Contents

Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
2.0	01.03.2021	Document renamed from "Guidance document DHPC content, recipients, publication HMV4" to "Guidance document DHPC HMP" Sections 5.1 and 7: new information on obtaining supporting/educational materials	pad
1.0	01.01.2019	Implementation of TPO4	pad

1 Abbreviations

ADR	Adverse Drug Reaction
DHPC	Direct Healthcare Professional Communication
HMP	Human Medicinal Products
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (TPA, SR 812.21)

2 Introduction and objective

This Guidance document is intended for administrative entities and therefore does not establish immediate rights and obligations on the part of individuals. Through this Guidance document for HMP, Swissmedic is ensuring transparency for applicants and other interested parties regarding the rules and processes with applicants. The conditions referred to in this Guidance document ensure consistency, transparency and efficiency.

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The obligation to provide information for the public is enshrined in Art. 67 of the TPA and affects both Swissmedic and marketing authorisation holders. This guidance document describes the content and communication channels to be used for a DHPC (letter to healthcare professionals) issued by the authorisation holder.

3 Scope

This guidance document applies to the Market Surveillance Section and is applicable to the drafting and publication of information about medicinal product risks by the authorisation holder.

4 Other valid documents

Document identification
TPA SR 812.21
Guideline on good pharmacovigilance practices (GVP) Module XV – Safety communication (Rev 1)

5 DHPC

The publication and sending of a DHPC should always be considered if there is an acute and relevant need for professionals to be informed, whether as a result of a necessary and relevant change in behaviour or in response to questions from patients. A DHPC can also be sent as an interim measure if all the data have not yet been evaluated.
Each DHPC is approved by Swissmedic.

A DHPC is mandatory in the following situations:

- Suspension or deletion of the authorisation for safety reasons
- Restriction of the indication, new contraindication, modification of the dosage for safety reasons
- Safety-relevant quality defects
- Supply bottlenecks for vital medicinal products.

A DHPC may also be necessary in the following situations:
- New major warnings or safety precautions
- New recommendations for preventing or treating ADR or to prevent misuse or medication errors.

5.1 Content

The following chapter provides an overview of the most important content of a DHPC:
The DHPC should be short and to the point. It must not contain any marketing elements such as information regarding a new indication to be introduced shortly or similar.
- The text contains the relevant facts and focuses on the safety signal (description and – stated separately – an interpretation thereof, including consideration of the benefit-risk balance).
- Statement indicating that the DHPC is being issued in agreement with Swissmedic.
- In the case of suspension/batch withdrawal: Recall to what level, and schedule.
- Short note on measures taken on an international level (in the EU, FDA) (where appropriate)
- Instructions to healthcare professionals on procedure to follow / instructions to patients
- Reference to revised product information (information for healthcare professionals and patient information)
- Information on follow-up measures/actions and the corresponding schedule (where appropriate).
- Call for reporting of ADR.
- Other relevant information: links/contact details
- Reference to literature (where relevant).
- Information on obtaining supporting/educational materials from the authorisation holder in connection with the DHPC (e.g. checklist for prescribing physicians, patient brochures, etc.).

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5.2 Mailing

5.2.1 Recipients

- Practising physicians/specialists prescribing the medicinal product concerned
- Practising physicians/specialists who may be confronted with the complications
- Senior physicians, head physicians in hospitals
- Hospital pharmacies
- Dispensing pharmacies

Any restriction of the above categories of recipients must be fully justified by the authorisation holder. If a DHPC concerns medicinal products that do not have to be sold in pharmacies (e.g. kava, St. John's wort, etc.) the categories of recipients must be expanded correspondingly and an additional press release must always be discussed. Other possible recipients: institutions such as homes and prisons, drug stores, health food shops, etc.

5.2.2 Envelope

In accordance with regulation 282 of the Pharma Code (www. scienceindustries.ch), the comment "IMPORTANT NOTICE" must appear on the envelope.

5.3 Publication

5.3.1 Marketing authorisation holder

The marketing authorisation holder must also publish the DHPC as an announcement in the journals Schweizerische Ärztezeitung and pharmaJournal. The content of the announcement is based on the DHPC but can be in shortened form. The announcement text and the DHPC must be approved by Swissmedic before the announcement is published.

5.3.2 Swissmedic

Swissmedic simultaneously publishes the DHPC that the authorisation holder will send on the Swissmedic website.

6 DHPC concerning several marketing authorisation holders

If a DHPC concerns several marketing authorisation holders, the long-standing practice is to encourage the mailing/publication of a single, joint DHPC/announcement. The authorisation holders are strongly encouraged to cooperate with each other in the interest of providing focused information for healthcare professionals and avoiding redundancy. If the authorisation holders are not prepared to cooperate, the authorisation holders concerned must mail and publish the approved text of the DHPC alone.

7 Structure of DHPCs

Name of the medicinal product, active substance: safety signal and measures
(Guidance: e.g. "Rare cases of metabolic acidosis – new precautionary measures", "Suspension of marketing authorisation for ...", "Batch recall")

Title

Statement indicating that the information/measure has been endorsed by Swissmedic.

Summary
(Guidance: The summary should be formatted as bullet points in bold type)

- Brief description of the safety signal, instructions for risk mitigation (e.g. new contraindications, warnings, etc.), alternative therapies (where applicable).
- Recall information (where applicable): to what level, date.

Background information

- Brief description of the indication for the medicinal product.

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- Key facts about the risk: ADR, degree of severity and progression, onset latency, risk factors, dose-dependence, evidence, positive rechallenge or dechallenge.
- Assessment of incidence (for spontaneous reports: number of cases, size of exposed population).
- Conclusions: benefit-risk considerations, information on risk identification, risk populations, statement on off-label use (where applicable).
- Reference to prior DHPC concerning the present risk (where applicable).

Measures and instructions/recommendations for professionals

- Clear instructions for physicians or pharmacists (dangers, e.g. in case of abrupt or uncontrolled discontinuation, must always be taken into consideration)
- Information on instructions to be provided for patients (if necessary)
- Reference to revised product information (information for healthcare professionals and patient information) including the following standard wording: “The updated medicinal product information will be published on www.swissmedicinfo.ch.”
- Timeframe for follow-up measures/activities taken by the company/Agency (where applicable).
- Whether and when the authorisation holder will provide more information (where applicable).

Contact details

A contact, company name, phone number and possibly a website (where applicable) should be provided for further questions and information on the subject.

Reporting adverse reactions

A reminder to report ADR with the following standard wording:

DE: Für Meldungen über unerwünschte Arzneimittelwirkungen (UAW) empfiehlt Swissmedic, das dafür entwickelte Meldeportal Electronic Vigilance System (ElViS) zu verwenden. Alle erforderlichen Informationen hierzu sind unter www.swissmedic.ch zu finden.

FR : Pour le signalement de tout effet indésirable (EI), Swissmedic recommande aux personnes concernées d’utiliser l’Électronique Vigilance System (ElViS), l’outil de déclaration d’effets indésirables. Toutes les informations nécessaires sont disponibles sous www.swissmedic.ch.

Appendices

- Text of the revised medicinal product information with changes highlighted (where applicable).
- List of literature references / links (where applicable).
- Links/addresses for obtaining supporting/educational materials from the authorisation holder in connection with the DHPC (e.g. checklist for prescribing physicians, patient brochures, etc.) (if applicable).

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