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# **Company Information Request Form**

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| Before making a submission to SMC, if unsure about whether the medicine is within SMC remit or the type of submission required, the Marketing Authorisation Holder (MAH) should complete all relevant sections of this form with available information and return to the secretariat. Based on the information submitted, SMC will provide guidance on submission requirements. It is the responsibility of the company to submit on time, so that SMC advice can be issued as close as possible to medicine launch. | |
| Company name |  |
| Company contact name and contact details |  |
| Date |  |

## Registration details

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| --- |
| Medicine name (generic and brand name) |
|  |
| Formulation, strength(s), route of administration |
|  |
| Full licensed indication(s) the query relates to |
|  |
| If the submission is not expected to cover the full licensed indication please provide details of any positioning you wish SMC to consider |
|  |
| Dose |
|  |
| MHRA regulatory status (including MHRA regulatory route) |
|  |
| Actual / anticipated date of marketing authorisation in UK (including web links where available) |
|  |
| Launch date in UK\* |
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* Launch date for a new medicine is the date when the medicine 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.

## Screening questions

Information on submission criteria for full and abbreviated submissions is provided in guidance documents on the [SMC website.](http://www.scottishmedicines.org.uk/Submission_Process/Submission_Guidance_and_Templates_for_Submission/Templates-Guidance-for-Submission/Templates-Guidance-for-Submission)

The most common reasons for a product being outwith SMC remit are given in the table below. Please indicate if you consider that the product is outwith SMC remit for one of the reasons specified. **For more detailed information please refer to the Guidance to companies on medicines** [**outwith SMC remit.**](http://www.scottishmedicines.org.uk/Submission_Process/Submission_Guidance_and_Templates_for_Submission/Templates-Guidance-for-Submission/Templates-Guidance-for-Submission)

|  |  |
| --- | --- |
| **Reason for outwith remit** | **YES / NO / UNSURE\*** |
| The medicine is not a prescription only medicine (POM) |  |
| The medicine is:   * a new formulation or combination of an existing preparation at no additional cost * a new presentation strength of an existing preparation at no additional cost * an unbranded or branded generic, hybrid medicine or biosimilar medicine * a vaccine * a blood product (except anti-bradykinin and C1 inhibitor therapies) * a medical gas * a surgical or wound intervention * used in parenteral nutrition * used for diagnosis only, treatment for acute poisoning or a tropical disease |  |
| A variation to the summary of product characteristics (SPC) where there is no change to the licensed indication and section 4.1 of the SPC remains unchanged |  |
| Other (please specify) |  |
| * delete as appropriate | |

* **If the medicine fits into any of the above categories**, then there is no need to complete the subsequent sections of the Company Information Request Form, as a submission is not required. Please return the form with the above information to indicate why the product is outwith remit.
* **If the medicine does not fit into these categories please:**
* Complete all sections of the Company Information Request Form that are relevant to your medicine
* Supply the most recent or draft Summary of Product Characteristics
* If you are unsure if the medicine is out of remit, please complete all sections of the Company Information Request Form that are relevant to your medicine.

## Product Information

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| 1. What is the basis for the enquiry? |
| A new chemical entity  A licence extension  A new formulation or new combination preparation of an existing medicine at higher cost  New licence extension for children or adolescents  New medicine within existing therapeutic class  Other: please state |
| 1. If this is a new combination product, provide registration details (and web links where available) of the UK licence status of the components for the indication(s) under review and SMC advice issued for all the components |
|  |
| 1. If this is a new formulation of an established medicine, provide details of SMC advice issued for any previous preparation(s) for the same indication(s) |
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| 1. If this is a new licence extension for children or adolescents, provide details of SMC advice previously issued for the medicine in adults |
|  |
| 1. Detail existing therapy, including what therapies might be replaced in Scottish practice |
|  |
| 1. Provide details of previous SMC advice for existing therapies |
|  |
| 1. If you consider that this medicine may be appropriate for an abbreviated submission (including therapeutic class), can similar clinical effectiveness or non-inferiority to a reference / parent preparation(s) or existing therapy be simply demonstrated? Provide a brief outline including basis of the assumption for similar effectiveness. |
|  |
| 1. If you consider that this medicine may be appropriate for an abbreviated submission, please supply the medicine acquisition costs or cost estimates (list price and patient access scheme [PAS] price where relevant) for the medicine and list price for relevant existing therapies in the cost table below. **Other associated costs should not be included**. |
| |  |  |  |  | | --- | --- | --- | --- | | **Medicine** | **Formulation** | **Dose** | **Cost per unit / course / month /year\*** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  |  * complete as appropriate |
| 1. If you consider that this medicine may be appropriate for an abbreviated submission but the net acquisition cost of your product is more than existing therapy:  * Please estimate any net budget impact with reference to medicine costs only. * Please describe any additional benefits in simple terms that might justify a cost premium (e.g. preservative-free, liquid formulation). NB. A cost premium that requires analysis of benefit is likely to require a full submission. |
|  |
| 1. Is the medicine likely to be associated with a PAS and / or has a PAS been previously associated with a different formulation / indication for this medicine? |
|  |
| 1. Provide any other information specific to this medicine or information you consider important to the review of your medicine not covered by other sections of this form. |
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*Please email the completed form to* [his.smcsubmissionportal@nhs.scot](mailto:his.smcsubmissionportal@nhs.scot)

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