

**National requirements on submission of documents during the national phase for new marketing authorisation applications via MRP/DCP**

Authority (MS)	Comments
AUSTRIA	<p>High quality translations of the SPC, Labelling and PIL should be submitted via Austrian eServices Plattform (<a href="http://www.basg.gv.at/en/ages-eservices/">http://www.basg.gv.at/en/ages-eservices/</a>) within five days after the end of a procedure. SPC/label/leaflet should be split up in three documents since the IT system publishes the SPC and the leaflet of the VMPs automatically to the Austrian medicinal product index. If harmonisation between NCAs is envisaged, the request for multilingual packs should be advised at submission of translations. A marketing authorisation will not be issued unless the translations have been submitted. Mock-ups should be submitted upon request.</p>
BELGIUM	<ul style="list-style-type: none"> <li>- An applicant that will be MAH for the first time in BE needs to choose a 'linguistic role' (either FR, either NL)</li> <li>- High quality translations of product literature to NL, FR, DE – if harmonisation between NCAs is envisaged, the request for multilingual packs should be sent asap to all NCAs involved</li> <li>- A declaration of conformity for the translations, signed by an authorised person responsible for publicity in BE</li> <li>- A draft MA document (in FR or NL, following the MAH's linguistic role) duly filled in</li> <li>- An approved distributor (with copy of agreement MAH and distributor, and a copy of the authorisation granted by a NCA from the EEA for the distribution of VMPs)</li> <li>- Mock-ups must be available upon request</li> </ul>
BULGARIA	<ul style="list-style-type: none"> <li>- The applicant should provide the high quality and adequate translation of the agreed summary of product characteristics, package leaflet and labelling within five days after the end of a procedure to <a href="mailto:d_novakova@itp.bg">d_novakova@itp.bg</a> and <a href="mailto:icvp@itp.bg">icvp@itp.bg</a>.</li> <li>- Mock-ups should be submitted upon request.</li> </ul>
CYPRUS	<ul style="list-style-type: none"> <li>- High quality Translation of final approved product information should be sent to <a href="mailto:mapapaprodromou@vs.moa.gov.cy">mapapaprodromou@vs.moa.gov.cy</a>.</li> <li>- If the application was submitted before 24/2/12 and the payment was only for the submission of the application then the MA will not be issued until the MAH pays for it.</li> </ul>
Croatia	<p>The Croatian Ministry of agriculture, Veterinary and food safety directorate is national competent authority (NCA) which issuing marketing authorisation for veterinary medicinal products. The NCA has an agreement with Croatian Veterinary Institute that participate in DCP, MRP and NP.</p> <ul style="list-style-type: none"> <li>- The applicant should submit high quality translations of the final approved SPC, labelling and PIL within five days after the end of a procedure. Please use the Croatian QRD templates. It should be submitted to <a href="mailto:bernard.jendranksinkin@mpps.hr">bernard.jendranksinkin@mpps.hr</a> and <a href="mailto:terzic@veinst.hr">terzic@veinst.hr</a></li> <li>-Mock ups should be sent for approval prior to the marketing of the product.</li> </ul>
CZECH REPUBLIC	<p>High quality translations of the final approved SPC/Package leaflet/Labelling should be submitted via email in Word format to the following contacts: Mrs. Iveta Obrovská: <a href="mailto:obrovaska@uskvbl.cz">obrovaska@uskvbl.cz</a> Mr. Daniel Dušek: <a href="mailto:dusek@uskvbl.cz">dusek@uskvbl.cz</a> The electronic version is satisfactory, the paper version is not required.</p> <p>Mock ups submission is not requested, therefore mock ups non submission does not block the MA granting.</p> <p>Following the MA issue all non-conformities with the approved product information texts will be solved through Market surveillance inspection.</p>

DENMARK	<p>Please use the Danish adapted QRD templates and guideline for Danish product information for veterinary medicines for the preparation of the national texts. See more information at our website:  <a href="#">Adapted QRD templates and guideline for Danish product information for veterinary medicines</a>.</p> <p>All electronic versions should be submitted as Word files.</p> <p>If applicable, please provide the updated application form(s) incorporating all changes made during the procedure.</p> <p>Alternatively please confirm that no changes in the application form(s) have been made since the initial submission.</p> <p>Please note that any responses, supplementary information and translated texts submitted by email should be sent to our general email address <a href="mailto:response@dkma.dk">response@dkma.dk</a> and not to any personal email addresses.</p> <p>Also, please note that any responses, supplementary information and translated texts submitted in hard copy or on electronic media such as CD or DVD should be sent to the following address: <b>Medicines Regulation and Marketing Authorisations, Danish Health and Medicines Authority, Axel Heides Gade 1, DK-2300 Copenhagen S, Denmark.</b></p> <p>A marketing authorization will not be issued until all documentation, including all responses and supplementary information sent by the RMS during the procedure have been submitted according to our guidelines:</p> <p><u>Guidelines on submission of electronic applications:</u>  <a href="http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/licensing-of-medicines/marketing-authorisation/application-for-marketing-authorisation/guidelines-on-submission-of-electronic-a--plications">http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/licensing-of-medicines/marketing-authorisation/application-for-marketing-authorisation/guidelines-on-submission-of-electronic-a--plications</a></p>
