

# Educational Material distribution plan - Combined hormonal contraceptives FINLAND

Subject	
<b>Medicinal product(s)</b>	Combined hormonal contraceptives including chlormadinone, desogestrel, dienogest, drospirenone, etonogestrel, gestodene, nomegestrol, norelgestromin or norgestimate.
<b>Marketing authorisation holder(s)</b>	The DHPC activities affect only marketing authorisation holders (MAHs) that have one or more products concerned on the market. For a full list of affected products and relevant marketing authorisation holders, that have confirmed their intention in cooperation with this plan, please refer to the list appended.
<b>Safety concern</b>	Risk of thromboembolism
<b>Regulatory context</b>	Outcome of a referral procedure (art. 31) EMEA/H/A-31/1356
<b>Date and status of communication plan</b>	<b>Initial:</b> Approved by Fimea on 27.3.2014 <b>Update 1:</b> Approved by Fimea on 15.5.2019 (removal of the requirement for a printed only Patient Information Card and optional English Educational Materials)

Strategy	
<b>Purpose of communication</b>	The purpose of this communication is to provide Educational Materials for the healthcare professionals to fulfil the recommendations provided in the initial DHPC letter from 21.-28.1.2014, as required by the National Competent Authority Fimea. The core elements of the Educational Materials have been provided by PRAC. National adaptation and implementation is to be agreed between the MAHs and the Fimea.
<b>Actionable recommendation(s)</b>	Recommendations to Healthcare professionals as risk minimisation: <ul style="list-style-type: none"> <li>- consider individual woman's current risk factors, particularly those for VTE, and differences in risk of VTE between products when prescribing a CHC.</li> <li>- ensure the woman is aware of the related risks and aware of the symptoms of VTE.</li> </ul>
<b>Target populations</b>	Healthcare professionals identified as actual prescribers of combined hormonal contraceptives: <ul style="list-style-type: none"> <li>• Health centre physicians</li> <li>• Gynaecologists</li> <li>• Occupational health physicians</li> <li>• Student health organisation clinics</li> <li>• Contraceptive / family planning clinics</li> <li>• Nurses with limited prescribing rights</li> </ul>

Strategy	
<b>Affected Member States</b>	Finland
<b>Communication tools</b>	<p><b>Initial dispatch</b></p> <p>Healthcare Professional introductory letter</p> <ul style="list-style-type: none"> <li>• MAHs and Fimea collaborated to dispatch a common introductory letter where the educational materials are introduced.</li> <li>• The initial introductory letter was dispatched <ul style="list-style-type: none"> <li>▪ via E-mail where confirmed addresses exist</li> <li>▪ in paper version where E-mails not confirmed</li> </ul> </li> <li>• All three educational material components are required by Fimea.</li> <li>• Material examples were submitted alongside the introductory letter.</li> <li>• The letter includes the sources (links to the MAH websites) where the Educational Materials can be downloaded, printed or further distributed from.</li> <li>• The MAHs' contact details are provided for ordering of materials if downloading is not possible.</li> </ul> <p>Separate starter packages (10 copies of each educational material components) have been submitted to the following target clinics as paper versions:</p> <ul style="list-style-type: none"> <li>• Health centres</li> <li>• Contraceptive clinics</li> <li>• Student health organisation clinics (YTHS)</li> <li>• Gynecological clinics</li> <li>• Gynecological policlinics</li> </ul> <p><b>Continuous process</b></p> <ul style="list-style-type: none"> <li>• MAHs and Fimea collaborate to keep the Introductory Letter and the Educational Materials up-to-date.</li> <li>• All three educational material components are required by Fimea.</li> <li>• The Introductory Letter includes the sources (links to the MAH websites) where the Educational Materials can be downloaded, printed or further distributed from.</li> <li>• The MAHs' contact details are provided for ordering of materials if downloading is not possible.</li> </ul>
<b>Urgency</b>	N/A

<b>Timetable</b>	
Dissemination of the translated approved DHPC in Finland	21-28 January 2014
Submission of translations of the core elements of the Educational Materials provided by PRAC to Fimea for linguistic review	31 January 2014
Submission of the proposed introductory letter to Fimea for linguistic review	14 February 2014
Translations, dispatch plan, introductory letter and target group proposal reviewed and validated by Fimea	20 March 2014
Dissemination of the national introductory letter on Educational Materials	7-11 April 2014
Dissemination of the printed materials to clinics	2 July 2014