 1.0. September 2017. Available via: https://www.cadth.ca/sites/default/files/pdf/HS_Consolidated_Process_Final.pdf.

South Korea

The HTA agency, National Evidence-based Healthcare Collaborating Agency (NECA), conducted preliminary studies in 2011 and 2012 aimed to adopt a horizon scanning system. As a result, the Horizon Scanning Service of Innovative Global Health Technology (H-SIGHT) was established in August 2013. As a first activity, H-SIGHT performed a pilot research of horizon scanning in the first half of 2014 and developed the H-SIGHT toolkit based on the toolkit from the EuroScan International Network. NECA obtained EuroScan membership in October 2013.

In 2014, NECA started their horizon scanning activities, called H-SIGHT (Horizon Scanning Service of Innovative Global Health Technology). The aim of the H-SIGHT is to identify, filter, prioritize emerging medical procedures, drugs, medical devices and national level health care programs or services and assess or predict their potential impact on health, costs, society and the national health care system in order to provide useful information of health technologies at the developmental stage, enhancing R&D resource allocation and establishing health care policies.

The process of H-SIGHT's horizon scanning activities consists of four steps, namely identification, filtration, prioritization and assessment. NECA identifies newly developed health technologies that could be introduced to the Korean health care system. For this purpose, new information technologies are suggested to be used. NECA staff and licensing experts then filter the technologies with respect to innovativeness and applicability to be introduced to the Korean health care system in one to five years. For this purpose, patent analysis of the bioscience field, keyword analysis and future technology prediction methods are used and they apply a so-called convergence search method. Due to differences in time for technology development, the level of evidence and related systems issues are depending on the search target. It is therefore necessary to perform search activities with sufficient consideration of each characteristic. Subsequently, NECA scores each health technology based on the prioritization criteria (disease burden, clinical impact, innovativeness, and economic impact, acceptability in the clinical field, social impact and current clinical evidence) and the results from a survey of relevant health professionals. Different weights are assigned to the items to be considered in the priority setting process, and the priorities are determined according to the overall score.⁶⁷

Thereafter, they select health technologies that are high ranked for further assessment with regard to safety, effectiveness and potential impact of the selected health technologies using literature reviews and experts' opinions. Finally, the horizon scanning reports on the new and emerging health technologies are disseminated.⁶⁸ The information is intended to serve a broad scope of end-users: decision makers, industries, health care professional purchasers, reimbursement agencies, patients and patient organizations.⁶⁹

United Kingdom (England/Wales)

For 20 years, until 1 April 2017, the University of Birmingham in the United Kingdom (UK) hosted the horizon Scanning Research and Intelligence Centre of the National Institute for Health Research (NIHR HSRIC).

From 1 April 2017 onwards, the NIHR Innovation Observatory, an independent research team based at Newcastle University in the UK, is contracted by NIHR to provide timely information on new and emerging health technologies with a potential significant impact on patients or the provision of health services in the near future. NIHR is a member of both INAHTA and EuroScan.

67 Park, J., Mo, J-A., Park, E., Cha Y, Lee, S., Shin, C. Predicting the potential impact of selective retina therapy: an assessment of current evidence. *Research & Reviews: Journal of Medical and Health Sciences*, 2016; 5(5): 8-15.

68 Information provided by Policy Forum Members as input on the outline of the Background Paper.

69 <https://www.euroscan.org/members-and-membership/current-organizational-members-club-and-association/national-evidence-based-healthcare-collaborating-agency-neca> [Visited October 5, 2017].

The key users of the NIHR Innovation Observatory include the National Health Service (NHS), the National Institute for Health and Care Excellence (NICE) – Technology Appraisal Programme/HTA research, NIHR research programmes and UK Government. In addition, the following organizations perform horizon scanning activities in the UK: All Wales Medicines Strategy Group (AWMSG), UK Medicines Information (UKMi), NHS England Specialized Services, Scottish Medicines Consortium (SMC), and Northern Ireland Health and Social Care Board.⁷⁰

The horizon scanning team of the NIHR Innovation Observatory undertakes identification activities and perform filtration. The NIHR Innovation Observatory identify mainly pharmaceuticals and cell therapies, followed by diagnostics and imaging, and devices and biotechnology.⁷¹

The identification of emerging health technologies starts up to three years before market authorization, with the aim to collect information 24-30 months prior to the launch of a health technology. For new pharmaceuticals and advanced therapies, they aim to provide an assessment report 20 months prior to expected market authorization; and use 15 months as the timeline for new indications of products that are currently licensed.

The NIHR Innovation Observatory have developed and will continue to develop advanced data systems that scan open and confidential data sources to inform pipeline analyses. These are supplemented by interactions with companies to verify and confirm. Data sources include trial registers, as well as secondary sources such as scientific literature, regulatory agencies (including Food and Drug Administration (FDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA)), clinical experts, patients/patient organizations, media, and tertiary sources (other horizon scanning organizations/trade data). The identification process includes two approaches: a) routine identification regardless of clinical specialty, and b) in-depth scanning and review of market pipelines for diseases / technologies. These reviews are requested by the government, NIHR or identified as priority by the NIHR Innovation Observatory itself. Members of the public can also suggest topics.

The filtration is mainly based on period to licensing, the priority areas set by the government (appropriateness for the NHS) and whether or not the health technology is cancer-related. The identified health technologies are reported as filtration notes, drug briefings, MedTech alerts or Intelligence notes (all health technologies).⁷²

Public and patient consultation is a critical element of the NIHR Innovation Observatory horizon scanning capability. It hosts a national public and patient forum called VOICE: Valuing Our Intellectual Capacity and Experience. This forum can be used to assist prioritization, gain consultation on an innovation (by companies as well as horizon scanning organizations), or educate members of a topic.

NICE undertakes additional filtration and conducts the prioritization to select health technologies for

70 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

71 NIHR Horizon Scanning Research & Intelligence Centre. 5-year contract report. April 2012 - March 2017. University of Birmingham, May 2017. Available via: <http://www.io.nihr.ac.uk/assets/Policies/annual-reports/NIHR-HSRIC-5-Year-report-2012-17.pdf>.

72 NIHR Horizon Scanning Research & Intelligence Centre. 5-year contract report. April 2012 - March 2017. University of Birmingham, May 2017. Available via: <http://www.io.nihr.ac.uk/assets/Policies/annual-reports/NIHR-HSRIC-5-Year-report-2012-17.pdf>.

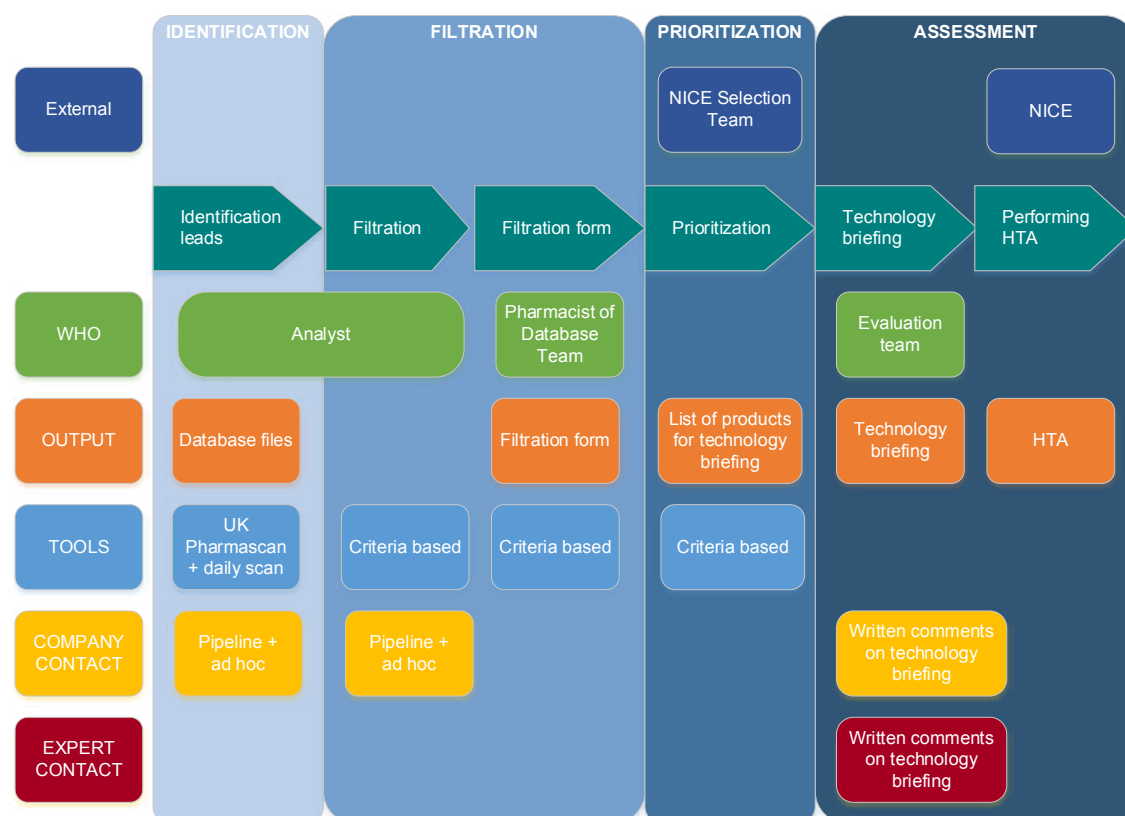
HTA.⁷³ The selection for a technology brief (for pharmaceuticals) as input to the scoping of a full HTA is determined by NICE using the following criteria: significant health benefit, significant impact on health-related policy, significant impact on the NHS resources, evidence on significant variation in use, and added value of national guidance.

