**Instructions to Applicants**

**Submission of Direct Healthcare Professional Communications (DHPC)**

In line with the DHPC criteria outlined in GVP Module XV – Safety Communication, any disclosure of safety information through DHPCs must be validated by INFARMED, I.P. before its distribution in Portugal, even if its content has been previously agreed by the Marketing Authorisation Holder (MAH) and the European Commission (EC), the European Medicines Agency (EMA), the Reference Member State (RMS) or a National Competent Authority (NCA).

I – Establishment of consortium

In cases where the DHPC concerns medicinal products of several MAHs, it is strongly recommended that a single consistent message be sent to healthcare professionals. The MAHs should collaborate, so that a single DHPC is prepared and circulated in Portugal, covering all concerned medicinal products.

Upon becoming aware of the need to distribute a DHPC in Portugal, the MAHs/Representatives of the involved medicinal products should establish a consortium in a timely manner and submit a joint proposal to Infarmed, via email at info.seguranca@infarmed.pt.

In cases where the prior establishment of a consortium is not feasible, the MAHs/Representatives of the involved medicinal products should contact Infarmed, by email to info.seguranca@infarmed.pt, expressing their willingness to join a consortium and allowing the sharing of their contact information with other MAHs/Representatives.

Infarmed will then share the contacts with all MAHs/Representatives, requesting the appointment of a main contact point for the consortium, and the submission of a single proposal for the DHPC and distribution plan.

**Note:** As recommended in *Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication (CP DHPC)*, it is encouraged that the MAH of the reference medicinal product (where available) in each Member State (MS) acts as the contact point for the NCA, on behalf of the other concerned MAHs in the same MS. If no reference medicinal product is marketed in Portugal, another MAH/Representative should take the lead, ideally the one with the largest market share in Portugal.

II – Application instructions

The validation request shall be addressed to the Directorate of Risk Management for Medicines (Direção de Gestão do Risco de Medicamentos – DGRM), via email at info.seguranca@infarmed.pt, and must include:

* Information on the MAH/Representative[[1]](#footnote-2)\* or the main contact point and other MAHs of the consortium, including the contact point’s name and email;
* In the case of a consortium, confirmation from each MAH/Representative delegating responsibility to the MAH/Representative acting as the main contact point for the consortium (email sent to info.seguranca@infarmed.pt following the initial submission of the joint DHPC proposal);
* Framing of the request (e.g.: CHMP agreement following a safety issue, condition/requirement of the marketing authorisation, European Commission Decision, in the scope of a referral or a single assessment of PSURs);
	+ Detailed description of the proposed distribution plan in Portugal, including:

- target population (whom the DHPC is targeted to, including the medical specialties);

- distribution method (by post, email, in hand, etc.);

- date for dissemination (according with the agreed communication plan or the proposed distribution date, if the former does not exist or it is not applicable for justified reasons).

Attached to the e-mail, the draft Portuguese version of the DHPC in Word format and the final approved English version (when applicable) should be provided, along with the communication plan agreed with the EC, EMA, RMS or NCA (when applicable).

III – Agreement and Dissemination of the DHPC

The MAH/Representative or the main contact point and the other MAHs of the consortium shall wait for Infarmed’s validation of the DHPC prior to any action, being expected that further elements or changes may be requested by Infarmed during the assessment.

The timelines for the assessment of the DHPC by Infarmed are the ones foreseen in the communication plan agreed with the EC, EMA, RMS or NCA. If no communication plan is available, it should be considered a maximum of 30 days’ timeframe for the validation.

After receiving the DHPC´s final validation email, a dated and signed final version (pdf) of the agreed DHPC shall be sent by the MAH/Representative or the principal contact point of the consortium to the email info.seguranca@infarmed.pt.

Portuguese versions of DHPC will be available on Infarmed’s website (in the fold of the medicinal product, available [at](http://app7.infarmed.pt/infomed/inicio.php) Infomed - <https://extranet.infarmed.pt/INFOMED-fo/>) on the date scheduled for its dissemination, except if the MAH/Representative or the principal contact point and/or other MAHs of the consortium express their disagreement duly justified, to the email address info.seguranca@infarmed.pt before that date.

Additionally, Infarmed will provide safety alerts related to the DHPC, through the integration of the health technology alert service (*Serviço de Alertas de Tecnologias de Saúde - SATS*) with the Health Technology Information Transfer system (*Cedência de Informação de Tecnologias de Saúde - CITS*), to entities with a protocol for the transfer of information with Infarmed, so that safety alerts can be integrated into the various electronic prescribing and dispensing systems for medicinal products and Infomed, as applicable.

1. \* In case of a Representative, a Power of Attorney must be provided. [↑](#footnote-ref-2)