State Agency of Medicines of the Republic of Latvia

Information for marketing authorisation holders

27 May 2016

Submission and agreement of Direct Healthcare Professional Communications with the State Agency of Medicines

Information regarding Direct Healthcare Professional Communication (DHPC) in situations described in detail in Module XV "Safety communication" of the Good pharmacovigilance practices.

Legislation

- 22 January 2013 Cabinet of Ministers Regulation No. 47 "Procedure for Pharmacovigilance"
- Good pharmacovigilance practices guidelines

Situations when distribution of DHPC should be considered

In accordance with module XV "Safety communication" of the Good pharmacovigilance practices DHPC should be distributed in the following situations relating to safety of medicinal products where urgent action is necessary or changes in the current procedure for use of medicinal products should be introduced:

- Suspension, revocation or withdrawal of marketing authorisation of a medicinal product due to safety considerations;
- Introduction of significant changes in the use of a medicinal product due to safety considerations by narrowing indications, introducing a new contraindication or amending the recommended dosage;
- Restriction or interruption of availability of a medicinal product related to its harmful effects on patient health.

Other situations when the necessity for distribution of DHPC should be considered:

- New significant warnings or precautions for use have been introduced in the summary of product characteristics and the package leaflet;
- New, previously unknown risks or changes in the frequency or severity of known risks have been detected;
- Substantiated data has been obtained showing that a medicinal product is not as effective as previously believed;
- New recommendations for prevention or treatment of an adverse reaction;
- New recommendations to avoid misuse or medication errors with medicinal products;
- An ongoing assessment of significant potential risks where information available at the moment is insufficient for taking regulatory measures. In this case the following information should be included in the DHPC: encouragement for close monitoring of the potential risk, which has raised the concerns with the medicinal product in clinical practice; encouragement for reporting adverse reactions related to this potential risk; indication how to minimise this risk, if possible;
- The competent authority may distribute or request the marketing authorisation holder (MAH) to distribute a DHPC in any situation where it considers it to be necessary in order to ensure safe and effective use of medicinal products.

Address for agreement of the DHPC with the State Agency of Medicines (SAM)

DHPC related to situations described in the section "Situations when distribution of DHPC should be considered" should be sent to the e-mail address em_dhpc@zva.gov.lv.

Please note that DHPC relating to the quality of medicinal products, counterfeit medicinal products, availability limitations or supply interruption of medicinal products with a potentially harmful impact on patient healthcare and to other issues should be sent to info@zva.gov.lv, phone number for queries: +371 67078424.

Recommendations for preparing a draft DHPC letter for submission

- The DHPC should comply with the requirements defined by normative acts and described in detail in guidelines (see section "Normative documents").

- The MAH should comply with the following text quality requirements upon preparing a DHPC letter:
  - Clear, precise and unambiguous;
  - Easy to perceive;
  - Laconic;
  - Compliant with literary norms of the Latvian language;
  - Adequate and consistent use of terminology.

  (Compliance with the aforementioned requirements will accelerate the agreement procedure)

- When preparing the letter an additional heading in Latvian "Vēstule veselības aprūpes speciālistam" *("Direct Healthcare Professional Communication")* should be added above its title.

- If a DHPC letter is to be distributed regarding several nationally authorised medicinal products in Latvia and/or centrally authorised medicinal products in the European Union, the MAHs of these medicinal products are recommended to prepare a single

common DHPC draft, as well as to mutually agree on the target audience and communication plan. The MAHs should agree which one of them will coordinate the process of DHPC preparation and agreement. When submitting the collectively prepared DHPC draft, target audience and communication plan, the cover letter should indicate that these documents have been prepared in collaboration with other MAHs of specific medicinal products distributed in Latvia. The original names of all the medicinal products should be indicated in the final version of the DHPC agreed by SAM. The DHPC should be signed by all the MAHs.

- If the DHPC has to be prepared regarding a large number of medicinal products distributed in Latvia, the task of preparation of the draft letter and its submission for approval to SAM may be assumed by the MAH of the reference medicinal product/one of the generic medicinal products. In this case the SAM agreed final version of the DHPC should be signed only by the MAH of the reference medicinal product/ the lead MAH of generic medicinal products.

- In both of the aforementioned cases it must be indicated in the title and at the beginning of the letter that the information included in the DHPC applies to all medicinal products authorised in Latvia that contain the specific active substance or substances (if the DHPC is related to the group effect of medicinal products).

- At the beginning of the DHPC letter it must be indicated that it has been agreed by the State Agency of Medicines.

- The name of the active substance and the original name of the medicinal product should be indicated in the topical heading of the letter.

- The following standard text in Latvian should be included in the "Call for reporting" section of all DHPC letters:

  "Atgādinām, ka saskaņā ar zāļu blakusparādību ziņošanas noteikumiem Latvijā ārstniecības personām un farmaceitiem jāziņo par novērotām iespējamām zāļu blaknēm Zāļu valsts aģentūrai (ZVA), sūtot ziņojumu (veidlapa "Ziņojums par zāļu blakusparādībām") pa faksu: 67078428 vai pa pastu, adrese: Jersikas iela 15, Rīga, LV-1003. Ziņojumus iespējams nosūtīt arī elektroniski ZVA mājaslapā www.zva.gov.lv. Papildinformācijas nepieciešamības gadījumā jāsazinās ar ZVA pa tālr.: 67078438.

