**SCOTTISH MEDICINES CONSORTIUM: Company Pipeline Proforma**

**Horizon scanning for new medicine developments**

|  |  |
| --- | --- |
| **Completed by** |  |
| **Company** |  |
| **Date** |  |

**Confidentiality statement**

The SMC horizon scanning report (Forward Look) contains information on expected medicine launch dates in the UK, predicted acquisition costs and potential uptake across NHS Scotland. This information is speculative and highly sensitive from an SMC and, in particular, industry perspective. Releasing this information to NHS Boards carries risks to both pharmaceutical companies and SMC. Accordingly, notwithstanding SMC’s commitment to open governance, SMC will keep information submitted to it confidential where disclosure could cause substantial commercial prejudice. **SMC will regard all information provided on estimated UK launch dates and estimated acquisition cost as commercial in confidence unless otherwise stated**.

**SMC confirms that confidentiality will be respected in relation to information accepted by it under an obligation of confidence either expressed or implied and will consult with any company that has submitted information prior to release of such information further to any Freedom of Information (Scotland) Act request if there is doubt about the status of such information**.

Due to the commercial in confidence nature of the content, access to the Forward Look report is through a secure website, which can only be accessed by key named individuals within NHS Scotland. These named persons are required to read a code of practice that accompanies the report and sign a confidentiality agreement. This ensures that recipients of the report are aware of the confidential nature of its content and the precautions that should be taken to maintain confidentiality.

**Introduction**

SMC requests advance notification from pharmaceutical companies on new medicines (i.e. new chemical entities, biosimilar medicines), new indications for existing medicines and new formulations of existing medicines that are in clinical development. The information provided will support the following.

* The production of the Forward Look report, which can be accessed through a secure website by named senior Health Board personnel across NHS Scotland. The report, published in October, supports financial planning for the managed introduction of new medicines, indications and formulations with the potential for significant cost or service impact.
* SMC workload planning. Awareness of new medicines, indications and formulations, including those expected to have limited financial impact or to be cost saving, supports effective scheduling of company submissions by SMC to ensure the timely provision of advice to NHS Scotland.

**Guidance notes**

**SMC recognises the introduction, implementation and uptake of the new MHRA regulatory routes is likely to lead to increased uncertainty over regulatory process and timeframes for new medicines/indications.**

Effective from January 2024 the MHRA will offer numerous routes to UK MA. This will include the new International Recognition Procedure (IRP) that will allow additional regulatory authorities to be considered as reference regulators (RRs). Recognition of EU centralized or mutual recognition MA decision (‘Reliance route’) will be incorporated into the IRP.

1. SMC would be grateful to receive details of medicines (including ATMPs or potential ultra-orphan medicines) or new indications / formulations that are:
* in clinical development, or have been filed with the Medicines and Healthcare Products Regulatory Agency (MHRA), or have been filed with a RR with the intention of subsequently filing with the MHRA for UK marketing authorisation (MA), **and**
* are likely to launch in the UK between **July 2024** and **December 2025**
1. Include the UK PharmaScan record number if available. **If the UK PharmaScan record is accurate and up to date, there is no requirement to complete the table with information available in the UK PharmaScan record**.
2. Please specify the preferred/intended licensing route:
* IRP – please specify RR
* MHRA national authorisation procedure
* MHRA accelerated assessment procedure
* Orbis
* Access
* Rolling review
1. Provide an estimated UK launch date (i.e. **date medicine is available for prescribing, irrespective of health technology assessment**) by calendar quarter.
2. In Forward Look, SMC provides estimates of the impact that significant new medicines, indications or formulations may have on NHS Scotland. A new medicine, indication or formulation is considered to be high impact if it is expected to have a:
* high net drug budget impact in NHSScotland (>£500,000 per annum at steady state); and / or
* major service implication.

**SMC would be grateful if you would indicate whether you consider that the listed medicines, indications or formulations will fall into the ‘high impact’ category.**

1. SMC does NOT require details of medicines that will not be marketed in the UK and medicines that are outwith SMC remit (e.g. branded generics, medicines that do not have prescription-only medicine status (POMs), and diagnostic agents). Information on medicines that are [outwith SMC remit](https://www.scottishmedicines.org.uk/media/7027/guidance-on-medicines-outwith-smc-remit-july-2-2022.pdf) are available on our website.

**Please return the completed company pipeline proforma to** **his.smchorizonscanning@nhs.scot****.**

**New medicines, indications or formulations in development**

Please list new medicines, biosimilar medicines, new indications and new formulations of existing medicines that are likely to launch in the UK between **July 2024 and December 2025.** Do not include generic medicines.

**Specify the anticipated licensing route**

Effective from January 2024 the MHRA regulatory routes will be as follows:

* IRP – please specify RR
* MHRA national authorisation procedure
* MHRA accelerated assessment procedure
* Orbis
* Access
* Rolling review

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **UK Pharma-Scan record number if available** | **Generic name (Brand name) Formulation** | **Anticipated indication** | **Anticipated MHRA licencing route*** *Please specify route (see above)*
 | **Estimated MHRA marketing authorisation date*** *Specify quarter and /or month*
 | **Estimated UK launch date\**** *Specify quarter and /or month*
 | **Is medicine likely to be high impact (net drug budget impact in NHSScotland >£500,000 per annum and / or has major service implications)***Yes/No* | **Additional comments (e.g. potential ultra-orphan, conditional market authorisation anticipated, clinicaltrials.gov/NCT trial number)** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

* Launch date for a new medicine is the date when the product 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.