



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

Guidance on Horizon Scanning Process

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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, licence extensions and new formulations of existing medicines. 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 product 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. Since 2017, *Forward Look* has focused on new medicines or indications that may be launched between July of the year the report is published to June of the following year, to support planning for their managed introduction within the following financial year. For example *Forward Look 14*, published in October 2018, included new medicines or indications due to launch during the period July 2018 to June 2019, to support planning for their managed introduction within the financial year 2019/20. 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.

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 by the time use reaches steady state in the UK; or,
- may be associated with major service implications.

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.

The purpose of this guidance document is to give stakeholders 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. Outputs

2.1 Forward Look Reports

Horizon scanning information is detailed annually in the *Forward Look* report and accompanying financial spreadsheets, issued in confidence each October to key Health Board personnel, including Chief Executive Officers and Directors of Medicine, Finance, Pharmacy and Public Health.

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'. Summary information on 'high impact' medicines is provided within the report in an impact profile supported by a set of financial spreadsheets that summarise the net budget impact of these medicines.

The report consists of two main sections. Section 1 contains impact profiles for 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. An example of an impact profile is shown in Figure 1. Information for each impact profile is gathered and documented throughout the year in a data capture document (DCD), an internal document that includes results from an extensive literature search as well as incorporating communication from an individual company or relevant clinical experts.

Figure 1: Forward Look Section 1 – Example of Impact Profile

Medicine C (Brand C) Intravenous Injection (Company)	
Proposed indication	Treatment of adults with moderate to severe psoriasis unresponsive to standard therapies.
Regulatory information	Plan to file with EMA Q1 2019. Estimated UK launch Q4 2019.
Mode of action	First in class [Brief description of mode of action inserted]
Categorisation	New medicine.
Estimated eligible population	Derived through published literature. Derived through clinical expert consultation.
Clinical evidence	Positive phase III clinical results published.
Anticipated dosage regimen	The recommended dose is 30mg by intravenous injection once per month.
Established comparator(s)	Medicine Y 100mg subcutaneously per week. Estimated cost £3,000 per annum (including VAT).
Comparator(s) in the clinical development pipeline	No.
Treatment duration	Continuous therapy.
Estimated medicine acquisition cost	Reflects an SMC estimate. Medicine C will be used as an alternative to existing therapy.
Service setting and anticipated impact	To be used in the secondary care setting. Non-significant service impact predicted.
Additional information	There is significant uncertainty surrounding the launch of this product. The predicted launch date may slip into the next financial year.

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. An example is shown in Figure 2.

Figure 2: Forward Look Section 2 – Example of Format

BNF Section 1: Gastro-intestinal system

Product	Proposed / Actual Indication	Company	Categorisation	Predicted Impact	Comment
Medicine A	Peptic ulcers	Company X	New indication	Low net budget impact predicted Compete with existing therapy	CHMP positive opinion in month / year
Medicine B	Crohn's disease	Company Y	New medicine	High net budget impact predicted	
Medicine C	Constipation	Company Z	New formulation	Low net budget impact predicted Low patient numbers expected	

2.2 Forward Look Financial Spreadsheets

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 in years 1 and at steady state (when uptake is assumed to have stabilised).
- Patient numbers for each of the above geographical areas and Board 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 steady state (assumed to be the maximum financial cost) for East, West and North of Scotland and individual Board. In year 1 the estimated cost takes into account the expected approval date of the new medicine by SMC. Therefore, for example, the year 1 cost for a medicine that is estimated to be reviewed by SMC 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.
- Columns to allow NHS Boards to apply a patient assess scheme (PAS) discount where relevant.

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]).

2.3 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 July update includes updates on high impact medicines only.

2.4 Ad Hoc Advice

Horizon scanning intelligence may be used to answer *ad hoc* enquires from staff within NHSScotland. Such enquiries 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.

3. Horizon Scanning Processes

3.1 Overview and Timelines

Horizon scanning work is carried out by a team including principal and senior pharmacists, finance experts, health service researchers and a project officer. Figures 3 and 4 provide an overview of horizon scanning processes and timelines.

