23 June 2023

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Human Medicines Division

Appendix I to the QRD templates for human medicinal products

Statements for use in Section 4.6 “Fertility, pregnancy and lactation” of SmPC

(Appendix 3 to the [Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: From Data to Labelling](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-risk-assessment-medicinal-products-human-reproduction-lactation-data-labelling_en.pdf))

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| **Fertility, pregnancy and lactation** |
| [BG](https://www.ema.europa.eu/bg/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_bg.docx) Bulgaria  | [IS](https://www.ema.europa.eu/is/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_is.docx) Icelandic |
| [CS](https://www.ema.europa.eu/cs/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_cs.docx) Czech | [IT](https://www.ema.europa.eu/it/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_it.docx) Italian  |
| [DA](https://www.ema.europa.eu/da/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_da.docx) Danish | [LT](https://www.ema.europa.eu/lt/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_lt.docx) Lithuanian |
| [DE](https://www.ema.europa.eu/de/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_de.docx) German  | [LV](https://www.ema.europa.eu/lv/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_lv.docx) Latvian |
| [EL](https://www.ema.europa.eu/el/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_el.docx) Greek | [MT](https://www.ema.europa.eu/mt/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_mt.docx) Maltese |
| [EN](https://www.ema.europa.eu/en/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_en.docx) English | [NL](https://www.ema.europa.eu/nl/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_nl.docx) Dutch |
| [ES](https://www.ema.europa.eu/es/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_es.docx) Spanish | [NO](https://www.ema.europa.eu/no/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_no.docx) Norwegian |
| [ET](https://www.ema.europa.eu/et/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_et.docx) Estonian | [PL](https://www.ema.europa.eu/pl/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_pl.docx) Polish |
| [FI](https://www.ema.europa.eu/fi/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_fi.docx) Finnish | [PT](https://www.ema.europa.eu/pt/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_pt.docx) Portuguese |
| [FR](https://www.ema.europa.eu/fr/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_fr.docx) French | [RO](https://www.ema.europa.eu/ro/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_ro.docx) Romania |
| [GA](https://www.ema.europa.eu/ga/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_ga.docx) Irish | [SK](https://www.ema.europa.eu/sk/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_sk.docx) Slovak |
| [HR](https://www.ema.europa.eu/hr/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_hr.docx) Croatian | [SL](https://www.ema.europa.eu/sl/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_sl.docx) Slovenian |
| [HU](https://www.ema.europa.eu/hu/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_hu.docx) Hungarian | [SV](https://www.ema.europa.eu/sv/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-and-lactation-summary-product-characteristics_sv.docx) Swedish |