9 October 2017
EMA/334164/2015

Guideline on good pharmacovigilance practices (GVP)

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

Draft finalised by the Agency in collaboration with Member States	17 November 2015
Draft agreed by European Risk Management Strategy Facilitation Group (ERMS FG)	24 November 2015
Draft adopted by Executive Director	8 December 2015
Start of public consultation	15 December 2015
End of consultation (deadline for comments)	29 February 2016
Revised draft finalised by the Agency in collaboration with Member States	27 September 2017
Revised draft agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG)	4 October 2017
Revised draft adopted by Executive Director as final	9 October 2017
Date for coming into effect	13 October 2017

See websites for contact details

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

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DHPC COMMUNICATION PLAN	
Medicinal product(s) / active substance(s)	
Marketing authorisation holder(s)	*In cases where the DHPC concerns several marketing authorisation holders of the same active substance or is part of a class review, it is strongly encouraged that a single consistent message is sent to healthcare professionals in each EU Member State.* *All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single DHPC is prepared and circulated in each Member State. The letter circulated in each Member State should cover all active substance-containing products authorised in that Member State.* *It is encouraged that the originator marketing authorisation holder (where available) in each Member State acts as the contact point for the national competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no originator product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.*
Safety concern and purpose of the communication	*Consider using the title of the DHPC to describe the safety concern*
DHPC recipients	*List all (groups of) recipients of the DHPC in this section, e.g. general practitioners, specialists, community pharmacists, hospital pharmacists, nurses, professional societies, national associations.*
Member States where the DHPC will be distributed	

Timetable *Delete steps which are not applicable*	**Date**
DHPC and communication plan (in English) agreed by PRAC	
DHPC and communication plan (in English) agreed by CHMP / CMDh	
Submission of translated DHPCs to the national competent authorities for review	
Agreement of translations by national competent authorities	
Dissemination of DHPC	