INSTRUCTIONS FOR MARKETING AUTHORISATION HOLDERS FOR DISTRIBUTION OF DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC) IN LUXEMBOURG

Marketing authorisation holders (MAH) concerned by the distribution of a Direct Healthcare Professional Communication (DHPC) are generally those whose products are actually on the Luxembourgish market. However, given the fact that a medicinal product may be imported from a neighbour country at any moment, it is recommended that MAHs whose products are authorized in those countries disseminate a DHPC in Luxembourg as well. The latter is usually decided on a case-by-case basis by the National Competent Authority.

In order to validate the distribution of a DHPC, the following information/documents should be submitted to the Directorate of health, Division of Pharmacy and Medicinal Products (DPM), via mailbox pharmacovigilance@ms.etat.lu.

1. BEFORE APPROVAL**:**

- Description of the regulatory circumstances leading to the need of DHPC distribution as well as of the safety concern.
- Type and number of the procedure (National/Mutual recognition (MRP)/Decentralised (DCP)/Centralised)
- List of concerned member states
- All product designations that are concerned by the DHPC as well as their marketing authorisation numbers
- In case of a centralised procedure, English version of the DHPC approved by EMA
- Translation in French of the approved English version in « MS Word » format; additional translation in German, if possible
- Final version of approved DHPC by the Competent Authority of the country of origin of the medicinal product, if applicable
- Proof of validation of the DHPC by the Competent Authorities of the country of origin of the medicinal product, if applicable
- Communication plan including
    - Timelines of approval and dissemination of the DHPC
    - Target healthcare professionals, their specialization as well as other target groups (organisations, associations, etc.)
    - Approximate number of recipients in Luxembourg
    - Description of the follow-up activities where necessary.

2. AFTER DISTRIBUTION**:**

- Copy of the final DHPC sent to the healthcare professionals (HCPs) with confirmation of date of distribution

- Information regarding the progress of the distribution plan and possible feedback, i.e. results of the follow-up activities to measure the efficacy of the DHPC.

Important points to consider concerning DHPC contents:

- In the title and introduction, it has to be mentioned that the letter is being sent in agreement with EMA and/or the Luxembourgish authorities, namely “Direction de la santé, Division de la Pharmacie et des Médicaments, au Luxembourg".
- The sentence « Communication directe aux professionnels de la santé » should be stated in the beginning of the letter.
- If the product is subject to additional monitoring, the black inverted triangle together with the short descriptive sentence should be present below the name of the medicine.
- A paragraph with contact details for adverse drug reactions (ADRs) notification as stated in the latest version of Annex V of QRD template, should appear in the end of the communication:

In specific cases, where several MAHs are required to distribute a DHPC for the same active substance and/or a class of products, it is highly recommended that only one communication is delivered to HCPs so that any possible confusion is avoided by sending several letters on the same topic.
Where a common DHPC is to be distributed, all steps mentioned above are executed by a coordinating MAH. The coordinating MAH is the liaison between DPM and the other MAHs involved.