

## DECENTRALISED PROCEDURE - REQUESTS TO ACT AS RMS

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The Heads of Medicines Agencies' Task Force on Resources in DCP in cooperation with CMDh has developed a common request form to be used when asking a National Competent Authority (NCA) to act as Reference Member State in a decentralised procedure. The Heads of Medicines Agencies has agreed to publish the request form on the CMDh website as well as on all national competent authorities websites.

The request form (<http://www.hma.eu/219.html>) should be submitted to the NCA in accordance with information provided by that NCA. Below is a list of links to the NCAs' webpages where their recommendations for requests to act as RMS are published.

MEMBER STATES	SUMMARY OF NATIONAL BOOKING SYSTEMS & LINKS TO NATIONAL WEBPAGES
AUSTRIA	<p>Applicants wishing to apply for a marketing authorisation through the Decentralised Procedure with AT as RMS, need to inform AGES PharmMed at an early stage about their intentions and agree on a date for submission with AGES. Completed CMDh request forms for the allocation of time slots need to be sent to <a href="mailto:rms@ages.at">rms@ages.at</a>. The period within which AGES PharmMed reserves slots is limited. The request form has to include the product name, active substance, ATC code, its therapeutic area, the legal basis of the submission according to Directive 2001/83/EC and the preferred submission date. Once agreed, the applicant cannot change the active substance/therapeutic group or the time slot. The applicant is advised to inform AGES PharmMed as early as possible if an agreed application will not be submitted at all in time. More detailed information on the booking system can be found on the AGES PharmMed website:</p> <p><a href="http://www.basg.at/arzneimittel/zulassung/mrpdcp-verfahren/ages-pharmmed-slots/">http://www.basg.at/arzneimittel/zulassung/mrpdcp-verfahren/ages-pharmmed-slots/</a></p>
BELGIUM	<p>The Belgian Agency gives priority to the applications for medicinal product in the following domains:</p> <ul style="list-style-type: none"> <li>- Oncology (with special focus on treatment of cancer pain and paediatrics)</li> <li>- vaccines.</li> </ul> <p>For existing substances, the Belgian Agency also gives priority to those where BE has been RMS or rapporteur in previous procedures.</p> <p>Applicants should send the request at least 3 months before the expected date of submission of the application and will receive a response within 3 weeks. Please note that applications with BE as RMS are booked for a specific active substance, dosage form and submission date. If the applicant intends to change one of those parameters, a new request should be introduced.</p> <p><b>Applicants are informed that there is no available timeslot in BE in 2010.</b></p> <p>Further information are available on the fagg-afmps website:</p> <p><a href="http://www.fagg-afmps.be/en/human_use/medicines/Medicines/MA_procedures/types/index.jsp">http://www.fagg-afmps.be/en/human_use/medicines/Medicines/MA_procedures/types/index.jsp</a></p>
BULGARIA	
CYPRUS	