ESTONIA	<p>-High quality translations of final approved product information in Word format should be sent to the e-mail address : <a href="mailto:mrp@ravimiamet.ee">mrp@ravimiamet.ee</a> and not to any personal e-mail addresses. The subject line has to include the procedure number.</p> <p>-Mock-ups should be sent for approval prior to the marketing of the product. The MAH should inform the State Agency of Medicines about the start of the marketing of the product in Estonia.</p>
FINLAND	<p>Please provide the final SPC(s) in Finnish, package leaflet &amp; labelling in Finnish and Swedish as Word documents together with colour mock-ups within 5 working days by e-mail .</p> <p>The instructions as published on the FIMEA website for creating SPC and PL files should be followed. These can be found at the following address:  <a href="http://www.fimea.fi/license_holders/marketing_authorisations/SPC_templates_and_publication">http://www.fimea.fi/license_holders/marketing_authorisations/SPC_templates_and_publication</a></p> <p>The documents should be sent to our general email address <a href="mailto:vet.applications@fimea.fi">vet.applications@fimea.fi</a> and <b>not</b> to any personal email addresses, unless requested differently by FIMEA.</p> <p>Please note that a Marketing Authorisation will only be issued after the translations as described above and colour mock-ups have been approved by the FIMEA.</p>
FRANCE	<p>High quality translations of final approved product information should be sent to the licensing unit e-mail address : <a href="mailto:enreg@anses.fr">enreg@anses.fr</a></p>
GERMANY Immunologicals	<p>High quality translations of the SPC, Labelling and PIL in accordance with the final English product information agreed during the procedure according to the QRD template should be submitted in word format by e-mail to <a href="mailto:veterinaermedizin@pei.de">veterinaermedizin@pei.de</a> within five days after the end of a procedure. A marketing authorisation will not be issued unless the translations have been submitted.</p> <p>The final approved texts by PEI are sent by email to the MAH.</p> <p>The MAH has to submit final mock ups before going to press to the same e-mail address to check readability and correctness. The mock ups must be in accordance with the final approved literature and include all the applicable blue box requirements.</p>

<p>GERMANY Pharmaceuticals</p>	<p>In principle, submission according to AMG Submission Ordinance (AMG-EV) (information available on the website of the Federal Office for Consumer Protection and Food Safety <a href="http://www.bvl.bund.de/DE/05_Tierarzneimittel/03_AntragstellerUnternehmen/01_ElektronischeTAMZulassung/tam_ElektronischeTAMZulassung_node.html;jsessionid=DCE4935668EADF07D1602A88F41C94F1.1_cid322">http://www.bvl.bund.de/DE/05_Tierarzneimittel/03_AntragstellerUnternehmen/01_ElektronischeTAMZulassung/tam_ElektronischeTAMZulassung_node.html;jsessionid=DCE4935668EADF07D1602A88F41C94F1.1_cid322</a>) However, for new applications high quality translations should be sent to <a href="mailto:mrp@bvl.bund.de">mrp@bvl.bund.de</a></p>
<p>GREECE</p>	<p>High quality translations of the SPC, Labelling and PIL should be submitted to <a href="mailto:malemisj@eof.gr">malemisj@eof.gr</a> after the end of a procedure. A marketing authorisation will not be issued unless the translations have been submitted.</p> <p>Please note that the <a href="#">QRD/CMDv template</a> must be used.</p>
<p>HUNGARY</p>	<p>The applicant should inform the Hungarian authority the date of marketing and mock-ups of all approved packaging units as well as the package leaflets should be provided together with this announcement.</p>
<p>ICELAND</p>	<p>High quality translations of the SPC, Labelling and PIL should be submitted to <a href="mailto:textar@lyfjastofnun.is">textar@lyfjastofnun.is</a> within five days after the end of a procedure. A marketing authorisation will not be issued unless the translations have been submitted.</p> <p>Please note that the <a href="#">QRD/CMDv template</a> must be used and the <a href="#">QRD convention</a> followed, as well as other relevant <a href="#">QRD documents and guidelines</a>.</p> <p>Mock-ups need not be submitted before the marketing authorisation is issued. However, at least one month before intended marketing final mock-ups should be <a href="#">submitted</a>. The Icelandic Medicines Agency considers it to be the responsibility of the marketing authorisation holder to ensure that the approved labelling is appropriately reflected on the mock-ups and that the design ensures legibility. Multilingual packages are strongly recommended, not the least a combination of two or more of the Nordic countries because of almost identical blue box requirements.</p> <p>A <a href="#">wholesale price</a> must be approved before marketing.</p> <p>Before marketing, a request for information to be published in the list of authorised products (<a href="#">Sérlyfjaskrá</a>) and the price list but be <a href="#">submitted</a>.</p>
