**Manufacturer-Commissioned Homecare Service Proposal (HSP) Form**

**NOTE:** This form should be completed and submitted by manufacturers seeking to offer a new or amended manufacturer commissioned homecare service to the NHS. Track changes or highlight should be used for any amendments made to the original form until the form is finalised, including when re-submitting a finalised form with an amendment to the original service.

There are different arrangements for the review of proposed services across the UK; information on the review process in each of the home countries is available from the relevant NHS homecare lead.

Completed form to be saved as a Microsoft Word® document using the following naming convention: *Generic Drug Name (Brand Name) Homecare Service Proposal YYYYMMDD.*

**General Information**

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| **Brand Name:** |  |

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| **Generic Name:** |  |

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| **Manufacturer Name:** |  |

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| **Manufacturer Contact Details:** | Please include the name, email address and telephone number for the lead contact for this service within the company. |

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| **NHMC Good Practice Principles:** | Please confirm that the manufacturer named above has completed the ‘Statement of Intent to Comply’ with the NHMC Good Practice Principles. If not, please detail reasoning.  |

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| **Patent Status:** | Anticipated year of patent expiry.  |

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| **HTA Review Status:**  | For newly launched medicines, please confirm that the medicine has been recommended for use in the NHS or provide the anticipated date for a decision if an assessment is planned or underway. Please provide this for each of the home countries e.g. NICE, SMC, AWMSG and other relevant decision-making bodies. |

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| **Medicine Pricing Agreements:** | Please provide a summary of existing or anticipated commercial agreements and where relevant (in the case of CMU frameworks) please quote the contract reference.e.g. a PAS, a Framework Agreement, an EAMS or pre-HTA free-of-charge stock agreement. There is no need to include prices. |

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| **NHS Commissioned Homecare:** | The preference of the NHS is to commission homecare independently where feasible. Please confirm whether an NHS commissioned Homecare Provider would be able to access the medicine and if so, whether there is the option of an “unbundled” price for the product (i.e. a discount on the product to compensate the NHS for independently funding the service fees). |

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| **New Service or Change to Established Service?**  | Is this a new service or a change to an established service?  |

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| **Reason for Proposal:** | If this is a new service, please outline the reason that it is being proposed. If this is an established service, please provide a summary of the proposed changes including the reasoning behind the change and anticipated timelines for implementation.  |

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| **Stakeholder Engagement:** | Please detail any stakeholder engagement on the service proposal that has already taken place. |

**Product Summary**

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| **Current Licensed Indication(s):** | Please summarise the product’s current licensed indications and any future licenses anticipated within the next 2 years. |

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| **Medicine Formulation and Route of Administration:** | Please detail the product’s formulation(s)/route(s) of administration. |

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| **Specific Storage Requirements:**  | Please detail any specific storage requirements, for example storage in a refrigerator. |

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| **Equipment & Ancillaries:** | Please detail any additional equipment or ancillaries that are required to support administration of the medicine. Please detail any equipment or ancillaries that will be funded as part of the service (and any maximum patient order quantities that apply) e.g. a 5 Litre sharps bin.  |

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| **Co-administered Medicines:**  | Please detail any anticipated co-administered medicines that may be needed either as a requirement of the product license (e.g. methotrexate in combination with an anti-TNF) or supportive care (e.g. an anti-emetic with a cancer medicine). Please confirm if co-administered medicines can be delivered in the same parcel as the pharma funded medicines if prescribed on the same prescription (with no additional delivery charge to the NHS). |

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| **Dose Intervals & Loading Dose:** | Please indicate standard dosage intervals for the medicine (e.g. weekly injection) and whether a loading dose/dosage titration is required initially.  |

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| **Duration of Treatment:** | Please indicate whether the average duration of treatment is expected to be under 1 year, 1 – 2 years or over 2 years. |

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| **Dosage Changes:** | Approximately what percentage of patients will require dosage changes while on the medicine?  |

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| **Early Discontinuation:** | Approximately what percentage of patients will require their treatment to be discontinued early? |

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| **Administration Safety Issues:** | Please specify any safety risks related to administration of the medicine that need to be managed, for example an observation period required post administration, risk of anaphylaxis, use of specialised equipment etc.  |

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| **Prescribing Settings:** | Please specify the anticipated prescribing setting for the medicine, for example primary, secondary and/or tertiary care. |

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| **Dispensing Settings:** | Please state the anticipated supply routes to patients for this product in addition to homecare i.e. hospital pharmacy, community pharmacy and outsourced outpatient pharmacies. The preferred supply route may differ in different parts of the country.  |

**Please estimate the number of patients in the UK that would be eligible to access the service over the next 5 years:**

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| **Year** | **Estimated no. new patients** | **Estimated total no. of patients** **(including new patients)** |
| **1** | **XX** | **XX** |
| **3** | **XX** | **XX** |
| **5** | **XX** | **XX** |

