**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 2024 and June 2025.**

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 and is up to date, please complete the highlighted fields. We welcome any additional information however there is no requirement to duplicate regulatory details.

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| --- | --- | --- | --- |
| **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 or gene/cell therapy?** |  |
| **Estimated Scottish eligible population (specify patient numbers and provide references)** |  |
| **Clinical evidence (provide references if applicable)** |  |
| **Established comparator(s)** |  |
| **Describe where the new medicine/indication will fit in the treatment pathway?** |  |
| **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.