Application for Assessment of Safety Advice Tools and Dissemination Plan

The completed form along with the relevant documents must always accompany the appication for assessment of safety advice tools.

The application and documents should be sent by email to: [ima@ima.is](mailto:ima@ima.is), subject line: Application for assessment of safety advice tools for [product name]

|  |  |
| --- | --- |
| New safety advice tools | |
|  | Date of planned marketing: Click or tap to enter a date. |
| Updated safety advice tools | |
|  | Specify the reason for the update and briefly which changes have been made: Click or tap here to enter text. |
| Product not on the market but participating in a tender. **The IMA must be informed of the outcome of the tender as soon as it is available, and the application must be withdrawn if the product will not be marketed.** | |
|  | Date of planned marketing: Click or tap to enter a date. |

**Information about the medicinal product**

|  |  |  |  |
| --- | --- | --- | --- |
| Product name: Click or tap here to enter text. | | | |
| Active ingredient: Click or tap here to enter text. | | | |
| Strenght: Click or tap here to enter text. | | | |
| Pharmaceutical form: Click or tap here to enter text. | | | |
|  | |  |  |
| Originator medicinal product | |  |  |
| Generic medicinal product | |  |  |
|  | The safety advice tools are identical to safety advice tools for the originator medicinal product or another generic medicinal product already on the market: | | |
|  | Yes, name of reference medicinal product: Click or tap here to enter text. | | |
|  | No, rationale: Click or tap here to enter text. | | |

|  |  |
| --- | --- |
| **About the safety advice tools**  List of all components to be assessed: | |
|  | Cover letter to HCPs (required)  Guides for healtcare professionals  Guides for patients  Patient card |
| Required documents: | |
|  | RMP  Annex II (for CP lyf)  Distribution plan  Rationale if required documents are not provided: Click or tap here to enter text. |
|  | |
|  | |

**Information about the applicant**

|  |  |
| --- | --- |
| Marketing authorisation holder: Click or tap here to enter text. | |
| Representative: Click or tap here to enter text. | |
| All requirements fulfilled and „[Instructions for preparing and submitting safety advice tools](https://www.ima.is/medicinal-products/pharmacovigilance/safety-advice-tools/)“ was adhered to | |
|  |  |
| **Contact information** |  |
| Name: Click or tap here to enter text. | Phone number: Click or tap here to enter text. |
| Email: Click or tap here to enter text. |  |
| Date of application: Click or tap to enter a date. | |

**Distribution plan**

Proposed list of recipients: Click or tap here to enter text.

|  |  |  |  |
| --- | --- | --- | --- |
| Component | | Click or tap here to enter text. | |
|  | Recipients | | Click or tap here to enter text. |
|  | Dissemination method | | Click or tap here to enter text. |
|  | Number of copies to be distributed | | Click or tap here to enter text. |
|  | Planned timing of distribution | | Click or tap here to enter text. |
|  | Planned timing of re-distribution | | Click or tap here to enter text. |
|  | Information on user-testing | | Click or tap here to enter text. |

|  |  |  |  |
| --- | --- | --- | --- |
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[Copy the table for each component of the safety advice tools]