



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

Guidance on Horizon Scanning Process

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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.

2. 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 and licence extensions. 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 18*, to be published in October 2022, will include new medicines or indications due to launch during the period July 2022 to June 2023, to support planning for their managed introduction within the financial year 2023/24.

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 costs associated with the adoption of forthcoming new medicines and hence provides a tool for illustrating the pressures on the budget allocation process.

3. Outputs

3.1 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.

PDF/word document

The report lists all new medicines or indications expected to have actual / anticipated UK launch date from July of the year the report is published to June of the following year with a particular focus on those with the potential for 'high impact'.

The report consists of two main sections. Section 1 highlights medicines that are expected to be associated with high net medicine budget impact and / or major service implications. These are arranged alphabetically by British National Formulary (BNF) chapters, with cancer medicines further sub-divided by tumour type.

Section 2 of the report contains tabulated information on all new medicines likely to be launched in the UK from July of the year the report is published to June of the following year.

Financial spreadsheets (non-cancer and cancer)

Financial spreadsheets accompany the *Forward Look* report. The financial spreadsheets summarise the estimated incremental net medicine budget impact of each 'high impact' medicine by geographical area (West of Scotland, East of Scotland and North of Scotland) and by individual NHS Board. There are two spreadsheets that categorise data as follows:

- New cancer medicines / indications, listed by tumour type and indication.
- New non-cancer medicines / indications, listed by BNF category and indication.

The spreadsheets include data on the following:

- Annual net cost of treatment per patient or net cost 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. In year 1 a proportion is applied to the estimated cost to take into account the expected SMC advice date (e.g. the year 1 cost for a medicine where SMC advice is expected in October will be reduced by half to reflect the proportion of the financial year it is expected to be available).
- A phasing factor which adjusts the impact in year 1 to reflect anticipated initial phased uptake of the medicine (i.e. to reflect that the full impact for all patients will not be realised at the date of SMC acceptance).
- Columns to allow NHS Boards to apply a patient assess scheme (PAS) discount where relevant.
- 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.

In addition, each financial spreadsheet includes a standalone tab that lists all medicines (low, high or uncertain impact) expected to launch within the timeframe of the current *Forward Look* report. This information is also included in Section 2 of the PDF report.

The financial spreadsheets are prepared in Microsoft Excel format to allow NHS Boards to modify factors (e.g. to adjust patient numbers for local epidemiology, or different rates of uptake based on local clinical expert opinion [see section 5]).

3.2 Forward Look Updates

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

- Details of additional new medicines anticipated to become available in the UK within the Forward Look report timeframe.
- 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.

3.3 Advanced Therapy Medicinal Product (ATMP) Report

The annual ATMP briefing summarises ATMPs expected to launch within an extended timeline to the current *Forward Look* report. Only brief details of the ATMP are included. The briefing is intended to give summary information on ATMPs in the pipeline to aid with service planning. ATMPs are also included in *Forward Look* reports as described above.

3.4 Ad Hoc Advice

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.

4. Horizon Scanning Processes

4.1 Overview and Timelines

Horizon scanning work is carried out by a team including pharmacists, health service researchers, a project officer and finance support. Figures 1 and 2 provide an overview of horizon scanning processes and timelines.

