

Information for marketing authorisation holders

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

**1. Normative documents**

- 1.1. [22 January 2013 Cabinet of Ministers Regulation No. 47 “Procedure for Pharmacovigilance”](#)
- 1.2. [Good pharmacovigilance practices guidelines, GVP Module XV Safety Communication, and Annex II – Templates: Direct Healthcare Professional Communication \(DHPC\) \(Rev. 1\)](#)

**2. 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:

- 2.1. Suspension, revocation or withdrawal of marketing authorisation of a medicinal product due to safety considerations;
- 2.2. 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;
- 2.3. Restriction or interruption of availability of a medicinal product related to its harmful effects on patient health.
- 2.4. Other situations when the necessity for distribution of DHPC should be considered:
  - 2.4.1. New significant warnings or precautions for use have been introduced in the summary of product characteristics and the package leaflet;
  - 2.4.2. New, previously unknown risks or changes in the frequency or severity of known risks have been detected;
  - 2.4.3. Substantiated data has been obtained showing that a medicinal product is not as effective as previously believed;
  - 2.4.4. New recommendations for prevention or treatment of an adverse reaction;
  - 2.4.5. New recommendations to avoid misuse or medication errors with medicinal products;
  - 2.4.6. 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;

- 2.4.7. In situations associated with medicinal product quality, counterfeit medicinal products, limitation of medicinal product availability or discontinuation of medical product supply, with a possible harmful effect on patient care and other matters;
- 2.4.8. 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.

### **3. Address for agreement of the DHPC with the State Agency of Medicines (SAM)**

- 3.1. DHPC must be sent to the e-mail address [em\\_dhpc@zva.gov.lv](mailto:em_dhpc@zva.gov.lv).

### **4. 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”). It is recommended that the sample form (Annex 2) is used, when preparing a DHPC.

- 4.1. 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)*

- 4.2. When preparing the letter an additional heading in Latvian “Vēstule veselības aprūpes speciālistam” (“*Direct Healthcare Professional Communication*”) should be added above its title. At the top right corner, next to the heading, there must be an orange image of the palm of a hand sized 1.8 by 1.5 cm (see Figure and the “Mock-up of the palm” PDF file enclosed). This is an international warning sign that indicates that the material has been approved for DHPC by SAM.



Please use the model form for the preparation of DHPC, see [here](#).

- 4.3. The name of the active substance and the original name of the medicinal product should be indicated in the topical heading of the letter, if necessary (e.g., for combination medicinal products, vaccines and other biological medicinal products).
- 4.4. At the beginning of the DHPC letter it must be indicated that it has been agreed by the State Agency of Medicines.
- 4.5. If a DHPC letter is to be distributed regarding several medicinal products authorised in Latvia and/or 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.

A statement must be included at the beginning of the letter indicating that information included in the DHPC applies to all medicinal products authorised in Latvia containing the specific active substance or substances (if the DHPC is related to the group effect of medicinal products).

Annex to the letter must include a list of concerned medicinal products and MAH contact information.

The DHPC agreed by SAM should be electronically signed by the letter coordinator on behalf of all of the concerned MAHs.

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

Atgādinām, ka saskaņā ar Farmakovigilances kārtību Latvijā ārstniecības personām un farmaceitiem jāziņo par novērotām iespējamām zāļu blaknēm Zāļu valsts aģentūrai (ZVA) elektroniski ZVA tīmekļvietnē [www.zva.gov.lv](http://www.zva.gov.lv), klikšķinot uz izvēlnes “Ziņot par zāļu blaknēm, negadījumiem ar ierīcēm, biovigilanci” un zem “Veselības aprūpes speciālistiem” izvēloties “Ziņot par zāļu blaknēm” vai skenējot zemāk attēloto QR kodu. 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 electronically via SAM website [www.zva.gov.lv](http://www.zva.gov.lv), by selecting “Report Adverse Drug Reactions, Incidents with Devices, Biovigilance” and under “For Healthcare Professionals”, choose “Report Adverse Drug*

Reaction”, or scan the QR shown below. For additional information please contact SAM via phone by calling 67078442.”).