The technology brief prepared by NIHR Innovation Observatory staff is sent to pharmaceutical industry and one or two clinical experts for review. A technology brief included the following information: target group, information about the technology, patient group, patient pathway, efficacy and safety and estimated costs and impact. The final technology brief is delivered to NICE with a non-commercially sensitive version publicly available on their website and twitter feed.

The process of the NIHR Innovation Observatory (and NICE) in conducting horizon scanning activities is presented in Figure 6.

The data systems developed by the NIHR Innovation Observatory involve the application of natural language processing with standardized ontologies and dictionaries to allow searching across multiple data sources, from (all) clinical trials and adverse events registries to PubMed and device approvals. These systems will be publicly available from 2018 onwards.

Figure 6. NIHR Innovation Observatory horizon scanning process (for pharmaceuticals)



Source: Based on Lepage-Nefkens et al (2017)⁷⁴

73 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

74 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeneluxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

United States

In the United States (US), the Agency for Healthcare Research and Quality (AHRQ) was the first public agency that started horizon scanning activities in December 2010 to inform its research planning⁷⁵, but it has been used more broadly – i.e., the output is also used by care organizations, as well as payers (health insurers, e.g. Aetna and Cigna) in medical policy reports.⁷⁶

The horizon scanning system is aimed to identify emerging health technologies and innovations, including drugs, devices, procedures, treatments, therapeutics, screening, diagnostics as well as care delivery innovations. The focus, though, lies on pharmaceuticals and biotechnological products. The aim is to identify health technologies, targeting 14 priority areas set by AHRQ (e.g. cancer, dementia, obesity, depression and other mental disorders, substance abuse), with the high potential impact within two to three years of their availability to enter clinical practice.⁷⁷ Furthermore, they track the diffusion of identified health technologies for two years after they are available for use in clinical practice. This means that the focus lies on late-phase trials. They also include health technologies earlier in the development, i.e. those that are subject to FDA regulatory pathways (e.g. orphan, breakthrough, accelerated approval, innovation pathway, and fast track).⁷⁸

AHRQ contracted the Emergency Care Research Institute (ECRI) for five years to conduct horizon scanning activities. After the contract ended, the activities for AHRQ were put on hold, but ECRI will continue horizon scanning for other customers.

AHRQ uses a protocol for horizon scanning activities, which includes the basic steps described in the beginning of this Section. The identification of health technologies, using an extensive list of sources, is aimed at those technologies with the highest potential impact on i) clinical care, ii) health care system, iii) patient outcomes, iv) costs, or v) a paradigm shift. Filtration criteria include: within per-defined time horizon, health benefit, number of patients, health care cost, cost per patient, innovation, morbidity, individual burden of disease, population burden of disease, government priority area, unmet medical need, off-label use, whether there has been a meeting with the relevant medical society to collect data, and change in delivery mode.

With regard to the prioritization, the analyst uses the following criteria and related questions: i) is the technology addressing an unmet need, ii) is the intervention in late phase development for the health care system, or can the intervention be adopted or diffused without going through a regulatory process?, iii) is the intervention novel, relevant, or innovative for addressing the need?, iv) would adoption or implementation of the intervention potentially shift/change/disrupt current care? During monthly topic nomination meeting, to which staff but also clinical experts are invited, a majority of votes sets priorities. Depending on the level of development of a health technology, it can either receive a status of 'track only' (for late phase trials) or 'advance to target'. The latter will be assessed in more detail, while the 'track only' technologies will be continued to scanned.

In the assessment phase, analysts provide an in-depth report using a standardized template, including topics such as potential competing and complementing technologies/services for the disease/condition, anticipated costs per patient, potential care settings, potential staffing and infrastructure implications.

75 Specifically investments in patient-centred outcomes research related to the Effective Health Care Program.

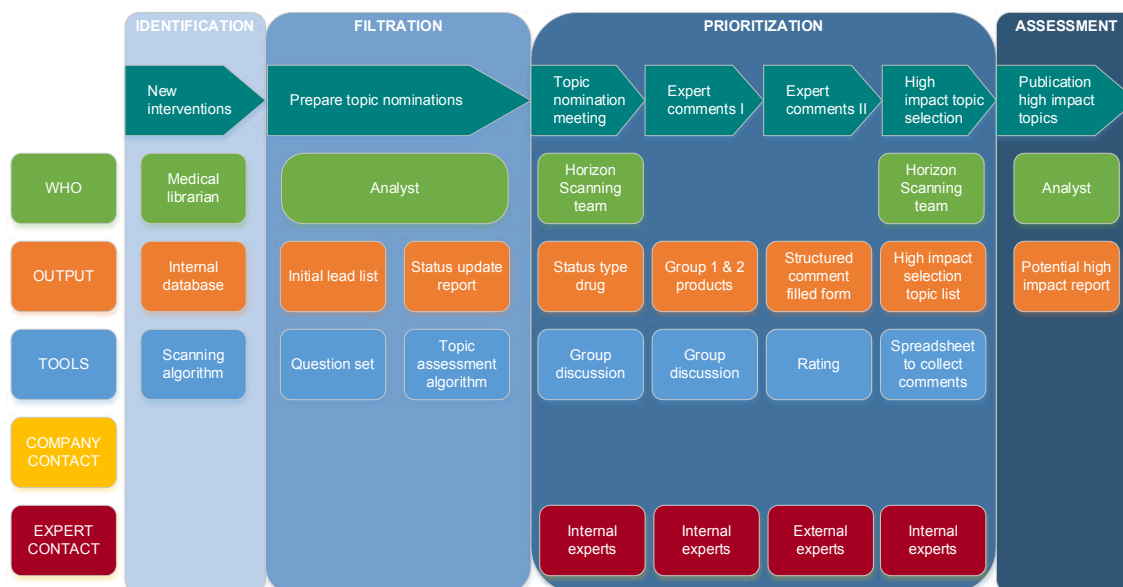
76 Schoelles, K. Robertson, D., Lynch, M., Doshi, J.A. Horizon Scanning: Identifying and Estimating Future Impact of Emerging Innovations on US Health Care. Values & Outcomes Spotlight. Methodology. March/April 2016: 6-10.

77 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

78 Schoelles, K. Robertson, D., Lynch, M., Doshi, J.A. Horizon Scanning: Identifying and Estimating Future Impact of Emerging Innovations on US Health Care. Values & Outcomes Spotlight. Methodology. March/April 2016: 6-10.

Internal and external experts are selected to score (1-4) the potential impact of a topic using eight aspects: potential importance of the unmet need it intends to address; potential to improve patient health; potential to affect health disparities; potential to disrupt the health care delivery system, potential for acceptance/adoption by patients; potential for acceptance/adoption by clinicians; potential impact on health care costs; overall potential to fulfil the unmet need. The horizon scanning team, together with internal staff, make the final decision on the high-impact rating topics. The final output is called a 'potential high impact report' that is published twice a year for each priority area. Examples of these reports include daclatasvir/sofosbuvir for treatment of chronic Hepatitis C virus infection and patient-based 3D printed biomodels to aid surgical planning.⁷⁹ The process is depicted in Figure 7.

Figure 7. AHRQ horizon scanning process (for pharmaceuticals)



Source: Based on Lepage-Nefkens et al (2017)⁸⁰

In 2014, AHRQ conducted a pilot study to estimate the potential 1-year cost of implementing health technologies related to two priority areas that were classified as having moderate or high potential impact. They encountered several challenges: 1) novel technologies are still in development, and therefore 'hard' data may prove difficult to find; 2) fragmentation of the US health care system impacts on which perspective to choose in the cost estimations, as well as on which population to base the cost estimates; 3) the time frame for conducting a rapid review is challenging in itself. This limits the time available for collecting additional data or conducting sensitivity analyses. This leads to the question about how much accuracy or precision of costs estimates are requested.⁸¹

Looking back, AHRQ was receptive to input from the industry to improve accuracy of information. The output ("potential high impacts reports") and regular updates were published on the Agency's website every 6-12 months. In summary, this initiative: (1) was open to input from industry; (2) non-confidential information released to the public and available to payers, health care providers, and others for decision-making; (3) to sustain it requires regular and permanent funding source.⁸²

79 ECRI Institute, Presentation at ISPOR, 21st Annual Meeting, Washington D.C., May 24, 2016. Horizon Scanning – Identifying And Estimating Future Impact Of Emerging Innovations On U.S. Healthcare. AHRQ Healthcare Horizon Scanning System.

80 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

81 Schoelles, K. Robertson, D., Lynch, M., Doshi, J.A. Horizon Scanning: Identifying and Estimating Future Impact of Emerging Innovations on US Health Care. Values & Outcomes Spotlight. Methodology. March/April 2016: 6-10.