<p>IRELAND</p>	<p>In order for the Irish Medicines Board to finalise the authorisation documents the applicant is requested to submit final mock-ups for the product as soon as possible.</p> <p>Mock-ups may be sent by e-mail to &lt;stated in communication&gt;, as an unprotected pdf file, or as hard copies, and should include the smallest and largest pack sizes. If pdf files are provided, the package leaflet must be provided as a separate pdf file to the other product packaging. Please note that the mock-ups should include all text as agreed during the procedure and any national requirements already requested. On approval of the final mock-ups, the authorisation documents will be issued.</p> <p>&lt;Only if UK and IE involved in procedure Please indicate if joint labelling between Ireland and the UK is requested.&gt;</p> <p>If satisfactory mock-ups are not submitted within 30 days of the end of the procedure, the marketing authorisation may be issued in the absence of mock-ups, at the discretion of the Irish Medicines Board. In this case, mock-ups must be submitted for approval, with the appropriate fee, prior to marketing of the product.</p>
<p>ITALY</p>	<p>High quality translation of final harmonised SPC and PL should be sent in electronic version only (word format) to the following e-mail address: - <a href="mailto:g.miele@sanita.it">g.miele@sanita.it</a> or - <a href="mailto:pil-dgsafv@sanita.it">pil-dgsafv@sanita.it</a> right after the end of the procedure.</p> <p>The office evaluates the quality of submitted SPC/PIL and sends back to the company the corrected version of this document. Finally the applicant sends back to the office two final paper copies of the version of SPC/PIL, plus the mock up which reflect exactly the final texts of the PIL. These final documents will be attached to the authorisation decree. These last documents should be dated, stamped and signed by a legal representative of the company.</p>

LATVIA	<p>-High quality Latvian translations of final approved product information should be sent to <a href="mailto:registracija@pvd.gov.lv">registracija@pvd.gov.lv</a></p> <p>-Mock-ups should be sent for approval prior to the marketing of the VMP. The MAH should inform the Food and Veterinary Service (<a href="mailto:registracija@pvd.gov.lv">registracija@pvd.gov.lv</a>) about the start of the marketing of the VMP in Latvia.</p>
LIECHTENSTEIN	<p>Since December 2010 an agreement between Liechtenstein and Austria with regard to the DCP/MRP is in force.</p> <p>The applications for Liechtenstein have to be sent to the Austrian Authority AGES/BASG (see link in Austria: <a href="http://www.basg.gv.at/en/medicines/faq/authorisation/">http://www.basg.gv.at/en/medicines/faq/authorisation/</a>). Liechtenstein has no national requirements.</p>
LITHUANIA	<p>-High quality Lithuanian translations of final approved product information should be sent to <a href="mailto:registracija@vet.lt">registracija@vet.lt</a></p>
LUXEMBOURG	<ul style="list-style-type: none"> <li>- The applicant is requested to choose the packaging which he intends to register in Luxembourg (Belgium, France, Germany, Austria). This packaging must include French and/or German language.</li> <li>- In order to allow the companies to include Luxembourg's registration number in their texts, this number is provided before official registration.</li> <li>- Before a market authorisation is issued a copy of the market authorisation from the country of origin should be provided with corresponding texts.</li> <li>- Preference for electronic submission (<a href="mailto:luxvet@ms.etat.lu">luxvet@ms.etat.lu</a>)</li> </ul> <p>No mock-ups are required.</p>
MALTA	<p>Within 30 days from the end of the MRP/DCP procedure the MAH contacts the agency on <a href="mailto:godwin.farrugia@gov.mt">godwin.farrugia@gov.mt</a> The MAH receives a simple form which has to be filled in and sent as a scanned copy to the same e-mail address. The hard copy can also be sent by post, though this is not necessary. It is at this stage that the fee has to be paid through a bank transfer. Appended or attached to the form there should be the proposed English versions of the PIL, SmPC and Mock-ups (which are of course still without the Maltese MA number)</p> <p>We find no objection if the product is a joint pack with another Member state, as long as it is in English and the Maltese MA number appears on the outer pack.</p> <p>At the end of this phase an MA licence is issued and sent to the MAH.</p> <p>If the MAH intends to market the product locally the approved distributor should be pointed out. A copy of agreement between the MAH and distributor is desirable.</p> <p>The form is neither available on the current agency's website nor will it be in the planned future one. The MAH must contact the designated official directly on <a href="mailto:godwin.farrugia@gov.mt">godwin.farrugia@gov.mt</a> and liaise directly with this official.</p>