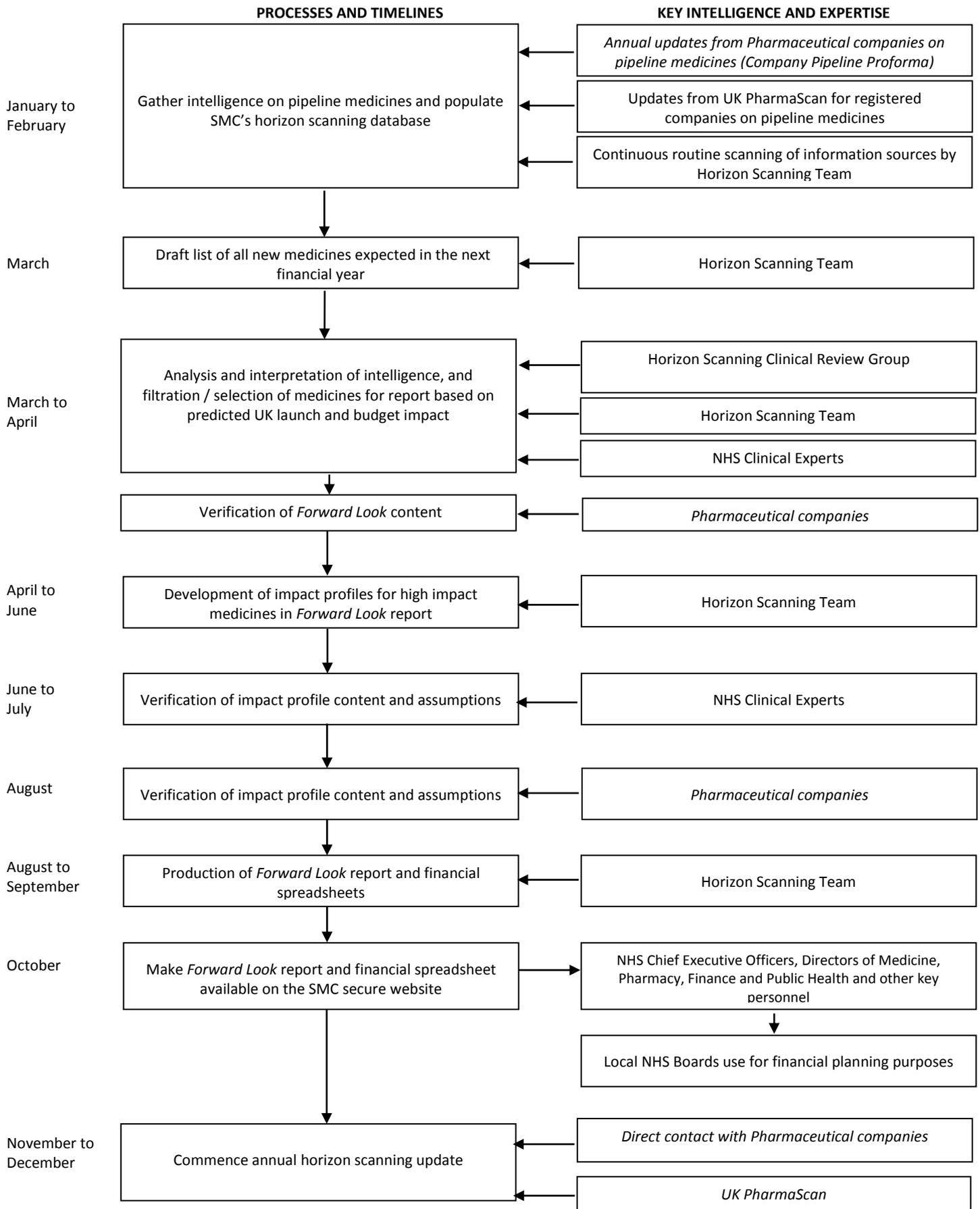
The timelines for the production of the annual *Forward Look* report are driven by financial timelines in NHS Boards. In October each year financial planners require estimates of the potential budget and service impact of new medicines likely to be introduced in the following year to inform decisions 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 historical data that indicate SMC advice on a product will be available on average nine months after the predicted UK launch. This time difference is due to delays in time to licence and/or launch and also delays in company submission to SMC. The Horizon Scanning Team continually monitors this time difference to inform future adjustment to the *Forward Look* report timeframe.