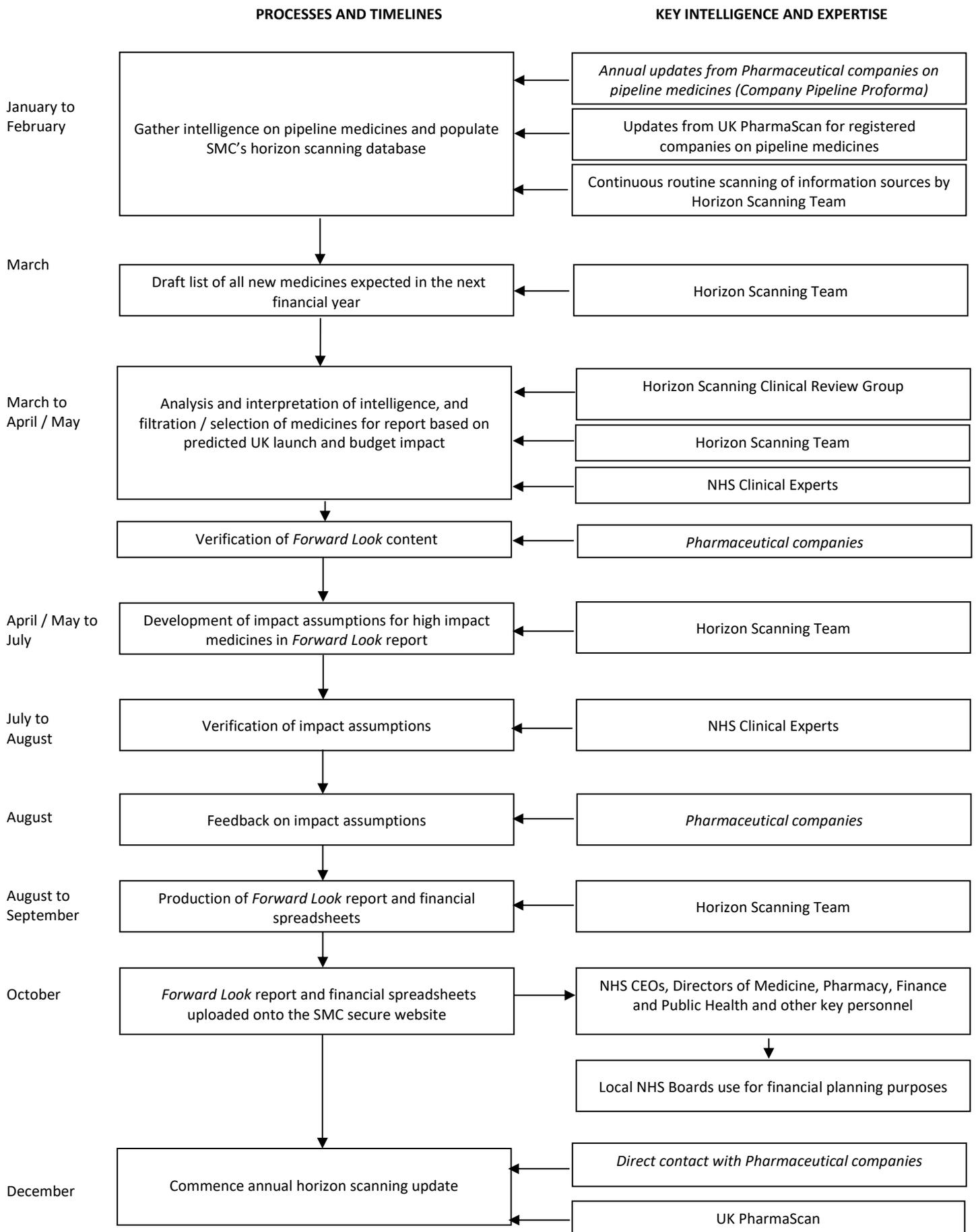
The timelines for the production of the annual *Forward Look* report are driven by financial timelines in NHS Boards. In October each year financial planners require estimates of the potential budget and service impact of new medicines likely to be introduced in the following year. This informs decisions in annual budget setting processes. The *Forward Look* report covers 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. The horizon scanning team continually monitors this time difference to inform future adjustment to the *Forward Look* report timeframe.

Figure 1: Overview of Processes and Timelines for Production of the Forward Look Report