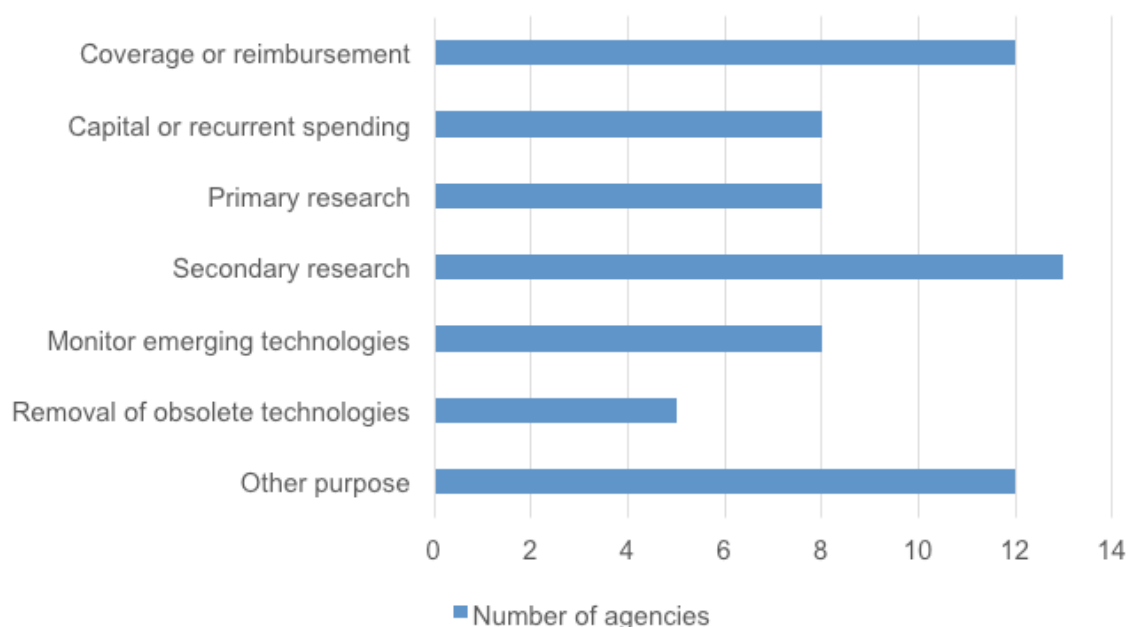
82 Information provided by a Policy Forum Member as input on the outline of the Background Paper.

Reflection - what lessons can be learned?

In 2013, Packer et al found that EuroScan members scan the horizon for devices, diagnostics (both 13 out of 15 members), interventional procedures (12 out of 15 members), pharmaceuticals and health programs (both 10 out of 15 members). Four members covered all types of health technologies in their horizon scanning activities and two members included all health technologies except health care setting.⁸³ Recently, EUnetHTA published an analysis of HTA and reimbursement procedures in EUnetHTA partner countries, including the use of horizon scanning for topic selection or workload planning. It was reported that the minority of (EUnetHTA partner) countries use horizon scanning in the field of pharmaceuticals (10 out of 29 countries); for non-pharmaceutical health technologies 10 out of 22 countries use horizon scanning.⁸⁴

The information from horizon scanning systems can be used for different purposes, as depicted in Figure 8.

Figure 8. Purposes of EuroScan member agencies conducting horizon scanning



Source: Based on Joppi (2017)⁸⁵

The end users differ as well and can include multiple and include national/regional governments; health professionals; purchasers of health services; research commissioners; and health care providers.⁸⁶

83 Packer C., Simpson, S., Terezinha de Almeida, R. EuroScan International Network Member Agencies: their structure, processes and outputs. *International Journal of Technology Assessment in Health Care*, 2015; 31 (1-2): 78-85.

84 EUnetHTA. EUnetHTA WP7 research and analysis activity 1: Final Report. An analysis of HTA and reimbursement procedures in HTA partner countries: final report, 2017. Available via: <http://eunetha.eu/outputs/analysis-hta-and-reimbursement-procedures-eunetha-partner-countries-final-report>.

85 Joppi, R. International Experiences of Horizon Scanning: An Introduction to Early Awareness and Alert Systems. Presentation. EuroScan Workshop. HTAi Annual Meeting, 18 June 2017. Referring to Packer C., Simpson, S., Terezinha de Almeida, R. EuroScan International Network Member Agencies: their structure, processes and outputs. *International Journal of Technology Assessment in Health Care*, 2015; 31 (1-2): 78-85.

86 Packer C., Simpson, S., Terezinha de Almeida, R. EuroScan International Network Member Agencies: their structure, processes and outputs. *International Journal of Technology Assessment in Health Care*, 2015; 31 (1-2): 78-85.

Furthermore, only a few horizon scanning systems provide foresight studies.⁸⁷ Foresight studies are seen to be beneficial to predict the health (care) and budget impact of disruptive health technologies through scenario analysis. Some countries, including Italy, Sweden and the UK, use the output of horizon scanning explicitly for budget impact calculations.⁸⁸ Using horizon scanning for forecasting potential budget impact requires an earlier time horizon, i.e. three to five years is most often used in prediction models. In Canada, CADTH and Health Canada (regulator) starting to work together on a project called "Foresight" with a long time horizon (i.e., 10-20 years) to prepare the health system.

In the recent report by Lepage-Nefkens et al (2017) and during a panel discussion about this report at the HTAi annual meeting in Rome⁸⁹, it was noted that:

- While the outputs and purposes of horizon scanning systems do differ, the inputs may be the same. Therefore, it might be possible to identify areas in a horizon scanning database that would provide information that is useful across health care systems. This point will be further addressed in *Section 5*;
- At the same time, there are aspects of horizon scanning that differ due to the purpose of the horizon scan. For example, the time horizon of a horizon scan depends on the goal of the horizon scanning system and can be up to five years, as is the case in South Korea. Joint collaborations would have to be sensitive to these differences;
- Some horizon scanning systems take into account information from Phase II trials (see Figure 9). This finding is also reported in the wider literature,⁹⁰ and is dependent on the purpose and target audience of the horizon scanning system;
- Confidentiality of data is an important issue. Making private data public is a serious challenge, although some Phase II studies (and Phase I) are public knowledge, e.g., where company projected pipelines are presented in annual reports;
- There should also be horizon scanning targeting unmet need, as payers do not want to pay for health technologies if there is no need for them. Furthermore, there are potential economic benefits for companies developing products to meet unmet need (see also *Section 6*). Unmet need is, however, often not listed as an explicit filtration criterion (see also *Section 6*). Examples of health technologies addressing unmet need that have been identified in the US system include e.g., joint sparing knee implants for patients in whom knee osteoarthritis has been diagnosed, antigen-specific immunotherapy for treatment of patients with resectable pancreatic cancer who have undergone surgery to remove the tumor and non-invasive computer-based psychophysics system for early detection of age-related cognitive decline and dementia in older patients at risk.⁹¹
- In order to be better prepared for the uptake of new health technologies, joint horizon scanning activities between counties are recommended. This point will be further addressed in *Section 5*.

87 OECD. New Health Technologies: Managing Access, Value and Sustainability, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

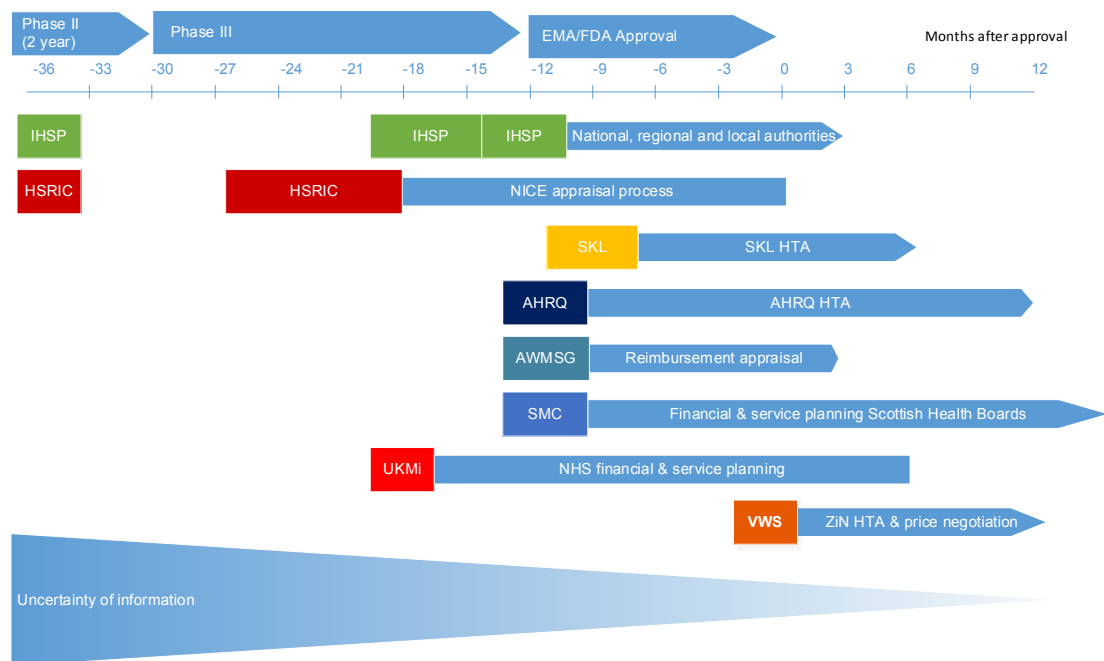
88 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

89 Panel (PN35). European Collaboration on Drug Policy: Horizon Scanning for Big Impact Pharmaceuticals. HTAi Annual Meeting, 18 June 2017.

90 For example. Do Nascimento, A., Teixeira Vidal, A., Terezinha de Almeida, R. Mapping stakeholders' preferences in prioritization criteria for horizon scanning in healthcare technologies [in Portuguese]. *Cad Saude Publica*, 2016; 32(7): e00177614. doi: 10.1590/0102-311X00177614.

91 ECRI Institute. Horizon Scanning Status Update: September 2015.

Figure 9. Time horizon used by different horizon scanning systems



Source: Based on Lepage-Nefkens et al (2017)⁹²

92 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

4. Stakeholder involvement throughout the process

In this Section, the following key issues are addressed:

- Who, when, and how to involve relevant stakeholders?
- Are there any best practices from which we can learn?

