22 January 2013
EMA/36988/2013

Guideline on good pharmacovigilance practices (GVP)

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

Draft finalised by the Agency in collaboration with Member States and submitted to ERMS FG	12 July 2012
Draft agreed by ERMS FG	20 July 2012
Draft adopted by Executive Director	25 July 2012
Start of public consultation	26 July 2012
End of consultation (deadline for comments)	21 September 2012
Revised draft finalised by the Agency in collaboration with Member States	10 January 2013
Revised draft agreed by ERMS FG	16 January 2013
Revised draft adopted by Executive Director as final	22 January 2013
Date for coming into effect	24 January 2013

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> would like to inform you of the following:

Summary

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

- <Brief description of the safety concern, 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>

Further information on the safety concern and the recommendations

<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>

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

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

<A 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>

<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

<Relevant sections of the Product Information that have been revised (with changes made visible)>

<Detailed scientific information, if necessary>

<List of literature references, if applicable>