

Guidance on Horizon Scanning Process

December 2023



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1. **Purpose of Document**

The purpose of this guidance document is to give stakeholders, particularly the pharmaceutical industry, an overview of SMC horizon scanning processes and outputs, including standard documentation. The Association of the British Pharmaceutical Industry (ABPI) has contributed to the development and maintenance of these processes through the SMC User Group Forum.

The aims, processes, timelines and outputs of the horizon scanning initiative are described, with an emphasis on how pharmaceutical companies can optimise their contribution. The document also outlines the type and sources of information that are of value to SMC in providing NHS Boards with a realistic forecast of the potential budget impact of new medicines.

1. **Background**

In 2003 the Scottish Government requested that the Scottish Medicines Consortium (SMC) establish a horizon scanning initiative to provide Scottish NHS Boards with advance intelligence on new medicines to support financial and service planning for their managed introduction into practice.

The main focus of the horizon scanning initiative is to provide financial planners with reliable information to support resource planning for the managed introduction of new medicines. In accordance with SMC’s remit, the horizon scanning initiative encompasses new medicines as well as new indications. The budget implications of new medicines are subject to a high degree of uncertainty. However, if financial planning processes are supported by robust intelligence about medicines in the pipeline and their potential cost impact, this should facilitate patient access to cost-effective new medicines at the earliest opportunity after SMC approval. Horizon scanning intelligence also assists SMC in workload planning in relation to new medicine assessments.

Since 2005 SMC has produced an annual horizon scanning report, entitled *Forward Look*, to provide NHS Boards with information on potentially ‘high impact’ medicines.

A new medicine or indication is regarded as ‘high impact’ if it:

* has a predicted net medicine budget impact (relative to comparators) for NHSScotland of greater than £500,000 per annum or,
* may be associated with major service implications.

Since 2017, *Forward Look* has focused on new medicines or indications that may be launched between July of the year the report is published and June of the following year. It is assumed that these medicines will be accepted for use by SMC and on average will have an impact approximately nine months after the predicted UK launch date. For example *Forward Look 20,* to be published in October 2024, will include new medicines or indications due to launch during the period July 2024 to June 2025, to support planning for their managed introduction within the financial year 2025/26.

SMC defines the launch date for a new medicine as the date when the medicine is expected to be in the UK supply chain (i.e. in the country). The launch date for a new indication of a medicine already marketed in the UK, is the GB marketing authorisation date.

The *Forward Look* report provides an insight into the potential drug costs associated with the adoption of forthcoming new medicines and hence provides a tool for illustrating the pressures on the budget allocation process.

1. **Outputs**
	1. **Forward Look Report**

Horizon scanning information is provided in the annual *Forward Look* report and the accompanying financial spreadsheets (non-cancer and cancer), issued in confidence each October to key Health Board personnel, including Chief Executive Officers and Directors of Medicine, Finance, Pharmacy and Public Health.

Since Forward Look 19, published in October 2023, this has been produced solely in spreadsheet format. Microsoft Excel is utilised to allow NHS Boards to modify factors (e.g. to adjust patient numbers for local epidemiology, to explore different rates of uptake based on local clinical expert opinion [see section 5], to search for all new instances of a particular medicine, or to filter new indications by formulation to aid service planning). The Forward Look report comprises 3 spreadsheets:

* **All medicines list spreadsheet** includes all new medicines / indications, listed by BNF chapter, anticipated to have a UK launch within the timeframe of the report.
* **Cancer medicines financial spreadsheet** provides information on net medicine budget impact for high impact medicines for cancer indications
* **Non-cancer medicines financial spreadsheet** provides information net medicine budget impact for high impact medicines for non-cancer indications

**Financial spreadsheets (non-cancer and cancer)**

The financial spreadsheets summarise the estimated uptake and incremental net medicine budget impact of each ‘high impact’ medicine by geographical area (West, East and North of Scotland) and by individual NHS Board.

The spreadsheets include data on the following:

* Annual net cost (estimated or list price) of treatment per patient or net cost (estimated or list price) per patient per course (i.e. net of the cost of substituted medicines). Non-recoverable VAT is added where believed appropriate.
* Estimated eligible population and the estimated uptake figures for patient numbers in the East, West and North of Scotland and individual Boards in years 1 and at steady state (when uptake is assumed to have stabilised). Patient numbers for each of the geographical areas and Boards are calculated based on mid-year population estimates from the National Records of Scotland. National Resource Allocation Committee (NRAC) shares are not used.
* Estimated total cost of each new medicine in year 1 and at year 2 or steady state (assumed to be the maximum financial cost) for East, West and North of Scotland and individual Board.
* Impact assumptions for each high impact medicine. These explain how the eligible population, uptake and cost of medicine were estimated and may also include additional information on predicted impact.
	1. **Forward Look Updates**

Information on medicines in development can change. Two updates are produced annually, in January and June each year, to highlight any significant developments or a change in information on medicines included in the main report.

