(MAH identification)

Name

Address

Contacts

President of the Executive Board of

INFARMED, I.P.

Parque de Saúde de Lisboa – Av. Brasil, 53

1749-004 Lisboa

Portugal

**Date: dd/mm/yyyy**

**Subject: MA revocation/ withdrawal request**

The company [[1]](#footnote-2) (MAH name), MAH of the medicine(s) listed below, hereby request the revocation of thereof.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Process number  | Name of the medicine | Dosage | Pharmaceutical form | International Nonproprietary Name (INN) | Number of packing registration(s) | Date of the MA |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

[[2]](#footnote-3)

The reason(s) for the withdrawal requested is(are) (tick the reason(s)):

|  |  |
| --- | --- |
| Company portfolio optimization. | ☐ |
| Disinterest in the sale/ commercialization of the product. | ☐ |
| Problems with the approved manufacturer (active substance or finished product)*Manufacturer:* (manufacturer's name)*Identified problem:* (problem specification) | ☐ |
| It was requested the transfer of the name of this medicine to another medicine. | ☐ |
| It was requested the reimbursement of this medicine to another medicine. | ☐ |
| Other: (State what) | ☐ |

For the medicinal product(s) to withdraw, listed above, please tick the applicable:

|  |  |
| --- | --- |
| The cessation of commercialization was reported on the SIATS portal.[[3]](#footnote-4) | ☐ |
| This medicine has been marketed in the last 3 years. | ☐ |
| This medicine has not been marketed for the last 3 years. | ☐ |
| There are alternative medicines to this medicine marketed with the same INN, strength and pharmaceutical form. | ☐ |
| There are alternative medicines for this medicine marketed with the same INN, with different strength and/or pharmaceutical form. | ☐ |
| There are not alternative medicines to this medicine marketed with the same INN, strength and pharmaceutical form. | ☐ |
| There are not alternative medicines for this medicine marketed with a INN different from than that of the medicinal product to be revoked/ withdrawn. | ☐ |
| There are not alternative medicines for this medicine marketed with the same INN, with different strength from than that of the medicinal product to be revoked/ withdrawn. |  |
| There are no alternative medicines marketed. | ☐ |
| Is there a shortage of this medicine? **Yes** ☐ and it is communicated in the SIATS 3 portal at **dd-mm-yyyy**;  **NO** ☐ |
| The renewal process is submitted and waits for dispatch/ approval. | ☐ |
| The date for submission of the renewal process has not been reached yet. | ☐ |
| Medicine subject to MP Restricted (followed in hospital environment), MP Restricted (diagnosed in hospital environment) **or** MP Restricted (specialist). | ☐ |
| Marketing authorization with pharmaceutical form and/ or dosage form considered essential for the maintenance of the reimbursement. | ☐ |
| Marketing authorization approved under RMP/DCP, with PT as RMS. **Yes** ☐ **NO** ☐If Yes ----------- RMS Transfer: **Yes** ☐ **NO** ☐If Yes ----------- New procedures number: (procedure number indicated by the new RMS as proof of the acceptance) |

The therapeutic indications for the medicinal product(s) to be revoked/ withdrawn are:

|  |
| --- |
|  |

The name and therapeutic indications of medicinal products marketed which constitute a therapeutic alternative to the medicinal product(s) to be revoked/ withdrawn are:

|  |
| --- |
| (Alternative medicine name - therapeutic indications) |

 (Signature and stamp of MAH)

1. If this revocation/ withdrawal request is not submitted by the MAH, attach a power of attorney where is given empowerment for such to the person who fill and sign the revocation/ withdrawal request. [↑](#footnote-ref-2)
2. Please insert the number of lines needed.

**NOTE:** After completion this application must be printed, signed, dated and sent by mail or delivered to the Expedient Service of INFARMED, I.P.. Any questions or clarification related to this application for withdrawal request should be sent by email to revogacao.AIM@infarmed.pt mentioning in the subject paragraph: the process number, name, strength and pharmaceutical form of the medicine. [↑](#footnote-ref-3)
3. The notification of the cessation of marketing is obligatory so that the request for revocation/ withdrawal can be considered and processed. [↑](#footnote-ref-4)