Federaal agentschap voor geneesmiddelen en gezondheidsproducten
Agence fédérale des médicaments et des produits de santé
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The implementation of the black symbol, the explanatory statements on additional monitoring and adverse drug reactions reporting in the product information for products authorized true MRP / NP according to the requirements of the new pharmacovigilance legislation

For medicinal product not under additional monitoring:

- In course of another regulatory procedure e.g. renewal, variation type IB/II affecting the product information.
  ➔ Implemented no later than April 2015
- If no regulatory activity: true IB variation
  ➔ Implemented no later than April 2016

For products under additional monitoring:

- In course of another regulatory procedure e.g. renewal, variation type IB/II affecting the product information
- If no regulatory activity: true IA_{in} variation (only implementation of black symbol, additional monitoring statement and the encouragement to report ADR's statement, every other change due to new version of QRD cannot be included in this IA_{in} variation)
  ➔ Submitted no later than 31/12/13.

For new applications true MRP/DCP , we will follow the RMS.
For new applications true NP, it will be mandatory for new submission after30/06/2013.