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

**Supporting Information for Board Implementation**

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| **NOTE:** The information provided in this document is based on the application form submitted by the pharmaceutical company and provides background information to the pricing scheme agreement.  |
| **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:** | 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 |
| **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:** |  |

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

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| **Indication(s) within scope of the FOC Scheme:** |  |
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| **Indications outside 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?** |  |
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| **SPC / PIL / Investigator’s Brochure (IB):** | A copy of the UK SPC and PIL or hyperlink will be provided. If UK SPC / PIL are unavailable, estimated date for publication will be noted. If the medicine is unlicensed and in development, the IB can be requested from the named supplier contact person. |
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| **Packaging:** | If the product being supplied does not yet have a marketing authorisation, information on packaging will be provided here. Additional information required for risk assessment of unlicensed medicines can be obtained from the named supplier contact.  |
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| **Anticipated SMC timelines:**  |  |
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| **SMC Positioning:** |  |

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| **Patient numbers – estimated by Supplier** |

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| **Epidemiology:** | 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:** | 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.  |

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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?** |  |
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| **For each of the indication(s) within scope of the FOC Scheme, is there an alternative treatment option available?**  | Alternative treatment options currently available or expected to be available during the lifetime of the FOC scheme |
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| **Comparator Treatments:** | Comparator products that are anticipated to be used in the SMC assessment.  |
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| **Place in Therapy** | 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:** | Estimation of 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, over 2 years.  |
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| **Prescribing Setting:** | Anticipated prescribing setting for the medicine, for example secondary and/or tertiary care.  |
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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:** | Summary of 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.  |

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| **Scheme operation** |

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| **Estimated number of patients that will receive treatment pre‑HTA:** |  |
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| **Medicine Supply arrangements (hospital):** | Information relating to any anonymised patient registration process, ordering details, and designated supply chain will be noted or added as an appendix to the form. |
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| **Medicine Supply arrangements (homecare):** | Guidance from the NHSScotland National Homecare Governance and Management Group will be noted or added as an appendix to the form. |
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| **Additional information to be provided to Boards, as suggested by the Decision making group.** |  |
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| **Scheme Start Date (as specified within the Agreement):** | dd / mm / yyyy |
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| **Enrolment period end date:**  | To be advised by PASAG Secretariat as soon as known (either date of issue of advice by SMC, or date of access via ultra-orphan pathway). |
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| **Ongoing supply arrangements for patients enrolled in scheme:** | To be advised by PASAG Secretariat at point of closure of enrolment period.Once a patient is enrolled in the scheme, they are eligible to receive free of charge stock until: * Ninety days after issue of SMC advice to Health Boards (advice is confidential for the first 30 days) where the new medicine is accepted for use or for restricted use in NHS Scotland; or
* Ninety days after the medicine is available for prescribing in NHSScotland under the ultra‑orphan pathway; or
* As long as patient(s) established on the medicine continue to require it on clinical grounds if the medicine is not recommended by SMC or where the patient is within a sub-group that falls outside of an SMC prescribing restriction.
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