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<b>CZECH REPUBLIC</b>	<p>The State Institute for Drug Control has a long-term booking system in place, with no cut-off date for booking of future slots. Requests for time slots can be submitted throughout the whole year, using the request form for DCP slots from the web site. The application for slot allocation shall be sent only electronically (by e-mail) to the following address: <a href="mailto:mrp@sukl.cz">mrp@sukl.cz</a>. Applicants are requested to notify SÚKL of any proposed change to an agreed date of submission as early as possible.</p> <p>SÚKL plans to modify the current booking system in order to improve allocation of resources and better schedule requested time slots. Information on the allocation of time slots that have become available will be published in a foreseeable time frame.</p> <p>A detailed and updated specification of the process of slot allocation for applicants for marketing authorisation via decentralised procedure with the Czech Republic as the Reference Member State can be found on the SÚKL website: <a href="http://www.sukl.cz/reg-85">http://www.sukl.cz/reg-85</a></p>
<b>DENMARK</b>	<p>The DKMA advises applicants wishing Denmark as RMS for an application for marketing authorisation through the decentralised procedure to inform and make an agreement with the DKMA before submitting the application. The DKMA has a booking system in place. The DKMA opens the window for requests twice a year approx. one year in advance of the six-month period for which DKMA allocates slot times. Requests for a time slot are made by using the CMDh request form. The form should be sent by e-mail to <a href="mailto:god-validering@dkma.dk">god-validering@dkma.dk</a>. Changes to already agreed time slots should be notified to the DKMA as soon as possible for a new submission date to be scheduled/agreed.</p> <p>Requests for a slot for duplicates, extensions and repeat use procedures can be made outside of the biannual allocation sessions. A more detailed guideline can be found on the website <a href="http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6948">http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6948</a></p>
<b>ESTONIA</b>	<p><a href="http://www.ravimiamet.ee/19059">http://www.ravimiamet.ee/19059</a></p>
<b>FINLAND</b>	<p>The Finnish Medicines Agency is open for RMS' requests 2 times a year in May and November for applications intended to be submitted during the following 6 months.</p> <p>More detailed information can be found on the Fimea website: <a href="http://www.laakelaitos.fi/prime130.aspx">http://www.laakelaitos.fi/prime130.aspx</a></p>
<b>FRANCE</b>	<p>Applicants wishing to apply for a marketing authorisation through the decentralised procedure with FR acting as RMS are advised to inform AFSSAPS at an early stage about their intentions by sending in electronic and paper formats of the common request form duly completed with an official letter to the project manager in charge of the therapeutic class (see information available on the AFSSAPS website).</p> <p>The AFSSAPS will allocate timeslots 3 times a year for the following year i.e. in 2010, timeslots are allocated for 2011.</p> <p>The timeslot request has to be confirmed by the applicant 6 months before the submission date agreed by AFSSAPS.</p> <p>A timeslot is allocated for a medicinal product with an agreed submission date. Neither the medicinal product nor the submission date can be changed.</p> <p>AFSSAPS can put products on a "waiting list" which are ready for a quick submission following a cancellation of a slot.</p> <p>Further details are published on the AFSSAPS website:  <a href="http://www.afssaps.fr/var/afssaps_site/storage/original/application/07aad0b4b47b5d1570eb7df63d7b9f51.pdf">http://www.afssaps.fr/var/afssaps_site/storage/original/application/07aad0b4b47b5d1570eb7df63d7b9f51.pdf</a></p>
<b>GERMANY</b>	<p>Applicants wishing to apply for a marketing authorisation through the Decentralised Procedure with Germany (BfArM) as RMS need to inform the BfArM in advance, preferable at an early stage of their intentions and agree a date for submission. The BfArM has a system in place to enable both, the applicant and the BfArM to make an optimal use of the available resources and to secure the future planning of the applicants. There is no cut-off date for 'slots' in a reasonable and realistic future.</p> <p>Advice on available 'slots' can be obtained by emailing <a href="mailto:Slotrequest-DCP@bfarm.de">Slotrequest-DCP@bfarm.de</a>. This email shall be accompanied with the completed (as far as possible) 'Common request form' as published on the CMDh website (<a href="http://www.hma.eu/219.html">http://www.hma.eu/219.html</a>) together with the preferred submission date.</p> <p>As the BfArM is organised according to the ATC code into therapeutic groups, the applicant cannot change by himself the agreed submission date or the active substance of the application. The applicant is advised to inform BfArM as early as possible if an agreed application will be delayed or not be submitted at all.</p> <p>More detailed information can be found on the BfArM website:  <a href="http://www.bfarm.de/cln_028/nn_1199932/EN/drugs/2_Authorisation/types/euAuthProcs/dcp_mrp/decentral-node-en.html_nnn=true">http://www.bfarm.de/cln_028/nn_1199932/EN/drugs/2_Authorisation/types/euAuthProcs/dcp_mrp/decentral-node-en.html_nnn=true</a>.</p>

