Submission of Risk Minimisation and Educational Tools and Materials by Marketing Authorisation Holders

Please complete the form below when submitting risk minimisation and educational tools and materials to the HPRA and refer to the ‘Guide to Submission of Educational Tools and Materials’ for further details on HPRA requirements.

Please outline the objectives and rationale for education materials as directed below, and ensure that the following documents are included in the submission, where relevant.

|  |  |
| --- | --- |
| Cover letter (outlining context for submission of educational tools/materials): | [ ]  |
| Objectives and rationale for educational materials:     Brief description of educational tools/materials proposed: |
|      Key elements of content      |
|  |
| Specify if:  |
| New materials Updates to previously approved materials | [ ] [ ]  |
| Word version of educational tools and materials (including track changes if applicable) | [ ]  |
| PDF version of educational tools and materials (including diagrams, photographic materials etc) | [ ]  |
| Proposed communication plan Proposed evaluation of effectiveness plan (where applicable) | [ ] [ ]  |
| Annex I – III of marketing authorisation (including relevant version of the SmPC/package leaflet | [ ]  |
| Annexes of the RMP describing the risk minimisation tools | [ ]  |
| Copies of literature articles referenced in educational materials (if applicable) | [ ]  |
| Other supporting data *(Please specify the supporting data included and outline whether data has been previously reviewed by a regulatory authority*):      |

Please send completed form to medvigilance@hpra.ie