\* The minimum size of the QR code is 2 by 2 cm.

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.”)

4.7. In the section “MAH contact information” the following information must be indicated – MAH contact person and their contact information (phone number and e-mail address).

4.8. 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.

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

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

## **5. Process of submission of the DHPC**

5.1. Submission of DHPC draft (project) and final version to SAM may only be done electronically by sending these to [em\\_dhpc@zva.gov.lv](mailto:em_dhpc@zva.gov.lv)

5.2. The following documents should be submitted:

5.2.1. DHPC draft in Latvian;

5.2.2. DHPC in English;

5.2.3. DHPC draft agreement and distribution plan within the EU, if applicable;

5.2.4. An updated summary of product characteristics and package leaflet in Latvian and in English with highlighted amendments, if applicable;

5.2.5. List of target audiences to be approved, in the following two variants:

5.2.5.1. Information for SAM – list of persons, indicating speciality and workplace, if planning on sending the DHPC personally

5.2.5.2. for publication on the SAM website:

5.2.6. List of professional associations

- 5.2.7. If the letter will be sent to doctors personally, indicate: “speciality” – personally
- 5.2.8. List of medical and pharmaceutical establishments and institutions
- 5.2.9. Cover letter indicating:
  - 5.2.9.1. Justification for the distribution of DHPC
  - 5.2.9.2. Target audience and distribution plan (type, date) of the DHPC in Latvia
- 5.2.10. Other supporting or supplementary documents, if necessary.

## **6. Approval process**

- 6.1. After submission of DHPC and related documents to SAM the approval process continues via e-mail correspondence with a SAM expert. The SAM expert and submitter should agree upon:
  - 6.1.1. the plan for approval 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;
  - 6.1.2. the DHPC text in Latvian by exchanging commentaries and amendments;
  - 6.1.3. the list of target audience.
- 6.2. 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:
  - 6.2.1. the conformity of terminology;
  - 6.2.2. the clarity and perceptibility of the information;
  - 6.2.3. whether the information corresponds with the medical and laboratorial possibilities available in Latvia.

## **7. Confirmation of DHPC agreement by the SAM**

When the SAM expert and the MAH have agreed on the final version of the letter, list of target audience and distribution plan, SAM shall send a confirmation of the approval of the letter to the MAH via e-mail and request the MAH to submit the agreed DHPC document package (see section No. 8).

## **8. 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](mailto:em_dhpc@zva.gov.lv) (the cover letter must be signed with a secure electronic signature).

The following documents should be submitted to SAM:

- 8.1. Cover letter, including the following:

- 8.1.1. information that the MAH is submitting to SAM the paper format/electronic DHPC approved by a SAM expert via e-mail correspondence (if DHPC is being distributed for several medicinal products clause 4.5 must also be followed)
- 8.1.2. The approved target audience
- 8.1.3. The approved mode and date of distribution
- 8.1.4. Information regarding the reimbursement status (if applicable)
- 8.1.5. List of attached documents
- 8.2. DHPC document version ready for distribution and publication on website, including the following:
  - 8.2.1. The planned date for initiation of distribution of the letter
  - 8.2.2. Signature (if the letter is prepared collectively by several MAHs, the final version should be signed by the coordinator)
- 8.3. List of target audience to be published on SAM website

## **9. DHPC inclusion in the public Medicinal Product Register of Latvia on SAM website**

The approved DHPC version shall be added to the appropriate medicinal product in the Medicinal Product Register of Latvia published on SAM website.

In case of any questions, please contact the experts of the SAM Medicinal Product Safety Division. Phone: +371 67078442, e-mail: [em\\_dhpc@zva.gov.lv](mailto:em_dhpc@zva.gov.lv).