

IPHA Guideline on Company Collaboration for Combined¹ DHPCs

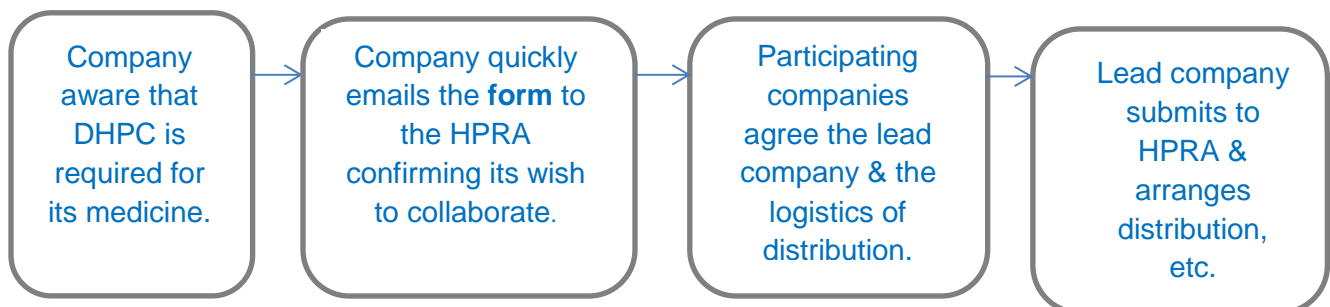
INTRODUCTION

The multiple distribution of Direct Health Professional Communications (DHPC) by a number of companies in relation to the same active ingredient or class effect can decrease the effectiveness of each of the individual communications.

Thus where a DHPC has been mandated by the HPRA or the European Medicines Agency (EMA) and two or more companies are required to distribute the same DHPC, it is recommended² that companies work together to submit and distribute a joint DHPC.

This will reduce the workload and result in cost-savings for companies through the splitting of costs. However, most importantly HCPs will receive a single approved communication on that particular product which should increase the clarity, effectiveness and reach of that communication.

PROCESS FLOW SUMMARY



This document should be read in conjunction with the “*HPRA Guide for Marketing Authorisation Holders on Direct Healthcare Professional Communications*”.

¹ i.e. where the DHPC relates to the same active substance or class effect etc.

² It is acknowledged that on occasion it may not be possible to collaborate due to differences in formulations or administration routes that could affect the information being provided or a company wishing to provide additional information/links with agreement from the HPRA.

PROCESS

1. Prior to the receipt of the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) or HPRA for the DHPC *and* when the draft DHPC is agreed, companies submit a completed DHPC Collaboration Form (Annex I) to the HPRA.
2. The HPRA will facilitate communication amongst interested companies by sharing the contact details submitted to them by companies (as per Step 1).
3. Participating companies should agree the following:
 - a. who is 'lead company' *i.e. the company responsible for the DHPC submission to the HPRA, organising the DHPC distribution, agreeing the printing vendor etc.*
 - b. the proposed distribution list for the DHPC.
 - c. the signatories and how they will be obtained.
 - d. the drug safety/medical information contact details (for inclusion in the DHPC).
 - e. timelines for inter-company review of the draft DHPC (prior to HPRA submission) and review of HPRA comments/questions.
 - f. distribution costs and how these will be split between companies.
 - g. How 'return to sender' letters will be managed.
4. The 'lead company' prepares the draft DHPC on non-headed paper and includes the relevant contact details, signatories and logo (if appropriate) for each company. The 'lead company' circulates the draft DHPC, via email, for review by participating companies.
5. The 'lead company' shares the quote for the costs with the participating companies, Participating companies agree how costs will be divided, plus payment dates and details.
6. The 'lead company' submits the draft DHPC and proposed distribution list to medvigilance@hpra.ie cc'ing participating companies. If HPRA comments/questions are received, the 'lead company' shares these with the participating companies and ensures agreement prior to submission of the response(s).
7. Following receipt of HPRA approval for the DHPC and distribution list, the 'lead company' forwards this to the participating companies.
8. The 'lead company' obtains the relevant DHPC signatories with assistance from the participating companies.
9. The 'lead company' arranges distribution of the DHPC, provides a copy of the final signed DHPC to the participating companies and confirms via email when it has been distributed.
10. The 'lead company' provides the participating companies with copies of the relevant correspondence and proof of postage for the companies' files. The 'lead' company arranges for the participating companies to receive an individual invoice for their share of the cost.
11. The participating companies pay their share of the costs promptly.

Direct Healthcare Professional Communication (DHPC) Collaboration Form

promptly email this completed form to medvigilance@hpra.ie

Company Name:	
Product Name (INN & Tradename):	
PA number:	
Subject of DHPC:	
I permit my contact details to be provided to other companies involved in the DHPC outlined above.	Yes <input type="checkbox"/>
Signature & Date:	
Print Name:	
Title:	
Email Address:	
Telephone Number:	