As the purposes of horizon scanning systems differ, their customers and/or end-users also differ. Stakeholders could be, for example, commissioners of research, health care provider organizations, health care providers, government/payers, HTA agencies, researchers, industry, media, capital risk investors, patients and/or the public.⁹³ Furthermore, several commercial organizations, both for profit and non-profit, can be contracted to perform horizon scanning activities. The majority of current systems directly serve an end user (e.g. NICE in the UK), and some of these end users actively request early assessments of new health technologies (e.g. the Ministry of Health in Brazil). Such practices would diminish the need for priority setting, which is, for example, done by NICE in the UK.⁹⁴

Stakeholders can be involved in all steps of a horizon scanning system. In some horizon scanning systems, stakeholders (e.g. health professionals, technology developers or the public) can inform the system about new and emerging technologies (e.g. Canada, UK). In addition, in the filtration step, the interest of the stakeholders should be taken into account, but staff of the horizon scanning system more often do the filtration themselves.⁹⁵ Different systems have different strategies as to how to involve the biopharmaceutical and medical device industries. In 2014, EuroScan surveyed members on industry engagement in horizon scanning activities. Of the 13 respondents, eight agencies mentioned to actively seek industry involvement in at least one stage of the horizon scanning process. The most common stages of collaboration are identification (sharing of pipeline information) and prioritization, undertaken by seven agencies. Three agencies collaborate with industry at the filtration, peer review, prioritization, and information updating stages, and four agencies collaborate with industry in the prioritization stage. No respondents collaborate with industry at the dissemination stage.⁹⁶

Furthermore, in some systems (e.g. US) external stakeholders are involved in the priority-setting phase. In the review of the information provided in the assessment phase, external stakeholders may be involved as well to check the completeness and accuracy of the information collected. The EuroScan toolkit explicitly recommends including external experts in the review of the information. In the US (AHRQ) horizon scanning system, discussions took place about the need for more information about how treatments are used in real clinical settings and the attitudes of physicians and patients towards existing treatments and innovations. They found that some type of crowdsourcing initiative might work.⁹⁷ In general, clinical experts are most often involved and increasingly other experts are involved. These include manufacturers, patients/patient representatives, health care system specialists, HTA experts, hospital management, and payers/insurers.⁹⁸

93 EuroScan International Network. A toolkit for the identification and assessment of new and emerging health technologies. Birmingham: EuroScan International Network, October 2014. Available via: <https://www.euroscan.org/assets/Uploads/EuroScan-Methods-Toolkit-October-2014-FINAL-CC-added.pdf>.

94 Douw, K., Vondeling, H. Selection of new health technologies for assessment aimed at informing decision making: A survey among horizon scanning systems. *International Journal of Technology Assessment in Health Care*, 2006; 22(2): 177-183.

95 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

96 Information provided by a Policy Forum Member as feedback on the draft Background Paper.

97 Kraus, C.N. The wisdom of crowds: can online clinical engagement impact Health Technology Assessment. Presentation at the Annual AHRQ conference, 10 September 2012. Available via: https://archive.ahrq.gov/news/events/conference/2012/track_e/23_kraus_schoelles/krause.html.

98 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

A non-exhaustive overview of selected countries to illustrate how stakeholders are involved in the set up and throughout the process of horizon scanning is shown below. The examples are chosen based on the input provided by the HTAi Global Policy Forum Members and HTAi Board Members.

Involvement of stakeholders – examples

Australia

As stated in *Section 3*, the representatives from all Australian State and Territory health departments, the Commonwealth Government's Department of Health, Department of Veterans Affairs and Therapeutic Goods Administration, MSAC and New Zealand's Ministry of Health and District Health Boards all play a role in the priority setting of the identified health technologies.⁹⁹ For example, the South Australian Policy Advisory Committee (SAPACT) distributes the list of identified health technologies to members of SAPACT, HTA committees, clinical networks and other clinicians for feedback. The respondents are asked to review the relevance and potential impact of the health technologies for the health system in the state of South Australia. While a similar approach is undertaken in the neighbouring state of Victoria, relevant program areas within the state's Department of Health and Human Services and public health services are also invited to nominate new and emerging health technologies for HealthPACT consideration.¹⁰⁰ This reflects that policy makers and clinicians are important stakeholders in horizon scanning. All members provide feedback to HealthPACT, which decides on horizon scanning priorities, depending on both national and jurisdictional priorities.¹⁰¹

Korea

NECA is in the process of involving stakeholders when necessary and at each stage of the horizon scanning process. In the identification stage, a system to involve experts is proposed to suggest information on new technologies, and licensing experts are involved in the filtration stage. In addition, in the prioritization and assessment phase, NECA involves experts from different areas, and they collect feedback on the results from relevant industries before the final report is disseminated. Furthermore, NECA is collaborating with R&D institutes for information exchange, and uses clinical consultation on medical devices and medical procedures of certified new health technology.¹⁰²

Sweden

As described in the 2016 HTAi Global Policy Forum Background Paper, the county councils in Sweden play an important role in horizon scanning.¹⁰³ The horizon scanning activities, targeting pharmaceuticals 12 months before expected marketing authorization, started in the Stockholm County Council in 2007, using the approach of NIHR HSRIC as a starting point. Since 2010, four main county councils, including Stockholm, are conducting horizon scanning activities on behalf of all county councils via the Swedish Council for Novel Technologies (NT council). The county councils further collaborate with regard to interpreting HTA reports, and priority setting for health economic based mini-HTAs. In some cases, this led to negotiations between manufacturers, county councils and TLV, necessitating a strengthened approach to horizon scanning and forecasting. In 2015, a national process for managed introduction and follow-up of new medicines was introduced. Currently, both processes are fully integrated; assessment reports are used to select pharmaceuticals for managed introduction and follow up at the national level (i.e. negoti-

99 South Australian Policy Advisory Committee on Technology Information Sheet (15-02). Horizon scanning for clinicians and decision-makers. Available via: <http://www.sahealth.sa.gov.au/wps/wcm/connect/f24e7b004c45fde3a205fbb3172da4a1/SAPACT+Horizon+Scanning+for+New+Technologies.pdf?MOD=AJPERES>.

100 Information provided by an HTAi Member as feedback on the draft Background Paper.

101 South Australian Policy Advisory Committee on Technology Information Sheet (15-02). Horizon scanning for clinicians and decision-makers. Available via: <http://www.sahealth.sa.gov.au/wps/wcm/connect/f24e7b004c45fde3a205fbb3172da4a1/SAPACT+Horizon+Scanning+for+New+Technologies.pdf?MOD=AJPERES>.

102 Information provided by a Policy Forum Member as input on the outline of the Background Paper.

103 D. Huserreau on behalf of the HTAi Policy Forum, 2016 Policy Forum Background Paper. Changing HTA Paradigms, 8 January, 2016. Available via: https://www.htai.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1512579960&hash=9b0c3a74df04f0f7f6dcb0d81c491fd4d802d01d&file=fileadmin/HTAi_Files/Policy_Forum_Public/PF_Background_Paper_2016_FINAL.pdf.

ation starts at market entry and the recommendation and decision is made three months afterwards).¹⁰⁴ Stakeholders, i.e. clinical experts, are involved in priority setting, as well as assessment of the prioritized health technologies. The experts are also often involved in a clinical working group of one of the county councils.¹⁰⁵

Forecasting is an important aspect of the Swedish system of horizon scanning. In 2010, the Stockholm County Council developed a new forecasting model for estimating the adoption and budget impact of new medicines due to concerns with traditional models.¹⁰⁶ The new model makes use of information from more than 20 medical and scientific groups, and it includes aggregate sales data. Since 2010, a forecasting model has been published each year. Using the output of the horizon scan, it models budgets per therapeutic subgroup. Predicted trends for the upcoming two years are adjusted for likely changes, including patent expiries among key therapeutic areas, changes in the organization of care, new guidelines, reimbursement decisions and/or the introduction of new medicines or new indications. There have been similar examples for other technologies, including mobile stroke units,¹⁰⁷ taking into account current concerns with the early assessment of new health technologies, including medical devices.¹⁰⁸ This issue will be explored further in Section 6.

UK (England)

The NHS in England does not currently have an effective horizon scanning mechanism to identify and track new and emerging devices, diagnostics, and digital health tools with potential economic and health care benefits to the health system.¹⁰⁹

NICE is currently in the process of establishing the MedTechScan, involving a wide range of stakeholders: NHS England; industry represented by the Association of British Health care Industries and the British In-Vitro Diagnostics Association; NICE; NIHRIO; Department of Health Office for Life Sciences; and Academic Health Science Networks.

MedTechScan is a digital system, which captures information about medical devices, diagnostics and digital health care products as they move from conception, through product development and appraisal cycles, onto commissioned adoption by the NHS. It will form part of a reformed and streamlined pathway, which efficiently takes products from innovation to market access, bringing benefit to patients, the medical technology industry and the economy. NHS England has commissioned NICE to develop MedTechScan. NHS England will use MedTechScan to support relevant commissioning processes and enable the timely introduction of new products. NICE will use MedTechScan to identify products for its guidance and advice.¹¹⁰

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- 104 Eriksson, I., Wettermark, B., Persson M., et al. The Early Awareness and Alert System in Sweden. Presentation. HTAi Annual Meeting, 17-21 June 2017.
- 105 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxa collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.
- 106 Wettermark, B., Persson, M.E., Wilking, N., Kalin, M., Korkmaz, S., Hjemdahl, P., Godman, B., Petzold, M., Gustafson, L.L. and the Regional Drug Expert Consortium in Stockholm County Council, Forecasting drug utilization and expenditure in a metropolitan health region, BMC health services research, 2010;10: 128.
- 107 Kolominsky-Rabas, P.L. Danatliev, A., Wahlster, P., Gantner-Bär, M., Hofmann, B., German, R., Sedlmayr, M., Reinhardt, E., Schüttler, J., Kriza, C., on behalf of the ProHTA Project Group. Technology foresight for medical device development through hybrid simulation: The ProHTA Project. Technological Forecasting & Social Change, 2015; 97: 105-114.
- 108 Markiewicz, K., van Til, J.A., IJzerman, M.J. Medical devices early assessment methods: systematic literature review, International journal of technology assessment in health care, 2014; 30(2): 137-146.
- 109 Yeo, A., UK NICE's MedTechScan will give NHS early view of innovation. News item. MedTech Insight, 11 October 2017. Available via: <https://medtech.pharmamedtechbi.com/MT121614/UK-NICEs-MedTech-Scan-Will-Give-NHS-Early-View-Of-Innovation>.
- 110 Information provided by a Policy Forum Member as feedback on the draft Background Paper.

