Submission of Risk Minimisation Plans to ANSM

The risk minimisation tools requested in Risk Management Plans (RMP) must be validated by the ANSM prior to their distribution. In order to facilitate the assessment, these recommendations should be followed:

Depending on the provisions of the RMP, the risk minimisation tools may condition the marketing of the medicinal product. They must be submitted to ANSM within a reasonable and sufficient time (minimum 2 months - without taking into account the printing/distribution time which is up to the laboratory).

In case of products previously used in a compassionate access programme (Temporary Authorisation Use), the marketing must take place within 3 months after the MA has been granted (circular DGS/DSS/DHOS 11/04/2007). The risk minimisation documents conditioning the launch must therefore be validated within this time period.

I. Submission of a risk minimisation plan :

The applicant must submit the risk minimisation plan in paper format AND electronic version :

ANSM
DQFR – PGF – code
143-147, Boulevard Anatole France
F-93285 Saint-Denis cedex

Code :
Medicine : 920
Generic : 950

For electronic submissions: soumissionPMR@ansm.sante.fr

1. *An application letter, indicating:*
   - The context of the application (Launch, Update of RMP, *Follow Up Measure*)
   - The distribution procedures planned: schedule, target population and mode of distribution.
   - Any useful information concerning the elaboration of the document (e.g. translation of a European document validated by the PRAC or proposed by the parent company; reviews by a group of experts, a learned society or patient association)
2. *The draft documents or minimisation tools:*

   Whenever possible, the documents should be submitted in pdf format, in order to guarantee their readability and the pertinence of the visual aids presented, if applicable.

   In order to make the review and the follow-up of corrections easier, the documents should also be submitted in a modifiable text format (Word).

   For visual or audiovisual documents, apart from the submission of the CD-Rom or DVD, a typed text indicating the scenario, describing or representing the image and transcribing the audio must be attached.

   If other European agencies (in particular the United Kingdom or Germany) have already validated the documents, a copy may be addressed to the ANSM, for information.

   Mock-up

   The mock-up of risk minimisation documents should be different to promotional material. It should be simple but attractive and legible.

   Documents to healthcare professionals should mention on the cover or in the introduction "*Ce document s'inscrit dans le cadre du plan de gestion des risques de* [name of the medicine]"

   Reporting side effects

   Risk minimisation documents should encourage reporting side effects and include this mention:

   [to healthcare professionals] : *« Nous vous rappelons que tout effet indésirable doit être déclaré au Centre régional de pharmacovigilance (CRPV) dont vous dépendez (coordonnées disponibles sur le site Internet de l'ANSM www.ansm.sante.fr ou dans le Dictionnaire Vidal®).) ».*

[to patients (except for alert card)] : *« Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin, pharmacien ou infirmier/ère. Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans la notice d'information. Vous pouvez également déclarer les effets indésirables directement via le système national de déclaration : Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance. www.ansm.sante.fr. En signalant les effets indésirables, vous contribuez à fournir davantage d'informations sur la sécurité du médicament.»*

If the medicine is under additional monitoring, this should be added before the mention of side effects reporting: *« ▼Ce médicament fait l'objet d'une surveillance supplémentaire qui permettra l'identification rapide de nouvelles informations relatives à la sécurité »*

3. *Reference documents (electronic submission only):*

   e.g. Annexes I to III of the MA, latest version of the RMP and the literature references mentioned in the documents.

II. Approval

The ANSM may ask the company to submit new draft documents, if considering that they are currently not in accordance with the RMP requirement.

At the end of the assessment procedure, ANSM will send comments to the company.

The final documents must be provided to ANSM in hard copy and electronic version for filing.

III. Updates

Following a major variation of the MA (with an impact on key elements of the Risk minimisation plan) or an update of the RMP, the minimisation documents should be submitted to the ANSM and will follow the same validation circuit.

The variation application should be submitted as a Word text with track changes (and justification of the modification for example indicating in a comment the reference to the variation procedure).

In case of major modifications to the document (paragraphs added, moved or major rephrasing), it is recommended to submit as a three column table (original text, modified text and justification of modification).

In case of submission of an updated document, the company should specify the distribution procedures planned.

The modification of formats, models or following a minor MA variation (for example modification of a section of the SPC without an impact on the body text of the document) should only be sent for information.

Note: Updating documents to add above-mentioned statements regarding to additional monitoring list or reporting side effect do not require prior approval by ANSM but should be sent for information.