The updates include:

* Details of additional new medicines anticipated to become available in the UK within the Forward Look report timeframe, identified by the horizon scanning team after the report publication
* Updates on medicines where the regulatory timeframe has changed
* Information on medicines featured in previous Forward Look reports where clinical development has since been delayed or discontinued
* Information on scheduled or ongoing re-submissions for medicines in the SMC work programme

The January update includes information on medicines predicted to have a high or low impact whilst the June update includes updates on high impact medicines only.

* 1. **Advanced Therapy Medicinal Product (ATMP) Report**

The annual ATMP report summarises new medicines or indications for ATMPs expected to launch within an extended timeline compared with the current *Forward Look* report. Only brief details of the ATMP are included. The report is intended to give summary information on ATMPs in the pipeline to aid with early service planning. ATMPs are also included in their relevant *Forward Look* reports as described above, allowing for more detailed service and financial planning.

* 1. ***Ad Hoc* Advice / Briefings**

Horizon scanning intelligence may be used to answer *ad hoc* enquires from staff within NHSScotland. These can range from simple enquiries about an expected UK launch date of a new medicine, to requests for more complex information. In answering enquires SMC maintains the confidentiality of any information provided in confidence by the pharmaceutical industry and would not disclose sensitive UK launch or cost data provided in confidence.

Where the Horizon Scanning team identifies a group of medicines are in development which may have a significant service implication, a more detailed, *ad hoc* briefing may be prepared to alert NHS Boards in Scotland to the nature of this likely service requirement, an example includes the *ad hoc* Monoclonal antibodies for Alzheimer’s disease briefing.

* 1. ***Diagnostic* Tests – Cancer Medicines Report**

This report is produced every six months for the Scottish Genomics-Test Advisory Group (SG-TAG) and supports service planning. It includes cancer medicines/new indications expected to require a diagnostic test, focussing on those requiring a new test, or for a broadened test population.

1. **Horizon Scanning Processes**
	1. **Overview and Timelines**

Horizon scanning work is carried out by a team including pharmacists, health service researchers and a project officer, with finance support. Figure 1 provides an overview of horizon scanning processes and timelines.

The timelines for the production of the annual *Forward Look* report are driven by financial timelines in NHS Boards. In October each year planners require estimates of the potential budget and service impact of new medicines likely to be introduced in the following year. This informs decisions in annual budget setting processes. The *Forward Look* report covers new medicine/indication launches anticipated between July of the year the report is published to June of the following year. This timeframe is based on data that indicate SMC advice on a medicine will be available on average nine months after the predicted UK launch, therefore the timeframe indicates medicines which will impact within the next financial year. The horizon scanning team continually monitors this time difference to inform future adjustment to the *Forward Look* report timeframe.

**Figure 1 SMC Horizon Scanning Production Process**

**PROCESSES AND TIMELINES**

**KEY INTELLIGENCE AND EXPERTISE**

Gather intelligence on pipeline medicines and populate SMC’s horizon scanning database

Analysis and interpretation of intelligence, and filtration / selection of medicines for report based on predicted UK launch and budget impact

 Verification of *Forward Look* content including antici[ated impact (high or low)

Development of impact assumptions for high impact medicines in *Forward Look* report

Verification of impact assumptions

Production of *Forward Look* report and financial spreadsheets

 *Forward Look* report and financial spreadsheets uploaded onto the SMC secure website

*Annual updates from Pharmaceutical companies on pipeline medicines (Company Pipeline Proforma)*

Continuous routine scanning of information sources by Horizon Scanning Team

Horizon Scanning Team

*Pharmaceutical companies (Company Medicine Profile)*

Horizon Scanning Team

NHS Clinical Experts

Horizon Scanning Cancer team

Horizon Scanning Team

Local NHS Boards use for financial planning purposes

Prepare diagnostic tests - cancer medicines report

NHS CEOs, Directors of Medicine, Pharmacy, Finance and Public Health and other key personnel

Commence annual horizon scanning update

*Direct contact with Pharmaceutical companies*

Updates from UK PharmaScan for registered companies on pipeline medicines

UK PharmaScan

Horizon Scanning Clinical Review Group (non-cancer medicines)

NHS Clinical Experts

 Draft list of all new medicines expected in the next financial year

Prepare Annual ATMP report

Prepare diagnostic tests - cancer medicines report

Horizon Scanning Team

January to

February

March

March to

April / May

April / May to

July

July to

August

August

August to

September

October

December

* 1. **Company Contacts**

When a medicine in clinical development is identified and is expected to be included in the *Forward Look* report currently in development, the pharmaceutical company is identified. If SMC has not had any previous contact with the company, the horizon scanning team will attempt to identify the most appropriate contact person within the company with responsibility for horizon scanning intelligence.