Reflection – what can we learn from these examples?

In the 2016 HTAi Global Policy Forum Background Paper,¹¹¹ the need for multi-stakeholder engagement in horizon scanning was mentioned. This point is confirmed in the report by Lepage-Nefkens et al on horizon scanning (2017), as involvement of external experts in the selection and assessment enhances transparency of the process and creates more likely support for the final decision. These suggestions align with current HTA practices to include different stakeholders during the HTA process.

111 D. Husereau on behalf of the HTAi Policy Forum, 2016 Policy Forum Background Paper. Changing HTA Paradigms, 8 January, 2016.

5. Context matters – when and how to collaborate on what?

International collaboration in horizon scanning is common, but there is room for improvement, with regard to both joint horizon scanning and the sharing of work.¹¹² In this Section, the following key issues are addressed:

- What can be done at international or regional level and what needs to be done at national and/or local level?
- What can we learn from existing examples?

What infrastructure can be shared, what information can be collaboratively collected, and how?

Some horizon scanning systems aim to share most of the information with the public, while other systems accept confidentiality. Joint horizon scanning can include the identification and filtration as well as initial prioritization. More extensive priority setting and assessment of impact can only be done locally, as this is context dependent.

With regard to the identification phase, it is clear that sources for identification of health technologies (e.g. clinical trials databases) are commonly available for everybody. This could imply that joint horizon scanning is possible. The country's policy context, however, is still important for local/national challenges.

Methodological options for joint (cross-country) collaboration can include a more passive approach (use someone else's horizon scanning output, minimize duplication of efforts, and enhancing exchange of information), or a more active approach (i.e. sources are scanned by the joint horizon scanning system). The approach taken depends on the scope and goals of a horizon scanning system. In the latter option, more resources are needed, but there is also more control on the input and goals of the joint horizon scanning system. According to Lepage-Nefkens et al (2017), the implementation of a joint horizon scanning system would have to potential to allow – over time - decision-makers to identify other areas of joint collaboration, including early dialogues, price negotiations, post-marketing data collection, and policy development, targeted towards more patient-centered care based on unmet need as well as joint HTAs.¹¹³

Ongoing initiatives - examples

The need and benefits of a joint horizon scanning system are shared across many horizon scanning systems (see Table 1), but until recently not much progress has been made to establish joint horizon scanning systems. Below we provide a non-exhaustive overview of initiatives that are taking place at both international and regional level.

112 OECD. New Health Technologies: Managing Access, Value and Sustainability, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

113 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

Table 1. Benefits and prerequisites of international collaboration on horizon scanning and with a central unit (as proposed for BeNeLuxA)

	International collaboration	Central horizon scanning unit with national horizon scanning experts
Benefits	No duplication of efforts, hence more efficient use of resources	Fair contribution of all countries
	Identification of possible joint activities based on the output of the horizon scanning system	Investment in relationship building with national stakeholders
	Enlarged expert network	Operational feasibility
	Increased (expert) knowledge base	Single point of contact for stakeholders
	Increased negotiating power	Dedicated employees ensuring stable quality
	Secured processing of inputs to the joint and output from the joint horizon scanning system through the national horizon scanning expert	Link with national stakeholders
Prerequisites	Agreement on scope of joint horizon scanning system	Sufficient resources for the central horizon scanning unit
	Alignment of joint horizon scanning system outputs with national health policy	Clear mandate of national horizon scanning expert
	Integration of joint horizon scanning system outputs in national processes	Investment in relationship building with companies and medical societies
	Commitment of individual countries to support the horizon scanning agency	Regular evaluation of organizational model
	Regular evaluation of the joint horizon scanning system	

Source: Based on Lepage-Nefkens et al (2017, p. 84)¹¹⁴

114 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

Collaboration at the international level

- **EuroScan International Network (EuroScan)**

As described in Section 2, EuroScan was founded in 1999, and currently includes 17 member organizations from 14 countries.¹¹⁵ EuroScan is “a collaborative network of agencies and scientific association of individuals and institutions for the sharing of information and development of methods for the early identification and awareness of key new, emerging or obsolete health-related technologies”. It aims to:

- Disseminate information on, and increase understanding of, early awareness and alert systems and activities;
- Share experiences, methods and outputs;
- Avoid duplication;
- Promote the introduction and diffusion of safe, effective and cost-effective health technologies in health systems around the world.

EuroScan has developed a toolkit for setting up horizon scanning activities. The collaboration is enhanced by offering a joint web-based database that lists all identified health technologies; 90% of the information in the database is publicly available. A recent review of the EuroScan database by colleagues from Fudan University in China showed that most listed health technologies appear in the area of oncology & radiotherapy, followed by cardiovascular disease & vascular surgery, and gastrointestinal, pancreatic and liver disease.¹¹⁶

A survey of EuroScan members in 2012-2013 showed that the perceived barriers to collaboration are different aims and requirements of the horizon scanning system, lack of staff and financial resources, language differences and restrictions on dissemination. Despite the potential barriers, members agreed that there is benefit in joint collaboration in horizon scanning, especially regarding identification activities, either involving all members of the network or between individual members.¹¹⁷

EuroScan has a Memorandum of Understanding (MoU) with INAHTA (since 2010), WHO (since 2010, resigned in 2015), HTAi (since 2011, resigned in 2015), HTAsiaLink (since 2016) and with RedETSA (since 2016). The purpose of the MoU with HTAi is to set a framework of co-operation to support information exchange and collaborative work related to the identification and assessment of new and emerging technologies, and to support the Disinvestment and Early Awareness Interest Group of HTAi.¹¹⁸ The aim of the Interest Group, formally established in 2010, is providing an international platform for sharing knowledge and expertise, both in methods for prioritizing and assessing obsolete or low-added value technologies, and regarding the practical application of disinvestment for health systems.¹¹⁹

115 Joppi, R. International Experiences of Horizon Scanning: An Introduction to Early Awareness and Alert Systems. Presentation. EuroScan Workshop. HTAi Annual Meeting, 18 June 2017.

116 Information provided by an HTAi Board Member as feedback on the draft Background Paper.

117 Packer C., Simpson, S., Terezinha de Almeida, R. EuroScan International Network Member Agencies: their structure, processes and outputs. *International Journal of Technology Assessment in Health Care*, 2015; 31(1-2): 78-85.

118 <https://www.euroscan.org/about-us/collaboration/> [Visited November 21, 2017].

119 <https://www.htai.org/interest-groups/disinvestment-and-early-awareness.html> [Visited November 28, 2017].

Collaboration at the European level

Horizon scanning, priority setting and topic selection for doing joint or collaborative assessments at the European level play an increasingly important role in EUnetHTA, as well in the post2020 activities of the European Commission. Main activities within EUnetHTA JA3 include the development and refinement of a system for horizon scanning, topic selection and prioritization of health technologies for relative effectiveness assessments.¹²⁰ EUnetHTA will take into account experiences of existing initiatives such as EuroScan and BeNeLuxA (see below).¹²¹

Collaboration at the regional level

- **BeNeLuxA**

In 2016, the Ministers of Health from four European member states, Belgium, the Netherlands, Luxembourg and Austria, signed a letter of intent to voluntarily cooperate in the field of HTA, horizon scanning, pricing and reimbursement and information sharing on pharmaceutical policy. The main objective of the initiative is to ensure access to innovative pharmaceuticals at affordable costs.¹²² With regard to horizon scanning, a working group chaired by the Dutch Ministry of Health was set up to meet and finalize a joint horizon scanning agreement in the field of pharmaceuticals. Lepage-Nefkens et al (2017) have written an extensive report on the characteristics (model and methodology) of this joint horizon scanning system, which is publicly available.¹²³ In June 2017, the proposal for this joint horizon scanning system was presented to all EU member states, providing other countries the opportunity to join the collaboration (deadline 1 November 2017). The building blocks of the joint horizon system consist of identification and filtration, while priority setting remains the competence of each country involved. The proposal is that there will be one central horizon scanning unit (central database), with horizon scanning experts in each country. In the first half of 2018, a call for tender is foreseen for organizations to establish the proposed joint horizon scanning system.

- **Nordic Pharmaceuticals Forum**

In June 2015, the Nordic Pharmaceuticals Forum, including Norway, Denmark, Sweden and Iceland,¹²⁴ was established to exchange information with regard to horizon scanning and on prices and markets.¹²⁵ In May 2017, the countries met to discuss collaboration in the field of horizon scanning activities. Both Sweden and Denmark have recently stated, during a technical meeting of the WHO Regional Office for Europe on access to new medicines¹²⁶ (see below), that a first step would be to have more insights in the medicines pipelines and patent expiry of pharmaceuticals.

- **WHO Regional Office for Europe**

In February 2017, the WHO Regional Office for Europe organized a technical meeting to discuss collaboration with the member states regarding the set-up of a pilot project on joint horizon scanning and strategic procurement opportunities in relation to new medicines. The meeting was a follow-up of a 2016 workshop on voluntary collaboration on public procurement of new

120 EUnetHTA. EUnetHTA WP7 research and analysis activity 1: Final Report. An analysis of HTA and reimbursement procedures in HTA partner countries: final report, 2017. Available via: <http://eunetha.eu/outputs/analysis-hta-and-reimbursement-procedures-eunetha-partner-countries-final-report>.

