# Horizon Scanning in the European Union

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Key messages

- Horizon Scanning (HS) is the process of identifying new and emerging technologies before uptake into practice to evaluate the potential impact to inform decision-making.
- In the European Union (EU), the EuroScan International Network was established in 1997 and over time, given its expanded geographic scope, was renamed as the International HealthTechScan (i-HTS).
- The HS process in the EU generally consists of identification, filtration, prioritization, assessment, dissemination and monitoring. HS is mostly used for pharmaceutical products.
- Cross-country collaboration through an HS network reduces resources required to develop an HS system and offers opportunities to learn from other countries' experiences.
- HS agencies, including publicly funded agencies, need to work hand-in-hand with government bodies to ensure use of the outputs of the HS process.

### What is Horizon Scanning (HS)?

Advancement of new technologies fosters significant benefits for the healthcare system, resulting in improved clinical outcomes of patients.<sup>1</sup> Majority of new technologies tend to have a high price point due to their complexity and substantial production costs.<sup>2</sup> This presents challenges for sustainable and fair access to medicines and health interventions even in high-income countries (HICs).<sup>3,4</sup> In addition, some innovations may not be effective or may not lead to additional health benefits compared to established practices.<sup>5</sup> Therefore, an innovative mechanism is required to identify and evaluate the potential outcomes and healthcare costs of such new technologies before widely used. To fill this gap, Horizon Scanning (HS) has been developed to inform policy-makers to use evidence to make strategic decisions and prioritize efforts before such high-cost medicines enter into the market.<sup>4,6</sup> HS is recommended as the first step of Health Technology Assessment (HTA) for countries in the European Union (EU) where HTA systems have been well established for over 20 years.<sup>7</sup>

### What is the definition and objective of horizon scanning?

HS is defined as identification of new and emerging technologies before uptake into practice to evaluate potential impact for inform decision-making.<sup>8</sup> It is intended to assess the extent of potential impact of new and emerging technologies including their economic impact, safety and efficacy, social and ethical considerations and any changes that may be needed at the system level in order to be recommended for use.

## Which countries use Horizon Scanning in the European Union (EU)?

According to a survey conducted in 2019, 10 out of 27 countries in the EU had already established their own national HS system.<sup>9</sup> Among them, six countries systematically use HS (Iceland, Italy, the Netherlands, Norway, Sweden and the United Kingdom), and a further four countries (Austria, Denmark, France and Ireland) have established ongoing HS activities.<sup>9</sup> The HS system in Italy was established in 2006 and is the oldest HS system in the EU region.<sup>10</sup>

### Who are collaborating on Horizon Scanning in the EU?

In 1997, a network comprising representatives from Denmark, the Netherlands, Spain, Sweden, the United Kingdom (UK), Canada, and Switzerland was established with the aim of facilitating cross-country collaboration. The objectives of this network are to foster knowledge sharing and exchange of skills and experiences related to the identification and evaluation of emerging technologies, as well as to develop methodologies for early awareness and alert activities. Furthermore, the network serves as a platform for exchanging information on the safety and efficacy of new technologies.<sup>9</sup> Two years later, it was set-up as the EuroScan International Network and expanded into a collaboration of 12 countries.<sup>11</sup> The network has since become a global one and renamed as the "International HealthTechScan (i-HTS)". This network includes regional groups, such as Africa (AfroScan), America (ScanAmericas), Asia (AsiaScan) and Europe (EuroScan).

In addition, other cross-national collaborations have emerged in the EU region such as the Valletta Declaration, Nordic Pharmaceutical Forum and International Horizon Scanning Initiative. Countries without national HS systems such as Croatia, Cyprus, Finland, Greece, Malta, Portugal, Romania, Slovenia and Spain have joined at least one of these networks with plans to establish an HS system in the near future.<sup>12</sup>

### What is the process for Horizon Scanning in the EU?

HS in EU countries is used to identify pharmaceutical products, technologies for diagnosis and health interventions, public health interventions, and treatment delivery systems.<sup>13</sup> However, based on a survey conducted in 2019, it was found that only Italy, Norway and the UK had HS systems in place to identify any type of health technologies, while other countries focused on identifying pharmaceutical products exclusively.<sup>9</sup> In 2017, more than one-third of the requests for HS to the European Medicine Agency were related to anti-cancer and immunomodulating agents.<sup>14</sup> Generally, there are six steps in the HS system in the EU, namely, identification, filtration, prioritization, assessment, dissemination and monitoring as shown in Figure 1.