Companies planning to launch medicines in the UK that have not had previous engagement with SMC are requested to make contact; to ensure that SMC is aware of their developments and is planning to include their medicines in future *Forward Look* publications. This allows for a streamlined introduction of new medicines into NHSScotland, should the medicine become licensed and accepted for use by SMC.

SMC maintains a database of named company contacts. It will include details of the primary company contact(s) in relation to the new product assessment process and also contacts for the horizon scanning function. For some companies the same person may be responsible for both aspects of communication with SMC. Contact is routinely made by email. It is helpful if companies can advise SMC of any personnel changes or any updated information to their contact details.

* 1. **Collation of Intelligence**

The horizon scanning team reviews a wide range of sources of information on new medicines in clinical development on an ongoing basis and maintains details of these within a confidential horizon scanning database. These include:

* UK PharmaScan (<https://www.ukpharmascan.org.uk>)
* Confidential NHS publications
* Public domain information from regulatory authorities, pharmaceutical and commercial analyst companies
* Other NHS organisations involved in horizon scanning work e.g. the National Institute for Health Research Innovation Observatory (NIHRIO) and the Specialist Pharmacy Service (SPS).

SMC is committed to using UK PharmaScan as a key source of horizon scanning intelligence for the production of our Forward Look horizon scanning reports. UK PharmaScan is the primary source of information on new medicines, indications and formulations in the pharmaceutical pipeline and is used by all of the UK’s national horizon scanning organisations and NHS England to plan and prepare the NHS for the introduction of new medicines and support faster NHS adoption. An information leaflet is available on the UK PharmaScan website at [Resources - UK Pharmascan](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ukpharmascan.org.uk%2Fresources&data=05%7C01%7Chazel.smith8%40nhs.scot%7Cf803bb169cb6436b31be08dbe9e10c8e%7C10efe0bda0304bca809cb5e6745e499a%7C0%7C0%7C638360925003588172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=i5bPsnneUMB6mEM3g63Pp7t%2Fd4fvnx0F%2Bmjocs8qS9Y%3D&reserved=0) which provides further information and the market access processes across the UK. Information in UK PharmaScan can be invaluable if it is kept up to date and it is comprehensive. We would encourage all companies to register with UK PharmaScan; please visit <https://www.ukpharmascan.org.uk/howtoregister>.

During production of a *Forward Look* report additional information and advice supporting the interpretation and application of horizon scanning data is obtained from a variety of sources, for example, epidemiological and prescription data from Public Health Scotland, as well as advice from clinical experts and pharmaceutical companies.

* 1. **Company Intelligence**
		1. **Pipeline updates from companies**

Pipeline updates are obtained by the SMC horizon scanning team either by access to UK PharmaScan or directly from the company if the company is not registered to use UK PharmaScan. If no UK PharmaScan record is available the company will be asked to complete all data requested in a standard Company Pipeline Proforma issued by SMC in **December** each year (see [website](https://www.scottishmedicines.org.uk/about-us/horizon-scanning/#:~:text=Horizon%20Scanning%20Pipeline%20Proforma) for the Company Pipeline Proforma). Note that information is requested for all new medicines (new chemical entities), new indications, new formulations of existing medicines, biosimilars and advanced therapy medicinal products likely to be launched within the requested *Forward Look* report timeframe.

* + 1. **Company Medicine Profiles from pharmaceutical companies for Forward Look**

Once the SMC horizon scanning team have collated the initial proposed list of medicines for the next *Forward Look* report, they notify individual companies by email around **April / May** detailing their medicines which are planned to be included in the report. The communication specifies those medicines that are expected to have a high incremental net medicine budget impact (relative to comparators) or a significant service impact for NHSScotland. These medicines will require a *company medicine profile* to be completed by the company (see [website](https://www.scottishmedicines.org.uk/about-us/horizon-scanning/#:~:text=Horizon%20Scanning%20Medicine%20Profile) for *company medicine profile; please note, the link is only released between April and June each year*).

Companies are asked to give careful consideration to the proposed content at this stage, particularly in relation to the estimated timelines for medicine availability in the UK, judgements that have been made about a medicine’s potential for financial impact, and about any important omissions (i.e. medicines that SMC has not identified for inclusion in the report should be highlighted).