121 <http://www.eunetha.eu/activities/eunetha-joint-action-3-2016-20/work-package-4-joint-production> [Visited October 14, 2017].

122 Cleemput, I. Horizon Scanning @BeNeLuxA. Challenges in pharmaceutical policy for European Countries. Presentation. HTAi Annual Meeting, Rome, 17-21 June 2017.

123 Lepage-Nefkens, I., Douw, K., Mantjes, G., de Graaf, G., Leroy, R., Cleemput, I. Horizon scanning for pharmaceuticals. Proposal for the BeNeLuxA collaboration. Belgian Health Care Knowledge Centre (KCE), 2017. Available via: <https://kce.fgov.be/publication/report/horizon-scanning-for-pharmaceuticals-proposal-for-the-beneluxa-collaboration>.

124 Iceland is currently not performing any horizon scanning activities.

125 European Council. Note from the General Secretariat of the Council. Furthering a member state driven voluntary cooperation to support access to medicines. Brussels, 27 January 2017. Available via: <http://data.consilium.europa.eu/doc/document/ST-5170-2017-INIT/en/pdf>.

126 World Health Organization. WHO Regional Office for Europe. Division of Health Systems and Public Health. Health Technologies and Pharmaceuticals Programme. Report from technical working meeting on access to new medicines – joint horizon scanning and strategic negotiations opportunities. 21-23 February 2017, Copenhagen, Denmark. Available via: <http://apps.who.int/medicinedocs/documents/s23295en/s23295en.pdf>.

medicines.¹²⁷ During the 2017 meeting, it was concluded that some degree of joint horizon scanning (identification and filtration), with support from WHO Regional Office in the identification phase, was welcomed by the participants. Participants felt that priority setting is better placed at national level. The main challenge will be to agree on a minimum set of criteria to be used for identification and the requirements needed for filtration to set up a joint horizon scanning system. To feed the discussion of the Regional Committee Meeting in September 2017 on access to new medicines, the Regional Office proposed to prepare a paper, in which the issues raised during the technical meeting will be further addressed.¹²⁸

Reflection – what can we learn from these examples?

It appears that several stakeholders, including HTA agencies, the WHO and ministries of Health in the European Region perceive collaboration in the field of horizon scanning to be beneficial. Potential benefits mentioned are efficiency gains due to avoidance of duplication of work in the identification phase, improved expertise and capacity building in the field of horizon scanning, the potential to deliver high quality and consistent data, as well as equal and timely access to new medicines for patients.¹²⁹ Furthermore, it seems that there is consensus that identification and filtration can be done jointly, while priority setting, assessment and dissemination is perceived to be best placed at the national or local level. The way in which collaboration takes place (e.g. exchange information or setting up a joint horizon scanning system), as well as the extent to which and when the involvement of stakeholders is requested (clinical experts, industry) is, however, dependent on the aim of the (joint) horizon scanning system. It might be beneficial to consider the activities that investors are doing, They meet regularly with technology developers to understand their future products and produce sophisticated revenue and profit models.

During a panel discussion on horizon scanning systems at the HTAi Annual Meeting in Rome (2017), it was stated that horizon scanning can be used for reaching further collaboration between countries throughout the HTA lifecycle (e.g. joint negotiation, joint procurement of health technologies as well as joint HTAs). However, until recently, horizon scanning activities have mostly been done separately by each health care system. The BeNeLuxA is an initiative that is aiming to jointly set up a system for horizon scanning, with wider ambitions towards joint HTAs, joint procurement and negotiations with industry.

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- 127 The results of this workshop can be found via: <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>.
- 128 World Health Organization. WHO Regional Office for Europe. Division of Health Systems and Public Health. Health Technologies and Pharmaceuticals Programme. Report from technical working meeting on access to new medicines – joint horizon scanning and strategic negotiations opportunities. 21–23 February 2017, Copenhagen, Denmark. Available via: <http://apps.who.int/medicinedocs/documents/s23295en/s23295en.pdf>.
- 129 World Health Organization. WHO Regional Office for Europe. Division of Health Systems and Public Health. Health Technologies and Pharmaceuticals Programme. Report from technical working meeting on access to new medicines – joint horizon scanning and strategic negotiations opportunities. 21–23 February 2017, Copenhagen, Denmark. Available via: <http://apps.who.int/medicinedocs/documents/s23295en/s23295en.pdf>.

6. What is the way forward?

Based on the information provided in the prior Sections, it seems that horizon scanning has not reached its full potential in assisting health care systems in proactively planning the adoption of disruptive health technologies and other innovative health technologies, as well as the disinvestment of obsolete health technologies. In order to provide a clear perspective on any sustainability issues for health care systems, horizon scanning should address the net impact of new health technologies. This requires a perspective on what other technologies may be reduced or become less of a burden for health care systems (e.g. because pharmaceuticals lose their exclusivity and are replaced by cheaper generics).

Packer et al (2012)¹³⁰ mentioned that current horizon scanning systems often have not published on their effectiveness. They presented the results regarding the accuracy of the UK horizon scanning system in terms of identifying and filtering new pharmaceuticals. They found that the horizon scanning system – over a period of 10 years – had a predictive positive value of 0.39 (i.e., 40 percent of the identified health technologies were filtered by NICE and selected for HTA), and that about eight percent of the pharmaceuticals that received a NICE appraisal were missed. In addition, in an earlier survey of 13 EuroScan members (2004) it was found that some horizon scanning systems missed important health technologies.¹³¹ Furthermore, Packer et al (2006), on behalf of EuroScan, studied the role of horizon scanning in diffusion of six health technologies in 10 countries. They found that “tools such as horizon scanning play some part in influencing the diffusion but need close scrutiny of how successfully they operate.”¹³²

The question is what does this imply for the health system? Packer et al (2012) concluded that these results might indicate that the filtration may be tightened to increase the horizon scanning system’s efficiency and that the question regarding implications has to be answered by the funders and/or end users of the horizon scanning system.¹³³ Similar results, implying room for improvement regarding impact of the horizon scanning system in relation to its goals, were found for the horizon scanning systems in Australia and Austria.¹³⁴ For example, in Austria end users mentioned that the horizon

130 Packer, C., Fung, M., Stevens, A. Analyzing 10 years of early awareness and alert activity in the United Kingdom. *International Journal of Technology Assessment in Health Care*, 2012; 28(3): 308-314.

131 Douw, K., Vondeling, H. Selection of new health technologies for assessment aimed at informing decision-making: A survey among horizon scanning systems. *International Journal of Technology Assessment in Health Care*, 2006; 22(2): 177-183.

132 Packer, C., Simpson, S., Stevens, A. (on behalf of EuroScan: the European Information Network on New and Changing Health Technologies). International diffusion of new health technologies: A ten-country analysis of six health technologies. *International Journal of Technology Assessment in Health Care*, 2006; 22(4): 419-428.

133 Packer, C., Simpson, S., Stevens, A. (on behalf of EuroScan: the European Information Network on New and Changing Health Technologies). International diffusion of new health technologies: A ten-country analysis of six health technologies. *International Journal of Technology Assessment in Health Care*, 2006; 22(4): 419-428.

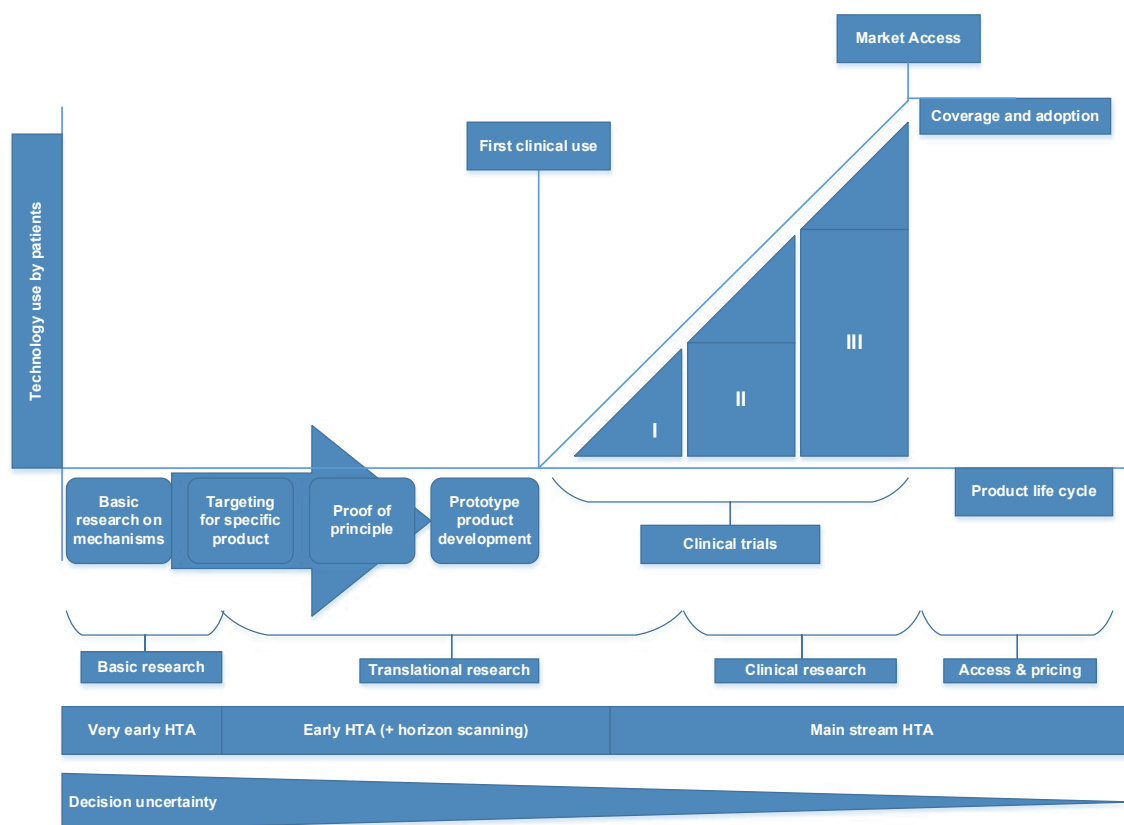
134 OECD. *New Health Technologies: Managing Access, Value and Sustainability*, Paris: OECD Publishing, 16 January 2017: 72. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

scanning reports were provided too late, i.e. on average within four months of marketing authorisation, to assist in proactively planning the adoption of oncology drugs. Furthermore, they noted that duplication of efforts in HTA could have been avoided by using horizon scanning for conducting joint assessments, as currently is envisioned by EUnetHTA (see *Section 5*).

