21.03.2019

# *Direct Healthcare Professional Communication - DHPC*

## General requirements

Before the dissemination of DHPC the Marketing Authorisation Holder (MAH) shall have the DHPC text and communication plan approved by the State Agency of Medicines (*according to article 4§ 3 of Regulation of the Ministry of Social Affairs no 26).*

If the safety information concerns a medicinal product of more than one MAH, the relevant MAHs shall draft the DHPC text together.

When drafting a DHPC, the guidance provided in GVP module XV (*Safety Communication)* and the template published on EMA website should be followed:

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2013/01/WC500137665.pdf

## Submission of DHPC to SAM

DHPC must be sent to e-mail **pharmacovig@ravimiamet.ee**

To guarantee fast and smooth process

- On the e-mail *Subject* line MAH should write "**Name of the medicinal product, active substance**", "**DCHP".**
- In the letter MAH should clarify what are the grounds of drafting /submission of the DHPC - either request of the EMA or EU Member State (i.e in case of MRP or DC products)
- DHPC as Word doc file in Estonian and English

The following must be always submitted:

- **Communication plan** (to whom DHCP is meant, distribution plan, timetable)
- **Estonian speaking contact** *(according to article 4§ 4 of Regulation of the Ministry of Social Affairs no 26).*

## Communication plan

MAH should ensure that every prescriber of the medicinal product receives the DHPC.

If MAH transmits the DHPC to target group (i.e prescribers) via e-mail through professional societies, the cover letter must contain clear request that the society must send a confirmation letter to the MAH regarding dissemination of the DHPC. In case confirmation is not received within sensible time, the MAH shall re-contact the society for delivery of DHPC. In case the dissemination of the DHPC via society is not feasible, the letter should be disseminated to target group by other means (e-mail, postal mail or direct contact). For comparison the MAH may use the list of health care professionals which can be found on Health Board website: the register of health care professionals - http://mveeb.sm.ee/Tervishoiutootajad/?

In case the DHPC concerns a medicinal product used in hospital it should be sent to relevant clinics / hospital departments and to hospital pharmacists.

The MAH must keep records of the target group given in the communication plan (to whom the DHPC was distributed and when).

**Section "Call for reporting - *Kõrvaltoimetest teatamine"***

DHPC must include the following text in the section "Call for reporting":

*„Kõigist tõsistest kõrvaltoimetest tuleb teavitada Ravimiametit või müügiloa hoidjat. Teatada võib ka mittetõsistest kõrvaltoimetest.*

*Ravimiamet: kasutage ravimi kõrvaltoimest teatamise vormi (leitav veebiaadressilt: http://www.ravimiamet.ee).*

*<name of the MAH> : <contact details>."*

In case the medicinal product is subject to additional monitoring:

*„▼Käesoleva ravimi suhtes kohaldatakse täiendavat järelevalvet, mis võimaldab kiiresti tuvastada uut ohutusteavet. Tervishoiutöötajatel palutakse teavitada kõigist võimalikest kõrvaltoimetest Ravimiametit või müügiloa hoidjat.*

*Ravimiamet: kasutage ravimi kõrvaltoimest teatamise vormi (leitav veebiaadressilt: http://www.ravimiamet.ee).*

*<Müügiloa hoidja nimi> : <kontaktandmed>."*

**Timelines of review/approval of the DHPC**

The State Agency of Medicines shall inform the MAH of the approval of the text and plan of distribution of the DHPC, a need for introducing changes or refusal from approval within **five working days** from the date of receiving the DHPC text and distribution plan or according to the EMA timetable.

**Publication of the DHPC on SAM website and distribution**

The MAH must notify the date of dissemination prior to actual dissemination. State Agency of Medicines will publish the DHPC on website: http://www.ravimiamet.ee/ohutusalased-teabekirjad and it will be included to the information of the respective product in the register of medicinal products.

By sending the DHPC electronically via society's e-mail, pharmacovig@ravimiamet.ee should be added as CC.

**Other important requirements**

DHPC must not contain advertising elements (no product logo or unrelated pictures)

The templates of the cover letters sent to the professional society or directly to the prescriber are presented in Annexes 1 and 2.

**Annex 1**

**Cover letter to Societies**

Subject: Ohutusalane teabekiri - ravimi {ravimi nimetus} ({toimeaine}) ja {riski kirjeldus}

Sisu: Lp ... Selts

Palun edastage lisas olev ohutusalane teabekiri seltsi liikmetele. **Palun saatke kinnitus, kui kiri on seltsi liikmetele edastatud.**

{Ravimi nimetus} ({toimeaine, näidustus}) müügiloa hoidja {müügiloa hoidja nimetus} kokkuleppel Ravimiametiga teavitab teid {riski kirjeldus} riskist.

Palun tutvuge lisas oleva teabega.

<Ravimit välja kirjutades tuleb patsiendile riski selgitada.> või <Ravimit {ravimi nimetus} saavaid patsiente tuleb nimetatud riski suhtes jälgida> (tekst võiks lühidalt anda juhised).

{Ravimi nimetus} ravimi omaduste kokkuvõtte ja pakendi infoleht on leitav Ravimiameti kodulehelt www.ravimiamet.ee – otsi ravimit

Ohutusalane teabekiri on leitav ka Ravimiameti kodulehelt: http://www.ravimiamet.ee/ohutusalased-teabekirjad.

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**Annex 2**

**Cover letter to HCP**

Subject: Ohutusalane teabekiri - ravimi {ravimi nimetus} ({toimeaine}) ja {riski kirjeldus}

Sisu:

Lp dr ...

{Ravimi nimetus} ({toimeaine, näidustus}) müügiloa hoidja {müügiloa hoidja nimetus} kokkuleppel Ravimiametiga teavitab Teid {riski kirjeldus} riskist.

Palun tutvuge lisas oleva teabega.

<Ravimit välja kirjutades tuleb patsiendile riski selgitada.> või <Ravimit {ravimi nimetus} saavaid patsiente tuleb nimetatud riski suhtes jälgida> (tekst võiks lühidalt anda juhised).

{Ravimi nimetus} ravimi omaduste kokkuvõtte ja pakendi infoleht on leitav Ravimiameti kodulehelt www.ravimiamet.ee – otsi ravimit

Ohutusalane teabekiri on leitav ka Ravimiameti kodulehelt: http://www.ravimiamet.ee/ohutusalased-teabekirjad.

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**History of changes**

| Time | Content of the main changes |
|---|---|
| 21.03.2019 | Section **Communication plan** is amended to include additional recipients in case DHPC concerns hospital medicines.<br><br>Section **Call for reporting - Kõrvaltoimetest teatamine** is amended – HCPs are obliged to report serious adverse drug reactions. Added information on medicines subject to additional monitoring.<br><br>Section **Publication of the DHPC on SAM website and distribution** is amended to include that DHPC will be included to the information of the respective product in the register of medicinal products.<br><br>Section **Other important requirements** is amended to include references to templates.<br><br>New templates – Annex 1 and 2 to be used in electronic dissemination. |