**Service Summary**

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| **Service elements included within the proposed service: (please indicate ‘Yes’ for those that apply)** |
| Dispensing |  |
| Aseptic Compounding of the Product |  |
| Home Delivery |  |
| Device Training |  |
| Patient Self-administration Competency Assessment  |  |
| Clinical Waste Collection/Disposal inc sharps |  |
| Provision of Funded Associated Ancillaries |  |
| Provision of Written Patient Information/Support Materials (other than the standard patient information leaflet in the pack) |  |
| Other Support  |  |
| Nurse Administration of Medicine |  |
| Other (please state) |  |

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| **Standard vs. Optional Service Elements?** |
| Please confirm which service elements are included within the standard service offering and which service elements are optional e.g. is it possible to access medicines delivery without device training and vice versa. The preference of the NHS is to have the option to opt-out of adherence support programmes and other elements of a Patient Support Programme. |

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| **Minimum Term and Notice Period** |
| Please detail the minimum term for which this service is being offered to the NHS and the notice period for making any significant changes to the service offering (e.g. change of provider; change in funded service levels). A minimum 6 months’ notice for any changes that reduce service levels is best practice. Please confirm that the NHS would be consulted in advance of making any future changes to the service offering.  |

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| **Scope of Service (Patients):** | Please confirm that the service is offered to ***all***patients receiving the medicine – or detail if there are any limitations, for example if the service is limited to patients with specific clinical indications or not offered where use of the medicine is out-with the license, including off license dosage. Please note, there are safety risks created by the complexity inherent in indication-specific service commissioning; this is not generally supported by the NHS.  |

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| **Scope of Service (Medicines):** | Please confirm if all available strengths/formulations of the medicine are available via the homecare service. If patients require delivery of co-administered medicines, please detail whether the costs of the products and/or the dispensing/delivery fee for these products is funded by the manufacturer as part of the service commissioning arrangements. |

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| **Delivery Frequency:** | Please detail the funded delivery frequency (e.g. the ability for the NHS to choose 4, 8 or 12 weekly delivery as required). Please bear in mind that in the case of a drug shortage or other supply problem the expectation is that if ‘extra’ deliveries are required in order to manage stock, the manufacturer will fund these deliveries. |

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| **Choice of Delivery Date:** | Please detail the level of choice given by the provider to the patient over the delivery day/slot e.g. whether the patient is able to choose from Monday to Friday, 08.00 – 18.00 or whether choice is limited by the provider only delivering to a certain locality on selected days of the week/month. Please ensure information is completed for all Homecare Providers. |

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| **Deliveries on Weekends and Evenings:** | Please detail whether weekend (Saturday or Sunday) and evening deliveries are a funded part of the service offering. Please ensure information is completed for all Homecare Providers. |

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| **Delivery Window:** | Please detail the standard delivery window e.g. AM/PM, 2 hour delivery window etc. and arrangements for notifying the patient of the specific slot e.g. booked a number of weeks in advance, text message the night before etc. Please ensure information is completed for all Homecare Providers. |

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| **Alternative Delivery Addresses:** | Please detail whether the patient can request delivery to locations other than their home e.g. place of work, a community pharmacy etc. Please note in some parts of the UK, there are policies that prevent use of community pharmacies as collection points for medicines pre-dispensed by a Homecare Provider. If community pharmacy collection is offered, it should be possible for a UK region or individual NHS organisation to choose that this is not promoted to their patients. Please ensure information is completed for all Homecare Providers. |

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| **Emergency Deliveries:** | Please confirm if there are any scenarios in which the NHS would be required to pay a fee for emergency (urgent) deliveries? (i.e. exclusions from the funded service offering). Please ensure information is completed for all Homecare Providers.  |

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| **Travel/Holiday Services:** | Please confirm if patients can nominate a temporary delivery location elsewhere in the UK mainland and Islands as part of the funded service offering. Please ensure information is completed for all Homecare Providers. |

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| **Geographical Variation in Service Delivery:** | Please detail any significant differences in the delivery schedule or service levels available for patients in remote and rural areas e.g. use of Royal Mail, couriers etc. Please ensure information is completed for all Homecare Providers. |

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| **Funded Transfer of Associated Paperwork:** | Registration and prescription forms need to be transferred securely between the NHS and Homecare Providers. Please detail if the costs of secure transfer of prescriptions is funded within this scheme. For example, will the cost of post office prepaid envelopes for tracked transfer of paperwork be covered? |

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| **Patient Information Materials:** | Please provide a summary of any manufacturer-developed patient information/support materials that will be provided to the Homecare Provider for distribution to the patient (other than the standard Patient Information Leaflet in the product pack). If provided, please detail when these will be delivered (e.g. initial delivery) and either include a copy of the materials with this form or detail when they will be available for NHS review.  |

