**Scottish Medicines Consortium: Company Medicine Profile**

**Request for information for new medicines with predicted high (or uncertain) impact expected to be available for prescribing in the UK between July 2025 and June 2026.**

Please complete this form for each new medicine or indication which the horizon scanning team has predicted to be high or uncertain impact. A new medicine or indication is considered to be high impact if the net medicine budget impact relative to comparators is >£500,000 per annum (when usage has reached steady state) for NHS Scotland and / or major service implication for NHS Scotland.

If a UK PharmaScan record is **available, complete, and up to date**, please complete the highlighted fields only. We welcome any additional information, especially if this is not included in the UK PharmaScan record, however there is no requirement to duplicate regulatory details.

|  |  |  |  |
| --- | --- | --- | --- |
| **SMC Horizon Scanning reference (IND) number, if known** | IND | **UK PharmaScan Record ID (if applicable)** |  |
| **Medicine name (including generic and proprietary name if known)** |  | | |
| **Proposed indication (wording in full, if known)** |  | | |
| **MHRA regulatory route / planned route** |  | | |
| **Date / expected date of MHRA filing** |  | | |
| **Date / expected date of MHRA marketing authorisation** |  | | |
| **Anticipated UK launch1 date** |  | | |
| **Anticipated MHRA marketing authorisation type (full or conditional)** |  | | |
| **Mode of action** |  | | |
| **Diagnostic test required to determine eligibility for medicine (provide details of test)** |  | | |
| **Route of administration** |  | | |
| **Anticipated dosage regimen** |  | | |
| **Is the medicine considered to meet the** [**SMC definition for ultra-orphan medicine**](https://www.scottishmedicines.org.uk/how-we-decide/ultra-orphan-medicines-for-extremely-rare-conditions/)**?**  **If so, will you be submitting an ultra-orphan proforma?** |  | | |
| **Is the medicine considered to be an ATMP, including gene/cell therapy?** |  | | |
| **Clinical evidence (provide references if applicable)** |  | | |
| **Established comparator(s)** |  | | |
| **Describe where the new medicine/indication will fit in the treatment pathway?** |  | | |
| **Estimated Scottish eligible population (specify patient numbers and provide references)** |  | | |
| **Predicted uptake (specify in patient numbers) of new medicine in Scotland in year one and when usage has reached steady state** |  | | |
| **Estimated time for usage to reach steady state (i.e. when medicine uptake in Scotland is presumed to have stabilised)** |  | | |
| **Treatment duration2** |  | | |
| **Estimated or actual list price of the medicine** |  | | |
| **Service setting and anticipated impact (e.g. likely to be delivered through homecare)** |  | | |
| **Additional information** |  | | |

1 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.

2 If treatment is planned “until progression” please include estimated/mean duration of treatment.