NETHERLANDS	<p>High quality translations of final approved SPC and Product Information should be sent by e-mail to : <a href="mailto:case@cbg-meb.nl">case@cbg-meb.nl</a> .</p> <p>In the subject line of the mail in addition to the European procedure number, <i>the case number</i> must be mentioned: case number&lt;space&gt;[number]</p>

NORWAY	<p>The Norwegian Medicines Agency (NoMA) grants a national marketing authorisation for veterinary medicinal products. Products that will be placed on the market in Norway must be approved with the Norwegian product information (SPC, package leaflet, and mock-ups). If the product is not intended for the Norwegian market the marketing authorisation could be granted without the Norwegian product information.</p> <p>In both above mentioned cases any issues regarding the product name must be solved before the authorisation is granted.</p> <p><u>Best Practice Guide:</u> Applicants are reminded to submit national translations taking into consideration the recommendations of the Best Practice on the submission of high quality national translations.</p> <p><u>In case the product will be marketed in Norway:</u> Please submit the proposed final product information in Norwegian within 5 working days after end of procedure. This includes the following:</p> <ul style="list-style-type: none"> <li>• SPC,</li> <li>• Package leaflet</li> <li>• Mock-ups for each strength</li> </ul> <p>These documents should be submitted by e-mail (text as Word-documents and mock-ups as PDF-files) to <a href="mailto:pi@noma.no">pi@noma.no</a>. Please use the templates which can be found on the EMA website: <a href="http://www.emea.europa.eu/htms/human/grd/grdintro.htm">http://www.emea.europa.eu/htms/human/grd/grdintro.htm</a>.</p> <p><u>In case the product will not be marketed in Norway:</u> We kindly ask you to send a confirmation within two weeks to <a href="mailto:pi@noma.no">pi@noma.no</a>. If the NoMA does not receive the Norwegian product information containing SPC, package leaflet and mock-ups or a confirmation within the deadline, the marketing authorisation will be granted without the Norwegian product information. Variations following the MA-procedure will also be approved without the Norwegian product information.</p> <p><u>Change in marketing plans:</u> If it is decided at a later stage that the product should be placed on the market, the Norwegian product information must be assessed and approved by NoMA. The Norwegian translations of SPC, package leaflet and mock-ups should be submitted within two months before the planned marketing date.</p> <p>Changes in the product information caused by variation procedures approved after the MA-procedure must be implemented in the Norwegian texts (marked with the track changes function, and different colours if more than one variation is entered). Please list the variation procedure numbers and approval dates in the e-mail.</p> <p>Do not hesitate to contact us by e-mail <a href="mailto:pi@noma.no">pi@noma.no</a> if you have any questions.</p>
POLAND	<p>High quality translations of the final approved SPC/Package leaflet/Labelling should be submitted via email in Word format to the person who coordinates the procedure since the validation phase.</p> <p>Once approved Polish translation of product text (SPC, PL, labelling), as well as colour mock-ups (labelling and PL), the MA holder should provide 3 copies of the approved product text as well as 3 colour mock-ups (labelling and PL, marked scale) originally signed by the authorised person (according to section 2.4.2 of application form). Additionally 1 copy of the SPC without any signature, dates, stamps etc. should be provided. The scan of the document will be placed in the database of the registered products on our website. MA can NOT be granted if mock ups are not provided.</p>
PORTUGAL	<p>The MAH should submit high quality translations of the SPC, Labelling and PIL in accordance with the final English product information agreed during the procedure, in word format by e-mail to <a href="mailto:jpsilva@dgav.pt">jpsilva@dgav.pt</a> within five days after the end of a procedure. A marketing authorisation will not be issued unless the translations have been submitted.</p> <p>The final approved texts by DGAV are sent by email only to the MAH.</p> <p>After receiving approval letter the MAH has 60 days to submit final mock ups to the same e-mail address. The mock ups must be in accordance with the final approved literature and include all the applicable blue box requirements. DGAV does not issue any approval for the mock ups.</p>