### Identification

Identification, the first step of HS, is the process of scanning sources to identify new or emerging health technologies.<sup>10,13,15-20</sup> Majority of agencies involved in the EuroScan network, started the identification process from the "experimental" phase (phase II - III) of technologies or within two years before roll out into the market.<sup>21</sup> Generally, sources for identification can be divided into four types as shown in Table 1.

Type of source	Country
Primary: The manufacturer, company websites, including press releases and investor report	EU-countries <sup>13</sup> , Sweden <sup>16</sup> , Italy <sup>10</sup> , UK <sup>18</sup> , Austria <sup>19</sup>
Secondary: Regulatory agencies like FDA, scientific journals, internet news releases, conference proceedings, and health technology media outlets	EU-countries <sup>13</sup> , Sweden <sup>16</sup> , Austria <sup>19</sup> , Italy <sup>10</sup> , UK <sup>18,22</sup> , Norway <sup>17</sup>
Tertiary: Other EAA systems or registries of clinical studies	EU-countries13, Sweden16, Italy10, Austria19
Consultation with stakeholders including clinical experts and technical developers	Italy <sup>10</sup> , UK <sup>18</sup> ,
Open call to stakeholders for submission of new and emerging technologies by using structured notification form	Italy <sup>10</sup>
Patients' suggestion	Netherlands <sup>27</sup> , UK <sup>18</sup>

Table 1. Type of sources involved in identification process

Primary sources include direct information from manufacturers or investors.<sup>8,10,13,16,19</sup> Secondary sources such as the media or other channels as well as published articles.<sup>8,10,13,16,17,19,22</sup>. Tertiary sources include information from other organizations engaged in identifying new healthcare technologies.<sup>10,13,16</sup>

Identification is usually conducted by staff from HS agencies<sup>20</sup> and stakeholders representing government bodies, clinical experts, medical associations and patient associations.<sup>10,15</sup>

#### **Filtration**

Filtration refers to identifying an initial list of potentially relevant drugs or interventions to include in the prioritization process.<sup>23</sup> There are three criteria to filter new and emerging technologies: 1) early phase of development (phase II – III) or early post-marketing stage<sup>16,19,23,2</sup> the targeted technology of interest<sup>15</sup> (for instance, pharmaceutical products or surgical procedures), and 3) completeness of information available in sources.<sup>15</sup>

#### Prioritization

Following the filtration process, new and emerging technologies are prioritized for investment based on the scope of interest as per national healthcare priorities.<sup>13</sup> Generally, it is based on criteria related to patient, disease, health systems and technology perspectives, as shown in Table 2. Prioritization is usually conducted through stakeholder consultations or focus group discussions.<sup>17</sup> During the consultation, individual stakeholders provide scores to products based on the four criteria and products are prioritized based on the total score received.<sup>10</sup>

#### Assessment

Assessment is the process of determining the potential impact of technologies prioritized depends on stakeholders' interests and needs.<sup>10,23</sup> It involves developing HTA model or having focus group discussions with relevant experts.<sup>17</sup>

Prioritization criteria	Country
Patient perspective • Number of patients eligible for the drug under considerations; Applicable to a small proportion of the population but with obvious and far-reaching benefits; Intended use of the new therapy; Anticipated clinical benefit; Ethical issue; Risk; Cost	Austria <sup>23,</sup> EU-countries <sup>13,</sup> Italy <sup>15</sup> , Sweden <sup>16,</sup> Norway <sup>17,</sup> UK <sup>18</sup>
Disease perspective ● Burden of disease	Sweden <sup>16</sup>
Health system perspective • Level of resource utilization	Austria <sup>23,</sup> EU-countries <sup>13,</sup> Sweden <sup>16,</sup> Norway <sup>17,</sup> UK <sup>18</sup>
Technology perspective • Novelty: Level of interest from media; Anticipated sub- optimal market uptake	Sweden <sup>16.</sup> Norway <sup>17.</sup> UK <sup>18</sup>

