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Format for risk management plan submissions

The new format of the RMP has been designed in a modular format to facilitate the work of pharmaceutical companies, regulatory authorities to manage the documents.

The long term aim at the EMA is that companies will only submit the modules which have changed and the electronic systems will build a RMP based on the latest version of each module. Unfortunately we don't have this system available at present so companies are still required to submit a complete RMP each time an update is required.

The guidance on the document format for RMPs has been published in 3 ways:

1. An integrated RMP with all the modules in one document
2. The complete set of individual modules
3. The abridged format suitable for use with generic products.

Companies submitting an application (or an updated RMP) for a generic product are advised to use the abridged version. Companies submitting an application for other medicines should choose the integrated RMP format.

Individual modules may be used within pharmaceutical companies but only the abridged or integrated format should be submitted to the regulators, unless otherwise requested.