Request for review of educational materials

This form shall be completed and submitted by email, along with relevant documents, when review of educational materials is requested. Email address: [ima@ima.is](mailto:ima@ima.is), subject: EDUMAT [product name]

|  |  |
| --- | --- |
| New educational material | |
|  | Date of planned marketing: Click or tap to enter a date. |
| Updated educational material | |
|  | Reason for update and an overview of changes: Click or tap here to enter text. |
| Medicinal product currently not marketed but is currently a part of a tender. **The IMA must be informed of the results and request for review must be withdrawn if marketing is no longer planned.** | |
|  | 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. | | | |
| Strength: Click or tap here to enter text. | | | |
| Pharmaceutical form: Click or tap here to enter text. | | | |
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| Innovator medicinal product | |  |  |
| Generic medicinal product | |  |  |
|  | Educational materials are aligned with educational materials for the innovator product or another generic medicinal product: | | |
|  | Yes, name of reference medicinal product: Click or tap here to enter text. | | |
|  | No, explanation: Click or tap here to enter text. | | |

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| **Information about the educational materials**  List of all components of the educational materials submitted for review: | |
|  | Cover letter (required)  Click or tap here to enter text. |
| Required documents: | |
|  | RMP (at least part V)  Annex II (for CAP)  Explanation if required documents are not provided: Click or tap here to enter text. |
| Applicant’s proposal for a list of recipients (by job titles, place of work, specialty – not by name): | |
|  | Click or tap here to enter text. |
| Applicant’s proposal for method of distribution / online publishing: | |
|  | Click or tap here to enter text. |
| Date of planned distribution / publishing of the educational materials: | |
|  | Click or tap here to enter text. |
| Following approval, applicant will request for the materials to be published on [www.serlyfjaskra.is](http://www.serlyfjaskra.is) ([see instructions on electronic publication of educational materials](https://www.ima.is/educational-materials/)) | |

**Information about the applicant**

|  |  |
| --- | --- |
| Marketing authorisation holder: Click or tap here to enter text. | |
| Representative: Click or tap here to enter text. | |
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| [Instructions for submitting educational materials](https://www.ima.is/educational-materials/) were followed and all requirements have been met | |
|  |  |
| **Information about the contact person** |  |
| Name: Click or tap here to enter text. | Phone number: Click or tap here to enter text. |
| E-mail address: Click or tap here to enter text. |  |
| Date of application: Click or tap to enter a date. | |