Feedback from the company at this stage is extremely helpful in ensuring that *Forward Look* features the relevant medicines and that the horizon scanning team’s preliminary estimates of a medicine’s anticipated incremental net medicine budget impact appear reasonable. Companies that are registered with UK PharmaScan and whose records are complete and comprehensive will only be asked to complete a company medicine profile with additional information relevant to NHS Scotland. SMC horizon scanning team acknowledges that companies may have difficulty providing all the information, particularly in relation to the provision of uptake and costing data up to a year or more prior to UK launch when studies may be incomplete. As this advice is a critical component of the information used by NHS financial planners to facilitate the managed introduction of cost-effective new medicines, the SMC horizon scanning team is committed to collaborative working with the pharmaceutical industry to achieve effective input in these challenging situations.

When companies cannot provide a detailed cost analysis and point data for estimates of uptake then best ‘ball-park’ range estimates can be useful, and can be provided with caveats. This will be taken into account when these are used together with other information to produce the draft budget impact estimates. General advice about proposed costing strategies or estimated uptake can also be very useful. The table below contains examples of information that SMC would find useful in the absence of more precise estimates.

|  |  |
| --- | --- |
| **Information useful to SMC horizon scanning team** | **Examples** |
| **Acquisition cost**An indication of potential cost range or upper or lower levels of range | * Expected to cost between £5,000 to £10,000 per patient per annum
* Expected to cost more than £80,000 per patient per annum
* Expected to cost less than £500 per patient per annum
 |
| **Cost relative to comparators**An indication of potential cost relative to existing treatments | * Will be priced in the same range as other drugs in class
* Likely to cost less than alternative treatments
* Likely to cost 10% to 20% more than alternative treatments
 |
| **Estimated uptake**An indication of uptake range or upper or lower levels of range | * Likely to be given to at least 90% of eligible population
* Likely to be given to less than 5% of eligible population
* Likely to be given to between 40% to 60% of eligible population
 |
| **Estimated uptake**An indication of estimated uptake relative to existing treatments | * Likely to replace existing drugs within the same class, but not increase numbers of patients prescribed this class
* Likely to be given to up to 10% of patients already receiving this class of drug
* Likely to increase the proportion of the eligible population receiving drug therapy for this condition by up to 90%
 |

UK PharmaScan contains fields to document anticipated uptake of medicines, costing data and indicative budget impact information. Given the challenges that companies often experience in providing costing information, cost may be inserted as a drug cost range (per patient per year or per patient per episode if less than one year).

* + 1. ***Ad hoc* contact with companies**

Companies may also be contacted on an *ad hoc* basis to clarify or provide additional information on particular medicines. Companies are encouraged to contact SMC via email ([his.smchorizonscanning@nhs.scot](file:///%5C%5Chislfspri01%5Cshare%5CSMC%5CHS%5CGuidance%20Document%5Chis.smchorizonscanning%40nhs.scot)) at any time to update the information held about particular medicines, for example a change in the estimated UK launch date. Companies registered to use UK PharmaScan should ensure that their product pipeline information is kept up to date on an ongoing basis and that changes to regulatory information are updated immediately the information becomes available to the company.

* 1. **Work Up of High Impact Medicines for Forward Look**

Medicines considered to be potentially high impact are investigated in detail by the horizon scanning team so that impact assumptions can be drafted. This includes undertaking a comprehensive literature search, and considering relevant information from the company (including the company medicine profile) as well as clinical experts.

Information is gathered on the following:

* How does the new product differ from existing products (e.g. pharmacology, route of administration)?
* What is the likely indication for the new product?
* How many people in Scotland would be eligible for treatment with the new product, and what proportion of the eligible population is likely to receive the new product?
* What is the incremental medicine acquisition cost of the new product relative to existing products?
* Would the new medicine be associated with any major service implications?

After identifying and assessing relevant available data, the impact assumptions are drafted and are peer reviewed within the horizon scanning team.

* 1. **Clinical Experts for Forward Look**

A Clinical Review Group meeting is held in April each year to review non-cancer medicines. The purpose of this meeting is to identify non-cancer medicines that are likely to be low impact from the *Forward Look* draft list, in order that the horizon scanning team can focus on those medicines expected to be high impact.

Once the horizon scanning team has drafted impact assumptions for a high impact medicine, advice is sought in confidence from clinical experts from a number of NHS Boards across Scotland, where possible. SMC works closely with expert clinicians practising within NHSScotland and maintains a database of clinical expert contacts. For rare conditions, additional efforts may be made to identify further relevant clinical experts, for example via requests to Scottish Area Drug and Therapeutics Committees (ADTCs) or identification of relevant clinicians practising within the NHS in England, Wales or Northern Ireland.

