

9 October 2017
EMA/36988/2013 Rev 1

Guideline on good pharmacovigilance practices (GVP)

Annex II – Templates: Direct Healthcare Professional Communication (DHPC) (Rev 1)

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
Revised draft Revision 1 finalised by the Agency in collaboration with Member States	27 September 2017
Revised draft Revision 1 agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG)	4 October 2017
Revised draft Revision 1 adopted by Executive Director as final	9 October 2017
Date for coming into effect of Revision 1*	13 October 2017

*Note: Revision 1 contains the following:

- Revision in the light of experience (see EMA/118465/2012 Rev 1* - Track-change version following public consultation for marked changes).

Note: This template should also be used for the preparation of a core EU DHPC (see GVP Module XV XV.C.2.1.).

See websites for contact details

European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

The European Medicines Agency is
an agency of the European Union



<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>

Background on the safety concern

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)>

<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>

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

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>

<For biological medicinal products, also include a reminder to report the product name and batch details>.

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

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)

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

<Additional scientific information, if applicable>

<List of literature references, if applicable>