In OECD countries, most horizon scanning systems seem to focus on new and emerging pharmaceuticals, mainly involving information from Phase III trials, taking usually a time horizon of two to three years. Nevertheless, there is no consensus about the time horizon to be taken in a horizon scanning system, as it is dependent on its aim. Obviously, it is important to balance the need for a longer time horizon and the uncertainty of the information with regard to the clinical and financial impact.

In addition, the type of health technology may play an important role in horizon scanning. For example, Markiewicz et al (2014) argue that early HTA and horizon scanning can be used to further develop a medical technology (see Figure 10).¹³⁵

Figure 10. Development of medical technologies and the role of horizon scanning



Source: Based on Markiewicz, van Til, IJzerman (2014)¹³⁶

An interesting initiative concerns the MaRS Excellence in Clinical Innovation Technology Evaluation (EXCITE) programme in Ontario (Canada). The purpose of the programme is to initiate early discussions between developers and relevant health system stakeholders, including government, health care providers and research to determine what information is needed to get the product successfully adopted. The evidence collected can be used for regulatory or licencing approval and reimbursement and purchasing

135 Markiewicz, K., van Til, J.A., IJzerman, M.J. Medical devices early assessment methods: systematic literature review, *International journal of technology assessment in health care*, 2014; 30(2): 137-146.

136 Markiewicz, K., van Til, J.A., IJzerman, M.J. Medical devices early assessment methods: systematic literature review, *International journal of technology assessment in health care*, 2014; 30(2): 137-146.

reviews.¹³⁷ In addition, the Innovative Medicines Initiative (IMI), a public-private partnership in the European Union, promotes dialogue and funding at the early life cycle of health technologies. It focuses on areas with unmet need (e.g. rare diseases) or social need.¹³⁸

Kolominsky-Rabas et al (2015), representing the ProHTA group,¹³⁹ used hybrid simulation techniques to support manufacturers and decision makers by providing early assessment of innovative products prior to their launch. By simulating the potential effects on medical and organizational processes, the authors were able to prospectively optimize the development of the innovation. They state that this method can be used in addition to early HTA and horizon scanning. One limitation of using simulation or forecasting techniques is of course the accuracy of data. Furthermore, the methods used by horizon scanning systems for forecasting are not always clearly described, and forecasting the potential utilization and expenditure of new health technology, an important tool for improving health care planning and budget/resource allocation, is not yet common practice.

As described in the 2016 HTAi Global Policy Forum Background Paper, one example of the lack of appropriate forecasting process is the recent launch of new high-priced products, such as medicines to potentially cure patients with the Hepatitis C virus, which has prompted the question regarding whether systems could have been more proactive in identifying and assessing what is coming.¹⁴⁰ As stated in the OECD report, pricing is not necessarily linked to the pipeline, as Gilead has made efforts to make Sovaldi available in low-income countries at discounted prices. The debates about high-premium priced health technologies, has also led to the question as to whether current market conditions, for example with regard to current (pharmaceutical) legislation and intellectual propriety rights, are sufficiently strong to stimulate the development of new health technologies that patients need at an affordable price.¹⁴¹

The place of “unmet need” is not yet clearly established among horizon scanning systems. HTA programs do have the responsibility to communicate with all stakeholders explicitly about how unmet needs are addressed. These programs should apply the unmet needs criteria consistently in the horizon scanning and HTA process. Improvements to be made in the area of unmet need as an explicit filtering criterion, is also mentioned in the OECD report on new technologies (2017). The report presents two examples, antimicrobial resistance and Alzheimer disease, where innovation is lacking behind due to market imperfections and challenges in conducting scientific research regarding these complex diseases. An overview of gaps in the (European) R&D agenda for antibiotics and recommended solutions is provided elsewhere.¹⁴² The authors conclude that the “current innovation system, does not always deliver health technology in the areas of greatest need” and that “decision-makers must become more pro-active and engage with industry to ensure that truly innovative products are developed.”¹⁴³ From a HTA perspective,

137 MaRS EXCITE. What is MaRS EXCITE? [Internet]. 2017 Available via: <https://www.marsdd.com/systems-change/mars-excite/mars-excite/> [Visited November 22, 2017].

138 Gutierrez-Ibarluzea, I., Chiumente, M., Dauben, H-P. The life cycle of health technologies. Challenges and ways forward. *Frontiers in Pharmacology*, 2017; 8; 14.

139 Kolominsky-Rabas, P.L. Danatliev, A., Wahlster, P., Gantner-Bär, M., Hofmann, B., German, R., Sedlmayr, M., Reinhardt, E., Schüttler, J., Kriza, C., on behalf of the ProHTA Project Group. Technology foresight for medical device development through hybrid simulation: The ProHTA Project. *Technological Forecasting & Social Change*, 2015; 97: 105-114.

140 D. Huserreau on behalf of the HTAi Policy Forum, 2016 Policy Forum Background Paper. Changing HTA Paradigms, 8 January 2016. Available via: https://www.htai.org/index.php?elD=tx_nawsecuredl&u=0&g=0&t=1512579960&hash=9b0c3a74df04f07f6dcb0d81c491fd4d802d01d&file=fileadmin/HTAi_Files/Policy_Forum_Public/PF_Background_Paper_2016_FINAL.pdf.

141 OECD. New Health Technologies: Managing Access, Value and Sustainability, Paris: OECD Publishing, 16 January 2017. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

142 Renwick, M.J., Simpkin, V., Mossialos, E. International and European Initiatives Targeting Innovation in Antibiotic Drug Discovery Development. The Need for a One Health – One Europe – One World Framework, Report for the 2016 Dutch Presidency of the European Union, 2016. Available via: <https://english.eu2016.nl/documents/reports/2016/02/10/2016-report-on-antibiotic-rd-initiatives>.

143 OECD. New Health Technologies: Managing Access, Value and Sustainability, Paris: OECD Publishing, 16 January 2017; 28-29. Available via: http://www.oecd-ilibrary.org/social-issues-migration-health/managing-new-technologies-in-health-care_9789264266438-en.

it is important to engage all stakeholders in this process. Furthermore, in engaging with the industry, the issue of confidentiality is very important and needs to be taken into account (see also *Section 3*). Moreover, it could be discussed when there is need in pre-competitive space to engage all industry partners involved in a certain disease area or technology development.

There is not a single model of stakeholder involvement in horizon scanning systems. The different systems involve a variety of stakeholders in the different steps of the scanning process and while some systems perform it in a systematic way, others do not. There is also a lack of analysis to understand if systematic multi-stakeholder involvement in the scanning process (along with the mix of stakeholders that should be involved) increases the effectiveness and efficiency on identifying and prioritizing those innovations with higher potential for the health system. Therefore, there is a need to better understand and analyze the processes of stakeholder involvement.

Finally, collaboration among horizon scanning systems is positively perceived and international collaborations are increasing, but there is room for improvement, especially with regard to avoiding duplication of work as stated above. Other potential collateral effects identified from joint horizon scanning systems (e.g. joint purchasing, price negotiations) currently remain in the realm of theory. Therefore, there is a need to thoughtfully analyze the pros and cons of a cross-country collaboration and carry out real life pilots to test it.

Key issues for the HTAi Global Policy Forum

In line with the objective of the 2018 HTAi Global Policy Forum meeting as stated in *Section 1*, (some of) the following questions will be discussed¹⁴⁴:

- How should health systems more clearly define public health needs and research agendas to support the right incentives for disruptive and/or emerging health technologies? Is there any role for HTA and the biopharmaceutical and medical device industries here?
- What are the mechanisms or processes to identify unmet medical/clinical need for proper innovation development and what collaborative efforts are needed to do so?
- Is there a need for standard outcome sets or disease guidance that captures from patient perspective what they need and would like to see in future therapies?
- How to align health care needs from policy making/payer perspective and industry R&D agenda?
- Who, when and how to involve stakeholders for an effective identification and filtration of potential high value disruptive and/or emerging technologies?
- How to better engage patients and caregivers in horizon scanning systems?
- Can horizon scanning systems play a more systematic role in fostering cross- stakeholders interactions in order to a) encourage the appropriate uptake of emerging and/or disruptive health technologies within existing health care systems, while they b) investigate financial sustainability challenges related to the uptake of emerging and/or disruptive (and potentially costly) technologies?
- How many horizon scanning systems are needed?
- Is it possible and desirable to develop a common shared agenda between HTA and industry to optimize the effectiveness and efficiency of current horizon scanning systems (from identification to preparing the health system for uptaking innovations)? If yes, what should be the rights and duties for each of them? E.g. what data can be shared and how (i.e. issues of data privacy/confidentiality)?