ROMANIA	<p>Mock-up should not be submitted before the marketing authorisation is issued. We consider this to be the responsibility of the marketing authorisation holder to ensure that the approved labelling is appropriately reflected on the mock-ups and that the design ensures legibility.</p>

SLOVAK REPUBLIC	<p>- Period from the end of the procedure D 90/210 till the MA is issued.</p> <p>Mock ups should be provided during the national procedure phase (30 days after day 90/210 but optimally together with the submission of the translations of the approved texts). Very often due to multilingual texts. Mock ups discrepancies are solved during this phase between our Institute and the MAH before issuing of MA. However mock ups non submission in this period does not block the MA granting.</p> <p>Post marketing control of all texts is ensured by our inspectorate.</p> <p>Mock ups should be sent in e-form via email in Word format to the following email contact including the "Title" of mock ups submission, product name and procedure number : <a href="mailto:wagnerova@uskvbl.sk">wagnerova@uskvbl.sk</a>.</p>
SLOVENIA	<p>Electronic high quality Slovene translation of SPC, PL and labelling to be provided in 5 days, preferably by e-mail to <a href="mailto:v-mrp-dcp@jazmp.si">v-mrp-dcp@jazmp.si</a> . Mock-ups are not required to issue MA.</p>
SPAIN	<p>High quality Translation of final approved product information should be sent to: <a href="mailto:mresvet@aemps.es">mresvet@aemps.es</a></p> <p>After the review of the translation mock ups are requested, before granting a MA, but the applicant can submit them in a next step with the commitment if the VMP is not marketed, the product is then suspended. Mock ups will be provided before marketing the product (withdrawal of the suspension).</p>
SWEDEN	<p>Products that will be marketed in Sweden must be nationally approved with Swedish product information including mock-ups in accordance with the final English product information agreed during the procedure.</p> <p>For products that will not be marketed in Sweden the national approval could be granted without Swedish product information. However, any issues regarding the product name must be solved prior to granting of marketing authorisation.</p> <p>Therefore, we kindly ask you to provide us with the information whether the product concerned will be marketed in Sweden. If the product is intended to be marketed in Sweden the national translations of the SPC/PIL/labelling text (as WORD-documents) and mock-ups (PDF-files are acceptable) <b>should be submitted within 5 days</b> to <a href="mailto:ric@mpa.se">ric@mpa.se</a>.</p> <p>In case the product will not be marketed in Sweden, please inform us <b>within two (2) weeks</b>, to <a href="mailto:marketing@mpa.se">marketing@mpa.se</a> . If no response is received within the stated time limit, the MPA will assume that the product will not be marketed and a marketing authorisation will be issued without any Swedish product information.</p> <p>In case a decision is made to market the product in Sweden a national translation of the product information and proposal for mock-ups should be submitted to the MPA for assessment. The national translations should be submitted in good time before the planned marketing date. The assessment time for the submitted translations is up to two (2) months. If variation procedures have been approved since the first MR/DC-procedure, the changes should be implemented in the Swedish product information. Please state in your cover letter a list of the variation procedure numbers, the approval dates and the sections in the SPC which are concerned.</p>

UK	<p>In order for the VMD to finalise the authorisation documents the applicant is requested to submit final mock-ups for the product as soon as possible. At the end of the assessment phase of an application procedure a letter is sent to the applicant as follows:</p> <p>'Before we can issue the formal approval documentation we would be grateful if you would submit full colour mock-ups to the VMD by &lt;Date2&gt;. The mock-ups should be sent in PDF format to the email address below <i>[stated at bottom of letter]</i>. The PDF files should be combined together into <u>one</u> document and not sent as individual files. The product name and application number should be clearly identified in the covering email.</p> <p>&lt;Only if UK and IE involved in procedure: It will be assumed that you wish to obtain/maintain joint labelling with Ireland unless otherwise stated in your covering letter.&gt;</p> <p>Please note mock ups should be submitted within 30 days from the end of the application procedure; if you are unable to meet this deadline please contact the VMD and request an extension of a further 60 days. If mock-ups are not received within the maximum 90 day deadline, the VMD will issue the relevant authorisation documentation with a condition that you must submit a variation, so that the VMD can assess the proposed mock-ups, prior to any marketing of the product. The variation will be a national unforeseen variation and will be charged for accordingly.'</p>
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