January to February	<ul style="list-style-type: none"> • Extract pipeline updates for medicines expected to be launched in the UK in the designated Forward Look timeframe from UK PharmaScan for companies registered to use the system. • Following request in December, receive annual horizon scanning updates from companies via the Company Pipeline Proforma for companies not registered to use UK PharmaScan. • Review all pipeline updates and request further information from companies where necessary.
March	<ul style="list-style-type: none"> • Draft a list of all new medicines, new indications of existing medicines and new formulations expected in the following report (i.e. provisional content of next <i>Forward Look</i> report).
March to April / May	<ul style="list-style-type: none"> • Start the filtration process to identify medicines with the potential for high budget and / or service impact. • Seek views on potential impact of new medicines from the Horizon Scanning Clinical Review Group (non-cancer) and NHS clinical experts as required. • Inform companies by email of all new medicines for inclusion in the next Forward Look report and detail which medicines are anticipated to have high impact. If company views are required on likely impact, seek feedback at this time (through completion of individual Company Medicine Profiles). • Review company feedback on provisional content of the <i>Forward Look</i> report.
April / May to July	<ul style="list-style-type: none"> • Development of impact assumptions for medicines anticipated to be high impact and send draft to NHS clinical experts for comment (i.e. eligible population, uptake and place in therapy).
July to August	<ul style="list-style-type: none"> • Review clinical expert comments and incorporate into impact assumptions as appropriate. • Send impact assumptions to pharmaceutical companies and seek feedback.
August to September	<ul style="list-style-type: none"> • When all relevant information gathered, extract information into the associated financial spreadsheet. • Collate report in the appropriate format. • Quality assure final content of report and financial spreadsheets.
October	<ul style="list-style-type: none"> • Forward Look report and financial spreadsheets uploaded to SMC secure website for key personnel in NHS Boards to access
December	<ul style="list-style-type: none"> • Request annual horizon scanning update from companies not registered to use UK PharmaScan and contact companies registered to use UK PharmaScan to request that they confirm that their UK PharmaScan records are up to date.

Interactions with the pharmaceutical industry are shown in italics

Figure 2: SMC Forward Look Production Process



4.2 Company Contacts

When a medicine in clinical development is identified and is expected to be included in the *Forward Look* report currently being worked on, the pharmaceutical company developing the medicine 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.

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.

4.3 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).

UK PharmaScan is a confidential national horizon scanning database populated by the pharmaceutical industry that provides intelligence to horizon scanning organisations of company pipeline medicines. 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. However, if information is missing or out of date, SMC will either need to obtain the information from other sources or contact the pharmaceutical company directly. This can be time consuming and if the information is not confirmed, it could result in information relating to a company's pipeline being missed from SMC *Forward Look* publications and therefore missed from NHSScotland's financial and service planning cycles.

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.

4.4 Company Intelligence

4.4.1 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 a standard Company Pipeline Proforma issued by SMC in **December** each year (see [website](#) for the Company Pipeline Proforma). Note that information is requested for all new indications, licence extensions and new formulations of existing medicines as well as new medicines (chemical or biological entities), biosimilars and advanced therapy medicinal products likely to be launched within the *Forward Look* report timeframe.

4.4.2 Company Medicine Profiles from companies

After the initial list of medicines has been collated for the next *Forward Look* report, SMC horizon scanning team notifies individual companies by email around **April / May** each year about their medicines 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. It is these medicines that will require a company medicine profile to be completed by the company (see [website](#) for company medicine profile).

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 any important omissions (i.e. medicines that SMC has not identified for inclusion in the report may be highlighted).

Company feedback at this stage is extremely helpful in ensuring that *Forward Look* features the relevant products and that the horizon scanning team’s preliminary estimates of a product’s anticipated incremental net medicine budget impact appear reasonable. Companies that are registered to use UK PharmaScan and whose records are complete and comprehensive will only be asked to complete a company medicine profile with additional information that they feel would be helpful. 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. For some companies these difficulties may be compounded by the need to have information sourced from or authorised by company divisions based outside the UK. 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. These can be provided with caveats indicating that they are early estimates. This will be taken into account when these are used together with other information (e.g. clinical expert advice) 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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).

4.4.3 Feedback on impact assumptions for inclusion in *Forward Look* report

Pharmaceutical companies may be invited to comment on the impact assumptions prepared by the horizon scanning team prior to publication of the *Forward Look* report. The horizon scanning team may seek clarification of specific points or companies can provide general feedback. The main areas where additional company feedback is valuable usually relate to:

- the estimated uptake of the new product within the eligible population; and
- the estimated acquisition cost of the new product.

Comments from the company are considered carefully by the horizon scanning team.

4.4.4 *Ad hoc* contact with companies

Companies may also be contacted on an *ad hoc* basis to clarify or provide additional information on particular products. Companies are encouraged to contact SMC via email (his.smchorizonsscanning@nhs.scot) at any time to update the information held about particular products, 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.

4.5 Horizon Scanning Team Work Up of High Impact Medicines

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?
- 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.

4.6 Clinical Experts

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 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.

5. 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 information is extracted from the report and incorporated 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.

6. 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.

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