¹⁴⁴ Some of these questions were posed during the panel on horizon scanning at the HTAi annual meeting in Rome (June 2017), as well as during the technical meeting of the WHO Regional Office (listed in the 2017 OECD report).

- What are the challenges of horizon scanning systems in addressing different types of health technologies, including medical devices, diagnostics, eHealth, public health interventions etc? How can they be overcome?
- How to improve the impact of horizon scanning systems in preparing the health system?
- What are the challenges for HTA and the industry regarding joint cross-country horizon scanning systems?
- Could these collaborations pave the way for joint working on more complex issues? If yes, what will be the obstacles to overcome?
- What tools and products can be developed in a joint cross-country horizon scanning systems collaboration? What is the role of industry in this?
- On optimizing horizon scanning systems and on promoting cross-country collaborations, how is the resource/workload divided; what is whose task/responsibility?
- Who should do the quality assurance of any horizon scanning system?
- What are the mechanisms or processes to be implemented for ensuring an appropriate time horizon (when is information about the new or emerging health technology needed)?
- What type of incentives should health systems develop, for all stakeholders, to promote the appropriate uptake of high value innovation (as guided by horizon scanning systems)? (E.g. reconsideration payment systems and credit systems for health professionals).

Annex 1 Overview of selected horizon scanning systems from different continents

Horizon scanning system	AU	BRA	CA	KOR	UK	US ¹⁴⁵
Goals/objective(s)	To provide advance notice of significant new and emerging technologies to health departments in Australia and New Zealand, exchanging information and evaluating the potential impact of emerging health technologies in their respective health systems	To predict which technologies have the potential to impact on health care in the Public Health System of Brazil. To provide decision-makers with useful information in a timely manner, allowing them to anticipate any issues with their introduction and prepare the health system. In addition, to inform society about new or emerging health technologies with clear, transparent and didactic writing.	To identify and evaluate the evidence on new or emerging health care technologies that may be important; and Assess what their potential impact may be, both for patient care and for the health care system	To predict the potential impact of emerging health technologies on health, costs, society and the national health care system in order to provide useful information of health technologies at the developmental stage, enhancing R&D resource allocation and establishing health care policies	To provide timely information on new and emerging health technologies with a potential significant impact on patients or the provision of health services in the near future	To inform research planning of AHRQ focusing on 14 priority areas
Type of technology	Non-pharmaceutical technologies, medical and surgical devices, diagnostic tests and procedures	All health technologies	Any new or emerging health technology, including drugs, devices, diagnostic tests or imaging, programs, medical interventions or surgical procedures	Emerging medical procedures, drugs, medical devices and national level health care programs or services	Mainly pharmaceuticals and cell therapies, but also diagnostics and imaging, devices and biotechnology and surgical and non-surgical procedures	Emerging health technologies and innovations, including drugs, devices, procedures, treatments, therapeutics, screening, diagnostics as well as care delivery innovations. Focus lies on pharmaceuticals and biotechnological products
Time horizon	Up to 3 years	Not clearly defined	6-18 months from being licensed for use in Canada	Up to 5 years	Up to 3 years	Within 2-3 years

Horizon scanning system	AU	BRA	CA	KOR	UK	US ¹⁴⁵
	Identification/ filtration					
Who	Health PACT Secretariat	CONITEC Horizon Scanning Team	CADTH Product Development Team	NECA staff, licensing experts	NIHR Innovation Observatory	ECRI staff (Horizon Scanning Team)
How	Literature, websites of regulatory agencies and other HTA agencies, clinical databases, and news sites	Literature, databases, websites	<p>Medical and technology media services, health care associations, networks and conferences, major medical journals, popular press and CADTH media monitoring, regulatory agency news, other HTA and HS networks and agency websites, CADTH rapid response, HTA or Optimal Use service queries.</p> <p>Filtering criteria include:</p> <p>i) what is the burden of disease, prevalence of the condition, or potential population impact of the technology in Canada; ii) is the technology within CADTH's HS time horizon; iii) does the technology have the potential to have a significant impact on patient outcomes or health care resources?; and iv) will the technology have an impact on health disparities?</p>	Patent analysis of the bioscience field, keyword analysis, future technology prediction and new information technologies are suggested	<p>NIHR Innovation Observatory perform routine scanning of all health technologies as well as in-depth scanning and review of market pipelines for diseases / technologies.</p> <p>Early interaction with industry takes place to provide information on new products in the pipeline. In addition, trial registers scientific literature, regulatory agencies (FDA, EMA, MHRA), clinical experts, patients/patient organizations, media, trade data and other horizon scanning organizations. Filtration is mainly based on period to licensing, the priority areas set by the government (appropriateness for the NHS) and whether or not the health technology is cancer-related</p>	Extensive list of sources, Filtration criteria include: within per-defined time horizon, health benefit, number of patients, health care cost, cost per patient, innovation, morbidity, individual burden of disease, population burden of disease, government priority area, unmet medical need , off-label use, whether there has been a meeting with the relevant medical society to collect data, and change in delivery mode.

Horizon scanning system	AU	BRA	CA	KOR	UK	US ¹⁴⁵
Output	List of all potential new and emerging technologies	One specific health technology or list with health technologies regarding a specific theme (e.g. breast cancer drugs)	List of filtered health technologies in database (one for drugs, one for other health technologies)	List of filtered health technologies regarding Innovativeness and applicability to be introduced to the Korean health care system in one to five years	Filtration notes, drug briefings, MedTech alerts or Intelligence notes	List of health technologies with the highest potential impact on i) clinical care, ii) health care system, iii) patient outcomes, iv) costs, or v) a paradigm shift
Stakeholder input	No	Information requests via Ministry of Health	Yes; decision-makers, CADTH staff, CADTH Board members and advisory committee members, as well as clinicians, patients and industry	No	Yes; in-depth reviews are requested by the government, NIHR or identified as priority by the NIHR Innovation Observatory itself. Topics can also be suggested by members of the public on its website	No
Prioritization						
Who	Health PACT Secretariat, Health PACT members	CONITEC members, academia, key stakeholders	CADTH Product Development Team	NECA staff	NICE staff	ECRI staff (Horizon scanning team) with input from clinical experts based on a majority of votes.

Horizon scanning system	AU	BRA	CA	KOR	UK	US ¹⁴⁵
How	Using pre-defined criteria: obvious efficacy, safety or ethical issues or controversies; not been assessed and is rapidly diffusing throughout the Australian health system; applicable to a large proportion of the Australian population and may have considerable clinical or cost impact, or it is applicable to a small proportion of the population but has obvious and far-reaching benefits.	Priority given to health technologies with a potential impact on clinical practice, on service organization and on the social and ethical aspects related to their use	Likely to be of significant interest and relevance to CADTH stakeholders. Members of several pan-Canadian committees and networks assist in prioritizing topics for the evaluation of drugs. With regard to medical devices, topics are prioritized using a multi-criteria internal process (not further specified).	Establish priority ranking using criteria: disease burden, clinical impact, innovativeness, and economic impact, acceptability in the clinical field, social impact and current clinical evidence and a survey of health professionals after which weights are established	Using criteria: significant health benefit, significant impact on health-related policy, significant impact on the NHS resources, evidence on significant variation in use, and added value of national guidance	Priority is given to i) is the technology addressing an unmet need, ii) is the intervention in late phase development for the health care system, or can the intervention be adopted or diffused without going through a regulatory process?, iii) is the intervention novel, relevant, or innovative for addressing the need?, iv) would adoption or implementation of the intervention potentially shift/change/disrupt current care?

Horizon scanning system	AU	BRA	CA	KOR	UK	US ¹⁴⁵
Output	List of prioritized health technologies of interest to be further assessed	List of prioritized health technologies of interest to be further assessed (not mandatory)	List of prioritized health technologies of interest to be further assessed	List of high ranked health technologies to be further assessed	List of high ranked health technologies to be further assessed	List of prioritized health technologies. Depending on the level of development of a health technology, it can either receive a status as 'track only' (for late phase trials) or 'advance to target'. The latter will be assessed in more detail, while the 'track only' technologies will be continued to scanned.
Stakeholder input	Yes	No	Yes, only for pharmaceuticals (see above)	Yes	Yes, the NIHR Innovation Observatory host a national public and patient forum that can be used to assist prioritisation, gain consultation on an innovation (by companies as well as horizon scanning organisations), or educate members of a topic	Yes

Horizon scanning system	AU	BRA	CA	KOR	UK	US ¹⁴⁵
	Assessment					
Who	Health PACT Secretariat, Health PACT members	CONITEC Horizon Scanning Team	CADTH Team	NECA staff	NHIR IO and NICE staff	ECRI staff
How	Assessment of efficacy and safety issues, estimated speed, geographic and practitioner use, existing comparators, estimated clinical impact, estimated cost impact, clinical need and burden of disease, ethical issues and religious considerations	Dependent on the needs of the stakeholders and the time available	Description of technology, its regulatory status and/or availability, patient population that may benefit, costs, implementation issues and reliability and quality of the evidence	Assessment of safety, effectiveness and potential impact of the selected health technologies using literature reviews and experts' opinions	Providing technology brief including target group, information about the technology, patient group, patient pathway, efficacy and safety and estimated costs and impact	In-depth analysis using a standardised template, including topics such as potential competing and complementing technologies/services for the disease/condition; anticipated costs per patient; potential care settings, potential staffing and infrastructure implications.
Output	Technology brief	Alerts, briefs and internal (Ministry of Health) documents	Bulletins, newsletters or a compilation of reports from CADTH and other agencies (so-called Round-up)	Horizon scanning reports	Technology briefs, HTA reports	Potential-high impact report
Stakeholder input	Not clear	Not clear	Yes, external (clinical) experts and industry	Yes	Yes	No

145 Initial funding source was depleted in 2017.