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| **Managing Product Price Changes:** | Please confirm whether in the event that the manufacturer agrees a price reduction for the medicine with the NHS (e.g. a standard contract price change) at a future date, that the price change will come into effect on the date agreed with the NHS i.e. the commissioned provider may be holding stock purchased at the previous higher price; is the NHS protected from the manufacturer-commissioned provider billing the NHS for delivery of the medicine at the previous higher price whilst they use up the previously purchased stock?  |

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| **Faulty Medicines/Devices and Product Complaints:** | Please detail the process in place for handling faulty medicines/devices and product complaints from service users. Include detail such as like for like replacement for faulty medicines/devices free of charge without the need for a prescription. |

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| **Nursing Oversight:** | If any part of the service is delivered by nurses, please detail whether the provider of the nursing service element is registered with the Care Quality Commission (CQC) in England, the Care Inspectorate (CI) in Scotland, the Care Inspectorate Wales (CIW) and the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland. Please detail the provider(s) registration number for each agency. |

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| **Nurse Device Training:** | If device training is part of this service, please detail the funded service level (e.g. whether this will involve a home visit, the number of visits and whether competency assessment if part of the service offering).  |

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| **Nurse Administration:** | If administration of the medicine is part of this service, please detail the funded service level (e.g. frequency of visits). Also please confirm whether the medicine is delivered to the patient by the nurse or separately.   |

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| **Other Support:** | If other support is part of this service offering, please detail the nature of the service (e.g. a reactive telephone help-desk; proactive calls, texts etc) and how it is provided including:* Who the service is provided by (e.g. a pharmacist, a nurse);
* When the service is provided (e.g. the frequency of follow-up);
* Whether there are any limitations in who the service can be provided to (e.g. if patients are using the medicine for an unlicensed use are they eligible for the standard delivery service but not the adherence support service);
* The scope of interaction with the patient (e.g. if there is a standard script for patient phone calls, please share).

Please document on a separate sheet if necessary. The preference of the NHS is to have the choice to opt-out of other support services.  |

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| **Digital Support** | If digital support is offered as part of this service offering, please detail the nature of the service, including if/when Digital Technology Assessment Criteria (DTAC) assessment completed/planned. If the support (or part of) is classified as a medical device please confirm the support complies with the medical device directives. [Digital Technology Assessment Criteria (DTAC) - NHSX](https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/) |

**Commissioning Arrangements Summary**

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| **Commissioned Providers** | Please detail which provider(s) have been commissioned to provide the service. |

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| **Summary of Commissioning Arrangements** |
| The preference of the NHS is for a choice of providers to be made available.For each commissioned provider, please confirm which service elements they will be delivering and whether they plan to use any sub-contractors in the direct delivery of the service to patients (including detailing where there is use of sub-contractors in remote and rural areas). Some manufacturers have chosen to separately commission nursing elements of the service from a nursing provider and a medicines homecare service from a Homecare Provider but present this as a single integrated service to the patient. There are particular risks associated with this commissioning approach. If this is the model selected, please also detail the arrangements in place to ensure clarity on roles and responsibilities (liability) of the respective providers and any arrangements in place between the providers to manage risks and ensure appropriate information governance.  |

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| **Contract Duration:** | Please detail the current contract length, end date and notice period for the contract that the manufacturer has entered into with the provider(s) for the delivery of the services.  |

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| **Performance Management:** | Please detail how service performance will be monitored and performance managed. Key Performance Indicator’s should be aligned where relevant to Royal Pharmaceutical Society Homecare Handbook Appendix 10. |

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| **Data Sharing:** | Please detail the data fields that will be shared between the Homecare Provider and the manufacturer under the provision of a Data Sharing Agreement which relate to patient data. For example patient post codes, demographic, health data. |

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| **Trust/Health Board Engagement:** | Please detail the agreement between manufacturer and Homecare Provider(s) on the expected communication timeframes - when will Homecare Providers be able to contact Trusts/Health Boards regarding this service? |

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| **Contingency Arrangements:** | Please detail contingency arrangements in place to ensure patient access to the medicine is maintained in the event that a provider is unable to continue to provide the service or is unable to provide the service at an acceptable standard.  |

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| **Exit Arrangements:** | Please detail how continuity of patient care would be maintained in the event that the manufacturer chooses to stop commissioning all or part of the service. |

**Related Manufacturer-Commissioned Services**

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| **Related Service Offerings:** | Please detail any other services associated with the medicine being offered by the manufacturer that are out with the scope of the medicines homecare service documented in this form, for example a telephone adherence support service or a separate phlebotomy service etc. provided by a third party outside of the arrangements documented in this form. |

**Correspondence with Manufacturer (Clarification) FOR NHS USE ONLY**

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| **NHMC** | **Manufacturer’s response** |
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| **Activity** | **Date** | **Comment** |
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