Figure 3: Overview of Processes and Timelines for Production of the Forward Look Report

January to February	<ul style="list-style-type: none"> • <i>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.</i> • <i>Following request in November/December, receive annual horizon scanning updates from companies via the Company Pipeline Proforma for companies not registered to use UK PharmaScan.</i> • 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	<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 and NHS clinical experts as required. • <i>Inform companies by email of all new medicines for inclusion in the next Forward Look report and detail which products 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).</i> • Review company feedback on provisional content of the <i>Forward Look</i> report.
April to June	<ul style="list-style-type: none"> • Prepare draft DCDs and send assumptions regarding eligible population, uptake and place in therapy to NHS clinical experts for comment.
June to August	<ul style="list-style-type: none"> • Review clinical expert comments and incorporate into DCDs as appropriate. • Prepare a summary (impact profile) for company review. • <i>Forward summary (impact profile) to companies for comment.</i>
August to September	<ul style="list-style-type: none"> • <i>Review company feedback on summary and incorporate into DCD as appropriate.</i> • When all relevant information gathered in DCD, extract information into Impact Profile and the associated financial spreadsheet. • Collate report in the appropriate format including section 2 of the report that includes all medicines expected in the designated time horizon. • Quality assure final content of report and spreadsheets.
October	<ul style="list-style-type: none"> • Make <i>Forward Look</i> report and financial spreadsheets available to NHS Boards.
November to December	<ul style="list-style-type: none"> • <i>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.</i>

Interactions with the pharmaceutical industry are shown in italics

Figure 4: SMC Forward Look Production Process



3.2 Company Contacts

When a medicine in clinical development is identified and added to SMC's tracking lists, 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 contact 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. It is possible that in 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.

3.3 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 customised 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 UK Medicines Information (UKMI) network.

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 NHS National Services Scotland (NHS NSS) or Health Protection Scotland (HPS), as well as advice from clinical experts and pharmaceutical companies.

3.4 Company Intelligence

3.4.1 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 Appendix A for the Company Pipeline Proforma). Note that information is requested for all new indications, licence extensions and new formulations of existing products as well as new medicines (chemical or biological entities), biosimilars and advanced therapy medicinal products.

3.4.2 Company Medicine Profiles from companies

After the initial list of products has been collated for the next *Forward Look* report, SMC horizon scanning team notifies individual companies by email around **April** each year about their products to be included in the report. The communication specifies those products that are expected to have a significant incremental net medicine budget impact (relative to comparators) or a significant service impact for NHSScotland. It is these products that will require a Company Medicine Profile completed by the company (see Appendix B, 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 product availability in the UK, judgements that have been made about a product's potential for financial impact and any important omissions (i.e. products 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 an impact profile template 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 and costs 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 final draft budget impact estimates that are then shared with the company for further comment. 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).

3.4.3 Feedback on final draft of impact profile prepared by horizon scanning team, for inclusion in Forward Look report

After the horizon scanning team has prepared the data capture document and clinical expert advice has been received (see sections 3.5 and 3.6 below) a summary impact profile (drafted by the horizon scanning team for inclusion in Forward Look report) for the medicine is sent to the company around **August / September** for review and comment.

Pharmaceutical companies are invited to comment on each section of the summary and any points on which input is specifically sought are highlighted. However, if preferred, companies can make general comments on the summary and / or on the main issues where their advice is valuable. These 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 SMC Horizon Scanning Team.

3.4.4 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 or telephone 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.

3.4.5 Safeguard of information provided by companies

SMC takes appropriate steps to safeguard the security of horizon scanning information provided by pharmaceutical companies. Information provided is not copied. All horizon scanning intelligence is maintained in strict confidence and stored securely. The in-house horizon scanning database is accessible by SMC staff only.

3.5 Data capture documents

A data capture document is an internal document used by SMC which includes the results of a full literature search, any relevant communication with companies (including the Company Medicine Profile) and clinical experts and all SMC assumptions and calculations regarding the potential impact of a medicine.

A systematic search is performed for information 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 all relevant data, a summary statement for each point is included in the data capture document together with any assumptions and uncertainties associated with the statements. The research methodology and data supporting the data capture documents are peer reviewed within the Horizon Scanning Team.