Advice from clinical experts can be invaluable at this stage as they can provide specific intelligence from a Scottish perspective on current treatment options, current treatment protocols and guidelines, patients eligible for treatment with the condition being considered and likely uptake.

1. **Confidentiality**

The provision by the pharmaceutical industry of intelligence, that is often commercially sensitive, is central to the success of SMC’s horizon scanning initiative. The risks to a pharmaceutical company associated with the release of this confidential information are comprehensively appreciated by SMC. SMC takes appropriate steps to safeguard the security of horizon scanning information provided by pharmaceutical companies. All horizon scanning intelligence is maintained in strict confidence and stored securely within the in-house horizon scanning database, accessible to SMC staff only.

Due to the commercial in confidence nature of the content, access to *Forward Look* reports, financial spreadsheets and updates is through a secure website. The secure website can only be accessed by key named individuals within NHSScotland, including Chief Executive Officers and Directors of Finance, Pharmacy, Medicine and Public Health. These NHS Board persons are made aware that information included within the *Forward Look* report is privileged, confidential and intended for those specifically authorised to access it for planning of resource and estimating budgets. In this regard NHSScotland personnel who have access to the *Forward Look* reports sign a confidentiality agreement each year that is accompanied by a code of practice on the appropriate use of the intelligence in the reports.

If NHS Boards receive requests under the Freedom of Information (FOI) Act relating to information within the report it is strongly recommended that they consult with partners at SMC prior to the release of any information. If boards, when using Forward Look, extract information from the report and incorporate into local documents, these must make reference to the commercially sensitive nature of the information and the recommendation to refer any FOI requests relating to it to SMC.

When NHS clinicians are consulted for clinical expert input they agree to maintain the confidentiality of any information they receive in relation to their work for SMC. When these clinicians are approached to comment on draft impact assumptions, the confidential nature of the information is highlighted and the need to maintain the confidentiality of this information is reiterated.

1. **Using the Forward Look Report in Practice**

NHS Boards have established processes, mainly through ADTCs and prescribing advisory structures, to utilise the intelligence in the *Forward Look* report for financial and service planning purposes. The information in relation to specific new medicines is often shared in confidence with local clinical specialists or groups to seek their opinion on the estimates used in the *Forward Look* report. This may provide reassurance, for example, with regard to the estimated number of patients to be treated, or may prompt some reworking of the figures to reflect local epidemiology, treatment of patients within clinical studies, or other aspects of how care is provided. After consideration has been given to the application of the *Forward Look* report in the Health Board (or region, for new cancer medicines), further internal reports may be prepared and provided to NHS Boards or regional advisory groups. If any part of the report is shared with individuals who are not named recipients of the report, they should be made aware of the confidentiality issues and they will be asked to sign and return a confidentiality agreement to SMC.

SMC and NHS Boards recognise that the figures in the *Forward Look* report may represent a ‘worst case scenario’ given that some of the new medicines listed might not reach the UK market within the predicted timeframe or at all. Of those that do reach the UK market within the timeframe, a proportion will not be accepted by SMC for use in NHSScotland, and in these cases the predicted cost impact will not be realised. To account for this, NHS Boards may choose to apply a ‘modifying factor’ to generate a more realistic figure for the costs that may be realised in practice. There are inherent risks in this approach, due to uncertainty around what constitutes an appropriate figure, and NHS Boards understand the need to regularly review local projections to reflect SMC advice and its forthcoming work programme.

The *Forward Look* financial spreadsheets have been developed to allow this ongoing, dynamic in-year adjustment by NHS Boards. For example, if a new medicine is considered by SMC but not recommended for use in Scotland, then the Board may remove it from their cost projections for the remainder of the current year. If the UK launch of a new medicine is delayed by approximately six months, then it is a straightforward step to adjust the projected costs accordingly.

Where SMC issues ‘accepted for use/restricted use’, or ‘accepted on interim basis for use/restricted use’ advice on a medicine, a full budget impact template for the medicine (provided by the company within their submission to SMC) will be distributed to NHS Boards together with the SMC advice on the product. This is to allow each Board to have access to a tool to assist with working out the implications of implementation of the product at a local level. If the advice on a product is ‘not recommended’ then the template will not be distributed to NHS Boards.

Scottish Medicines Consortium
Healthcare Improvement Scotland

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| --- |
|  Glasgow Office Delta House 50 West Nile Street Glasgow G1 2NP |

[www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)