1 8 December 2015
2 EMA/36988/2013 Rev 1 Draft for public consultation

3 Guideline on good pharmacovigilance practices (GVP)

4 Annex II – Templates: Direct Healthcare Professional Communication (DHPC)

Date for coming into effect of first version	24 January 2013
Draft Revision 1* finalised by the Agency in collaboration with Member States	17 November 2015
Draft Revision 1 agreed by the European Risk Management Facilitation Group (ERMS FG)	24 November 2015
Draft Revision 1 adopted by Executive Director	8 December 2015
Release for consultation	15 December 2015
End of consultation (deadline for comments)	29 February 2016
Anticipated date for coming into effect	Q2 2016

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6 *Note: Revision 1 contains the following:

7 - Revision in the light of experience.

8

Comments should be provided using this template. The completed comments form should be sent to gvp@ema.europa.eu.

9

10 Note for public consultation:

11 The public consultation is restricted to the yellow highlighted revised texts (i.e. replaced by new texts
12 with deletions and additions) or deleted texts (i.e. not replaced). However, if revisions or deletions
13 impact or contradict other existing text, comments on such non-highlighted texts will be processed and
14 taken into account for the finalisation process.

15

16

<Date>

<Active substance, name of medicinal product and main message *(e.g. introduction of a warning or a contraindication)* **>**

Dear Healthcare professional,

<Name of marketing authorisation holder> in agreement with <the European Medicines Agency> and the <National Competent Authority> would like to inform you of the following:

Summary

Guidance: This section should be in bold/larger font size than the other sections of the DHPC and preferably in bullet points.

- <Brief description of the safety concern in the context of the therapeutic indication, recommendations for risk minimisation *(e.g. contraindications, warnings, precautions of use)* and, if applicable, switch to alternative treatment>
- <Recall information, if applicable, including level (pharmacy or patient) and date of recall>

~~<A statement indicating that the information is being sent in agreement with the national competent authority or the European Medicines Agency, if applicable>~~ ***Background*** ~~***Further information on the safety concern and the recommendations***~~

Guidance: This section may include the following information:

<Brief description of the therapeutic indication of the medicinal product>

<Important details about the safety concern (adverse reaction, seriousness, statement on the suspected causal relationship, and, if known, the pharmacodynamic mechanism, temporal relationship, positive re-challenge or de-challenge, risk factors)~~, also the reason for disseminating the DHPC at this point in time~~ >

<An estimation of the frequency of the adverse reaction or reporting rates with estimated patient exposure>

<A statement indicating any association between the adverse reaction and off-label use, if applicable>

<If applicable, details on the recommendations for risk minimisation>

<A statement if the product information is to be or has been revised, including a description of the changes made or proposed> *Guidance: No need however to include or attach the precise (translated) text of the product information which, at the time of dissemination of the DHPC may not be available as final approved translations)*

<Place of the risk in the context of the benefit>

<The reason for disseminating the DHPC at this point in time>

<Any evidence supporting the recommendation (e.g. include citation(s) of key study/ies)>

<A statement on any previous DHPCs related to the current safety concern that have recently been disseminated~~tributed~~>

<Any schedule for follow-up action(s) by the marketing authorisation holder/competent authority, if applicable>

~~***Further information*** <Link/reference to other available relevant information, such as information on the website of a competent authority>~~

~~<Therapeutic indication of the medicinal product, if not mentioned above>~~

Call for reporting

<A reminder of the need and how to report adverse reactions in accordance with the national spontaneous reporting system, including the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

<Mention if product is subject to additional monitoring and the reason why>

~~<Details *(e.g. name, postal address, fax number, website address)* on how to access the national spontaneous reporting system>~~

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes (if applicable)

~~<Relevant sections of the Product Information that have been revised (with changes made visible)>~~ <Link/reference to other available relevant information, such as information on the website of a competent authority>

<Additional ~~Detailed~~ scientific information, if ~~necessary~~ applicable>

<List of literature references, if applicable>