**Pre‑Health Technology Assessment (HTA) Free of Charge (FOC) Pricing Scheme Proposal Form**

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| **NOTE:** This form should be submitted by pharmaceutical companies seeking to offer medicines to NHSScotland at no (or nominal) charge in advance of the medicine being recommended for use in Scotland by the Scottish Medicines Consortium (SMC). The completed form will be shared with a national decision making group (a sub‑group of the National Acute Pharmacy Service Leads group) to enable them to provide advice to National Procurement on the acceptability of the scheme for implementation in Scotland. Completed application to be saved as a Microsoft Word® document using the following naming convention: *generic name (Brand Name®) Pre-HTA FOC Application YYYYMMDD V0.1 (Initial).*  |
| **General Product Information** |

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| **Product Brand Name:** |  |
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| **Product Generic Name:** |  |
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| **Supplier Name:** |  |
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| **Supplier Contact Details:** | Please include the name, email address and telephone number for the lead contact within the company. |
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| **FOC Pricing Scheme ID *(completed by PASAG Secretariat):*** | FOCXXX |

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| **Presentation(s), Actual or Anticipated NHS List Price(s), and Proposed Price(s) within scheme** |

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| **Strength** | **Form** | **Pack Size** | **NHS List Price (£)****(exc. VAT)** | **Proposed price within pre-HTA FOC pricing scheme (£) (exc. VAT)** |
| **Strength** | **Form** | **Size** | xxxx.xx | 0.00 |
| **Strength** | **Form** | **Size** | xxxx.xx | 0.00 |
| **Strength** | **Form** | **Size** | xxxx.xx | 0.00 |
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| **Presentations outside scope of the Free of Charge Scheme:** | Please advise if there are any presentations marketed or expected to be marketed outside the scope of the scheme. |
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| **Commercial Agreements:** | Please provide a summary of existing and / or anticipated commercial agreements in the UK for the product e.g. a PAS or a National Framework Agreement. Detailed pricing information is not required. |
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| **Reason for Proposing a Pre-HTA FOC Scheme:** | Please provide a summary of the reasoning behind the proposed FOC pricing scheme.  |

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| **Indication(s) within scope** |

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| **Indication(s) within scope of the FOC Scheme:** | Please detail the specific indication(s) that will be within scope of the FOC Scheme. |
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| **Indications outside scope of the FOC Scheme:** | Please detail if there is any anticipated use of the medicine in indications outside the scope of the FOC Scheme.  |

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| **Marketing Authorisation and SMC status** |

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| **In the event of no UK MA approval, is the medicine licensed elsewhere?** | Please advise if the medicine is currently licensed in any other country and if possible provide a copy of the Summary of Product Characteristics (SPC) / Patient Information Leaflet (PIL) in the English language. |
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| **SPC / PIL / Investigator’s Brochure (IB):** | Please provide a copy of the UK SPC and PIL or insert hyperlink here. If UK SPC / PIL are unavailable, please indicate here and advise estimated date for publication. If the medicine is unlicensed and in development, please provide the IB. |
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| **Packaging:** | If the product being supplied does not yet have a marketing authorisation, please confirm that the product packaging clearly displays the product’s approved name and has supporting Quality Assurance certification.  |
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| **Anticipated SMC timelines:**  | Please detail the anticipated SMC submission and publication dates for the indications within scope of the FOC Scheme and the anticipated date for an SMC decision. If the expected time to publication of an SMC decision is greater than 6 months, please explain the delay. |
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| **SMC Positioning:** | Please indicate if the submission to the SMC will be different to the indication(s) within scope of the scheme e.g. if submission to SMC relates to a sub-population within the licensed indication.  |

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| **Patient numbers** |

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| **Epidemiology:** | Please provide a high level summary of disease prevalence and incidence in Scotland.  |
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| **Please estimate the number of patients in NHSScotland that will receive treatment, for all indications within scope of the FOC Scheme, in year 1 and year 5 following HTA acceptance:** |
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| **Year** | **Estimated numbers of new patients** | **Estimated total number of patients (including new patients)** |
| **1** | **xx** | **xx** |
| **5** | **xx** | **xx** |
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| **Estimated annual cost per patient:** | Please detail the estimated annual cost of the medicine to the NHS per patient (ex VAT) at list price in each of the indications within scope of the FOC Scheme. Please explain the methodology for the calculation |

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| **Unmet need** |

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| **Is the medicine, for the indication(s) within the scope of the FOC scheme, to be used for patients with life‑threatening or seriously debilitating illnesses?** | If yes, please provide justification.  |
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| **Early Access to Medicines Scheme (EAMS):** | For the indication within the scope of the FOC scheme, please note here if the medicine was included in the UK EAMS, and/or if EAMS was applied for. |
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| **Orphan Designation:** | Has the medicine been designated an orphan medicinal product by the European Medicines Agency? If yes, then include date of designation, and designation number.  |
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| **For each of the indication(s) within scope of the FOC Scheme, is there an alternative treatment option available?**  | Please detail if there is an alternative treatment option currently available or expected to be available during the lifetime of the FOC scheme? |
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| **Comparator Treatments:** | Please detail the comparator products that are anticipated to be used in the SMC assessment.  |
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| **Place in Therapy** | Please detail the anticipated place in therapy of the medicine e.g. relative to other current interventions.  |

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| **Prescribing, dispensing, administration and monitoring** |

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| **Duration of Treatment:** | Please indicate how long an average patient is expected to remain on the medicine in the indications within scope of the FOC Scheme e.g. short course of treatment, treatment course under 1 year, 1 – 2 years, or over 2 years (please detail by indication) |
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| **Prescribing Setting:** | Please specify the anticipated prescribing setting for the medicine, for example secondary and/or tertiary care. If the treatment of Scottish patients if expected to be initiated or monitored by a specialist centre elsewhere in the UK, please indicate.  |
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| **Dispensing Setting:** | Please state the anticipated supply routes to patients for this product i.e. hospital pharmacy, and/or medicines homecare.  |
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| **Associated Costs:** | Please summarise any costs associated with use of the medicine that would be incurred by the NHS e.g. companion diagnostics, staffing costs if administration needs to be observed, monitoring costs, supportive medicines etc. If a companion diagnostic and/or monitoring test represents a change in practice, this should be described here with detail on how this can be reasonably introduced in NHSScotland.  |

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| **Scheme operation** |

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| **Scheme Start Date:** | Please indicate the anticipated start date for the scheme? E.g. a specific date or from the point of marketing authorisation. |
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| **Estimated number of patients that will receive treatment pre‑HTA:** | Please indicate the number of patients in Scotland that are expected to be initiated on treatment pre-HTA review and that are within the scope of the scheme. Please outline the assumptions behind the stated figure.  |
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| **Medicine Supply arrangements (hospital):** | Please detail the supply arrangements to hospitals for the free-of-charge medicines provided under the scheme including the name of the wholesaler and a contact point on distribution queries. If the template order form for FOC Schemes (see Guidance/Policy) is not used, please explain alternative arrangements and justification for a non-standard approach (please provide a copy of the order form or screenshot of electronic system as appropriate). |
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| **Medicine Supply arrangements (homecare):** | Please confirm if free stock is available to patients via the homecare setting. If so, please provide details of the homecare providers concerned. If a manufacturer‑commissioned homecare service is being proposed, a separate proposal relating to the homecare service should be sent to the NHSS National Homecare Governance and Management Group for review. Engagement is co-ordinated by the NHS National Services Scotland (NSS) Homecare Lead: nss.pchc@nhs.net. |
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