  ("We remind you that in accordance with the regulations regarding reporting of adverse drug reactions in Latvia healthcare professionals and pharmacists should report observed suspected adverse reactions to the State Agency of Medicines by sending a report ("Adverse Drug Reaction Report" form) via fax (+371 67078428) or via mail to the SAM, address: Jersikas Street 15, Riga, LV-1003. Reports may also be sent via internet from the SAM website www.zva.gov.lv. For additional information please contact SAM via phone by calling +371 67078442.").
  If the relevant medicinal product is a biological medicinal product, the text should be supplemented with: "Šīs zāles ir bioloģiskas izcelsmes, tāpēc, ziņojot par blaknēm, jānorāda zāļu oriģinālnosaukums un sērijas numurs" *("This medicinal product is a biological medicinal product, therefore, the original name and serial number of the medicinal product should be indicated when reporting adverse reactions.")*

- In the section "Contact information" the following information must be indicated – MAH national level contact person regarding pharmacovigilance issues in Latvia and their contact information (phone number and address), so that healthcare professionals may communicate in the state language.

- If the DHPC concerns a large number of medicinal products with the same active substance/group of medicinal products and the DHPC is prepared and submitted single-handedly by the MAH of the original medicinal product/by the lead MAH of the generic medicinal products, it should be indicated in the section "Contact information" that in case of questions or uncertainties the MAHs of the relevant generic medicinal products should also be contacted using the contact information available in summaries of product characteristics and package leaflets.

- If the DHPC concerns medicinal products that are not distributed in Latvia, SAM should be contacted regarding the procedure for agreement. It should be noted that as soon as a medicinal product enters circulation in Latvia (also when prescribed only to separate patients), it is the responsibility of the MAH to ensure the provision of updated safety information to the relevant target audience.

- The distribution of DHPC to healthcare professionals must not be related to activities promoting the prescription, use or marketing of medicinal products.

- The contact information of healthcare specialists that MAH has obtained within the DHPC communication plan must not be used for purposes of advertising medicinal products.

Process of submission and agreement of the DHPC

1. **Submission of DHPC draft (project) to SAM**

   Should be submitted only electronically by sending to em_dhpc@zva.gov.lv

The following documents should be submitted:

- DHPC draft in Latvian;
- DHPC in English;
- DHPC draft agreement and distribution plan within the EU – if applicable;
- An updated summary of product characteristics and package leaflet in Latvian and in English with highlighted amendments, if applicable;
- Lists of target audiences to be approved:
  o Information for the SAM – list of persons, indicating speciality and workplace, if planning on sending the DHPC personally;
  o For publication on the SAM website:
    - list of professional associations,
    - if the letter will be sent to doctors personally, indicate: "speciality" – personally,
    - list of medical and pharmaceutical establishments and institutions.
- Cover letter indicating:
  - Justification for distribution of DHPC;
  - Target audience and distribution plan (type, date) of the DHPC in Latvia;
  - The planned date of DHPC draft approval;

- Medicinal product consumption data regarding the previous year, other justification or supplementary documents, if necessary.

2. Agreement process

After submission of DHPC and related documents to SAM the agreement process continues via e-mail correspondence with a SAM expert. The SAM expert and the submitter should agree upon:

- the plan for agreement and distribution of the letter (type, date), basing on the degree of urgency of the specific medicinal product safety issue or the agreement within the EU;
- the DHPC text in Latvian by exchanging commentaries and amendments;
- the target audience**.**

During the agreement process SAM may request the MAH to consult with terminologists, linguists, medical and pharmaceutical professional associations, as well as separate specialists in order to clarify and verify:

- the conformity of terminology,
- the clarity and perceptibility of the information,
- whether the information corresponds with the medical and laboratorial possibilities available in Latvia.

When the SAM expert and the MAH have agreed on the final version of the letter in Latvian, the expert will ask the MAH to send the DHPC **document draft package** via e-mail:

- Final version of the letter without track-changes (without commentaries) as a *Word* document for final proofreading;
- Final versions of the SAM approved lists of target audiences;
- Project of the cover letter indicating:
    - that the MAH is submitting to SAM the paper format/electronic DHPC approved by a SAM expert via e-mail correspondence (year, date, month);
    - the approved target audience;
    - the approved mode and date of distribution;
    - consumption data regarding the previous year, information regarding the reimbursement status (if applicable)
    - statement that the MAH agrees to the publication of the letter on SAM website, the agreed date;
    - list of attached documents.

3. Confirmation of DHPC agreement by the SAM

If the draft documents are found to be compliant with the aforementioned requirements, SAM shall send a confirmation of the approval of the letter to the MAH via e-mail: "**The letter has been approved by SAM**" and shoul ask the MAH to submit the agreed DHPC document package (see section No. 4).

4. Submission of SAM agreed DHPC document package to SAM

The MAH shall submit the approved document package to SAM, preferably in an electronic (pdf) format by sending it to the e-mail address em_dhpc@zva.gov.lv (*must be signed with a secure electronic signature*) or in paper format.

The following documents should be submitted to SAM:

- DHPC document version ready for distribution indicating:
  - the date (the planned date for initiation of distribution of the letter to the target audience),
  - company logo (if the letter is prepared collectively by several MAHs, the final version is submitted without company logos)
  - signature (if the letter is prepared collectively by several MAHs, the final version should be signed on behalf of particular MAH by the authorised person);
- A copy of the original letter in English;
- The SAM approved list of target audience to be published on the SAM website;
- The final version of the cover letter (in case of an electronic submission, the cover letter should be signed with a secure electronic signature).

If the agreed DHPC package has been submitted to the SAM only in paper format, the MAH shall send the following documents to the SAM expert in pdf format via e-mail for publication on the SAM website:

- A pdf file of the final DHPC document;
- A pdf file of the list of target audiences for publication on the SAM website.

In case of uncertainties, please contact the senior experts of the SAM Efficacy and Safety Division. Phone: +371 67078442, e-mail: Inese.Studere@zva.gov.lv; Gunta.Pauksena@zva.gov.lv.