3.6 Clinical Expert Advice

The SMC Horizon Scanning Team works closely with expert clinicians practising within NHSScotland. These are identified from the SMC clinical expert database. Advice is usually sought from around five or six clinical experts from a variety of NHS Boards throughout Scotland whenever possible for each product that is considered to be high impact. However, for rare conditions the number of relevant clinicians in the SMC expert panel may be less than this. In these circumstances, additional efforts are 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.

Clinical experts may be contacted for advice on a new clinical development prior to completion of the data capture document and impact profile if the likely financial and / or service impact is uncertain. Help 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.

4. 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. Thus SMC staff are particularly aware of the necessity to maintain its confidentiality and various processes have been established to store the data securely, to restrict access to it and to ensure NHS Board recipients understand the precautions associated with its use.

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 included in the SMC clinical expert panel 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 profiles, the confidential nature of the information is highlighted and the need to maintain the confidentiality of this information is re-iterated.

5. 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, particularly 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. For medicines predicted to have a high cost impact that are accepted by SMC, a detailed local budget impact model may be prepared. For example, a detailed model based on epidemiological data, literature estimates and information from budget impact templates issued to Boards in confidence alongside the SMC Detailed Advice Document. Assumptions in the model would be confirmed with local specialists including predicted rate of uptake. A detailed model of this type may be used to inform a business case for the use of the medicine prepared by the relevant clinical team, if appropriate.

For some high cost new medicines the actual expenditure in practice can then be tracked alongside the local detailed budget impact model, although for various reasons this can be problematic. When variance between predicted and actual budget impact is identified, clinical expertise may be sought in an attempt to understand or justify the variance, although in practice this is challenging.

Appendix A: Company Pipeline Proforma (sent in December of Forward Look cycle)

New medicines, indications or formulations in development

Please list new medicines, biosimilar medicines, new indications and new formulations of existing medicines that:

- Have been filed for European or UK marketing approval (i.e. pre-registration)
- Are in clinical development and likely to launch in the UK between **July 20XX and December 20XX**
- Are Advanced Therapy Medicinal Products (ATMPs) or potential ultra-orphan medicines and likely to launch in the UK between **July 20XX and December 20XX**

UK PharmaScan record number if available	Generic (brand) name and formulation	Category (new medicine, indication, formulation, ATMP)	Indication	Estimated European filing date. Specify EMA / MHRA	Estimated European licence date	Conditional or full marketing authorisation anticipated	Estimated UK launch date	Medicine is likely to meet the revised definition for an ultra-orphan medicine	Is this likely to be 'significant'? (see definition in foot note)*

*A new medicine, indication or formulation is considered to be significant if it is expected to have a:

- high potential net medicine budget impact for NHSScotland (i.e. >£500,000 per annum); and / or,
- major service implication.

Appendix B: Company Medicine Profile (sent to companies for completion, when applicable, in April of Forward Look cycle)

Scottish Medicines Consortium

Request for information for new medicines with predicted significant impact expected to be launched in the UK between July 20XX and June 20XX.

Please complete the Company Medicine Profile for each significant new medicine or indication with predicted significant impact expected to be available to prescribe in the UK between July 20XX and June 20XX. A new medicine or indication is considered to have significant impact if it has a moderate to high net medicine budget impact relative to comparators (i.e. >£500,000 per annum when usage has reached steady state) for NHS Scotland and / or major service implication for NHS Scotland.

UK PharmaScan Record ID (if applicable)	
Medicine name (including generic and proprietary name if known)	
Proposed indication	
Regulatory timeframe	
Marketing authorisation type (full or conditional)	
Mode of action	
Route of administration	
Anticipated dosage regimen	
Is the medicine considered to be an 'end of life' medicine?	
Is the medicine considered to meet the 2018 SMC revised definition for ultra-orphan medicine?	
Does the medicine have Designated Advanced Therapy Medicinal Product status?	
Estimated eligible population (please provide references if applicable)	
Clinical evidence (please provide references if applicable)	
Established comparator(s)	
Will the medicine displace an existing therapy or be used in addition to existing therapy?	
Predicted uptake of new medicine (year one and when usage has reached steady state)	
Estimated time for usage to reach steady state	
Treatment duration	
Estimated medicine acquisition cost	
Is there likely to be a Patient Access Scheme?	
Service setting and anticipated impact (e.g. likely to be delivered through homecare)	
Additional information	

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