5.4.1 Template for Direct Healthcare Professional Communications

<Date>
<Document reference number>

Direct Healthcare Professional Communication on the association of <INN and Invented Name(s)> with <safety concern>

Summary
<A brief description of the safety concern, recommendations for risk minimisation (e.g. contraindications, warnings, precautions of use) and, if applicable, switch to alternative treatment, preferably in bullet points>
<Recall information, if applicable (e.g. pharmacy or patient level, date of recall)>
<A statement indicating that the information has been endorsed by a national Competent Authority/the Agency/the Marketing Authorisation Holder, if applicable>

Style guide: The Summary section should be in larger font size than the other sections of the DHPC.

Further information on the safety concern
<Important details about the safety concern (adverse reaction, seriousness, statement on the suspected causal relationship, e.g. the pharmacodynamic mechanism, temporal relationship, positive re-challenge or de-challenge, risk factors), also indicating the reason for disseminating the DHPC at this point in time>
<Placing of the risk in the context of the benefit>
<Revised Product Information text or, preferably, reference to revised Product Information in Annex>
<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>
<A statement indicating the context in which the assessment has been conducted (national procedure/CHMP procedure/European consensus)>
<A schedule for follow-up action(s) by the Marketing Authorisation Holder/Competent Authority, if applicable>

Further information on recommendations to healthcare professionals
<If needed, details on the recommendations for risk minimisation>
<If needed, additional detailed instructions on how to use the new safety or therapeutic effectiveness information>

Call for reporting
<A reminder of the need to report adverse reactions in accordance with the national spontaneous reporting system>
<Details (name, postal address, fax number, website address) on how to access the national spontaneous reporting system/Details on how to report to the Marketing Authorisation Holder>

Communication information
<Date and key messages of communication to the public>
<Content and dissemination mechanism of information to the general public or Patients, if applicable>
<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>
Annexes:
<Text of the revised Product Information (with changes made visible), if applicable>
<Detailed scientific information, if necessary>
<List of literature references, if applicable>