Table 2. Prioritization Criteria for new and emerging technologies

The assessment criteria take three perspectives: patient, economic evaluation and type of new drug or technology. The patient perspective considers the potential impact at the patient, in terms of level of satisfaction, level of effectiveness, and level of utility.<sup>10,17,18</sup> The economic evaluation perspective focuses on estimating accurate economic impact following the uptake.<sup>10,18</sup> Lastly, the level of innovation and probability of implementation in the near future are taken into account from the technology perspective.<sup>17</sup>

Internal peer-review is conducted to check for accuracy and consistency of the assessment report before being published.<sup>10</sup> The assessment report is distributed to experts from the medical advisory committees such as Medical Services Advisory Committee or other dedicated organizations assessing the safety and efficacy of new drugs or interventions.<sup>16</sup>

#### **Dissemination**

Dissemination is the process of delivering the output of HS to the target audience in a timely manner.<sup>23</sup> Fundamentally, dissemination reports provide information on: target population, description of the procedure and technology, clinical importance and epidemiological data of the disease, current development stage, potential benefit of the technology over current alternatives, safety, effectiveness, cost-effectiveness, social, ethical and organizational impact.

The reports are disseminated in the forms of alert report, brief, early assessment report or newsletters to the target audience from government bodies, pharmaceutical and technology industries, medical and patient associations.<sup>15</sup> For members of the EuroScan network, the HS reports are uploaded on EuroScan database for an international audience.<sup>15</sup> However, some of the reports like internal reports are confidential and distributed only to decisionmakers, the HTA department, and other internal stakeholders for peer review.<sup>10</sup>

### Monitoring and updating

It is important to periodically monitor key performance indicators such as time dedicated to activities, potential obstacles to activities, and the workload of conducting HS.<sup>10</sup> It is also important to keep abreast and update the information. This is because of the nature of uncertainty of the information in early assessment which can change or be updated frequently before the technology is implemented. It may be necessary to consider re-assessment in some cases.<sup>10,19,23</sup>

### How is Horizon Scanning used as a policy tool?

Countries with national systems with systematic use of HS such as Italy, the Netherlands, Norway and the UK have fully integrated the HS system into their pharmaceutical policy frameworks and is used in the decision-making process.<sup>9</sup> The HS system is widely used to assess new technologies in the area of oncology, preventing infectious diseases such as vaccines, immunological and rare diseases due to their nature of rapidly evolving and limited treatment options.14,24,25

### What are the challenges of Horizon Scanning in the EU?

The HS system in the EU is one of the most established system that is established since 1985.<sup>26</sup> However, it is not a system without challenges.

First, there are limited resources available for short-term and long-term operations in terms of finances, appropriate expertise and logistical constraints.<sup>10</sup> In some instances, there is low participation of stakeholders, possibly due to limited interest and knowledge especially of new technologies such as Advanced Therapy Medicinal Products (ATMPs).<sup>10,13,15,18</sup> This is reflected in that fact that only 10 out of 27 of the EU countries have established an HS system to date.9

Second, accuracy of prediction in assessing possible implications of new and emerging technologies might be insufficient because of limited knowledge of drugs and technologies at the early development stage.<sup>8,10,18,23</sup>

Third, the ultimate goal of HS is to support the managed entry of new technologies into the health system and it is crucial that this information reaches policy makers. Nevertheless, there are some challenges in coordination and communication between technical experts and government bodies.<sup>9</sup> For instance, some of the internal reports on HS results are only delivered within HTA agency and without being distributed to decision makers.<sup>10</sup> There is also a risk that the findings may not be used by policy -makers if the HS process is conducted by organizations that are not directly connected with the government health system.9

What are the strengths of international collaboration and networking for Horizon Scanning?

International collaboration and networking can alleviate many of the limitations of the national HS process. The i-HTS network is one of the best examples of an HS network where working groups among members in the network are set up for HS of specific technologies such as ATMPs, and by collaborating together, can reduce the extent of resources required and expand the availability of expertise.<sup>9</sup> Additionally, it creates opportunities to develop an effective HS system by taking lessons learnt from HS experiences of other countries. Last but not least, sharing HS information in the network is time-saving, avoids duplication and enhances learning best-practices of HS methodologies and activities across the system.<sup>10,15</sup> References

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