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GREECE	<i>Under development</i>
HUNGARY	<p>A letter of intent has to be submitted according to the template ("letter of intent" &lt;<a href="http://www.ogyi.hu/dynamic/letter_of_intent_template_160408.doc">http://www.ogyi.hu/dynamic/letter_of_intent_template_160408.doc</a>&gt;) to which the completed form of 'Request for RMS in a decentralised procedure' published by the CMDh has to be attached as well (<a href="http://www.hma.eu/219.html">http://www.hma.eu/219.html</a>).</p> <p>The request will only be assessed after receiving the above mentioned information.</p> <p>Slot requests have to be submitted from 1st January to 1st May every year and can only contain requests for the next year. HU does not give slots for more than one year in advance.</p> <p>The planning period is from 1st January to 30th June. All the applicants will be informed about the decision of HU on their requests until 30th June.</p> <p>If the Hungarian National Institute of Pharmacy accepts the RMS request the applicant is asked to submit the Module 1 on a CD/DVD one month before the proposed day-14.</p> <p>Neither the slot-time nor the product can be changed once the slot has been accepted.</p> <p>The validation criteria for the submission are the following:</p> <ol style="list-style-type: none"> <li>1. electronic documentation (CD/DVD) in editable format (word or pdf)</li> <li>2. product information and readability test in word format</li> <li>3. the files have to be created according to CTD structure</li> <li>4. originally signed cover letter in paper format</li> </ol> <p>email: <a href="mailto:mrp-dcp-new-rms@ogyi.hu">mrp-dcp-new-rms@ogyi.hu</a></p> <p><a href="http://www.ogyi.hu/page.php?item=471">http://www.ogyi.hu/page.php?item=471</a></p>
ICELAND	<a href="http://www.imca.is/Licences_for_Medicinal_Products/Marketing_Authorisations_MA/RMS_Requests/">http://www.imca.is/Licences_for_Medicinal_Products/Marketing_Authorisations_MA/RMS_Requests/</a>
IRELAND	<p>The Irish Medicines Board (IMB) wishes to participate actively as RMS in the decentralised procedure. The IMB receives many more requests than they are able to accommodate and in order to ensure they act as RMS in as many procedures as possible, they are planning to introduce a new booking system for managing requests for 2011 and beyond.</p> <p>Once available, guidance on this new system will be published on their website. In the meantime any queries or requests should be sent to <a href="mailto:rmsrequests@imb.ie">rmsrequests@imb.ie</a> using the common request form.</p>
ITALY	
LATVIA	<p>Applicants wishing to apply for a marketing authorisation through the Decentralised Procedure (DCP) with Latvia (SAM) as RMS need to inform the SAM in advance.</p> <p>The requests for DCP with Latvia as RMS should be sent by e-mail to <a href="mailto:rms-lv@zva.gov.lv">rms-lv@zva.gov.lv</a></p> <p>This e-mail shall be accompanied with the completed (so far as possible) "Common request form" as published on the CMDh website (<a href="http://www.hma.eu/219.html">http://www.hma.eu/219.html</a>) together with the preferred submission date.</p> <p>The applicants will be informed whether a time slot has been booked for their submission or not. SAM should be notified of any changes in agreed submission dates as early as possible. The next slots for decentralised procedures are available for 2012 Q4.</p> <p><a href="http://www.zva.gov.lv/index.php?id=515&amp;lang=&amp;top=386&amp;sa=393">http://www.zva.gov.lv/index.php?id=515&amp;lang=&amp;top=386&amp;sa=393</a></p>
LIECHTENSTEIN	
LITHUANIA	
LUXEMBOURG	
MALTA	<a href="http://www.medicinesauthority.gov.mt/marketingauth.htm">http://www.medicinesauthority.gov.mt/marketingauth.htm</a>

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THE NETHERLANDS	<p>Every six months, the MEB provides one month during which applicants are given the opportunity to apply for time slots for DCP requests with NL as RMS. Time slots are always allocated for a period of six months. Request forms submitted outside this month are rejected.</p> <p>With some regularity applicants withdraw DCP procedures with NL as RMS for which they have been assigned a time slot. In case time slots have become available, the MEB publishes this information on the website. It is also possible to register for an email alert for DCP time slots that have become available with NL as RMS. This procedure of allocating time slots that have become available is completely separate from the normal allocation procedure for DCP time slots.</p> <p>Further details for both procedures are published on the MEB website:  <a href="http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/decentralised-and-mutual-recognition-procedures/what-is-the-policy-of-allocating-time-slots/default.htm">http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/decentralised-and-mutual-recognition-procedures/what-is-the-policy-of-allocating-time-slots/default.htm</a></p>
NORWAY	<p>The Norwegian Medicines Agency (NoMA) opens for RMS requests four times a year. After each period the NoMA will consider the received requests and give their response to the applicant whether the request is accepted or not. The applicant is asked to send the request 6-9 months before planned submission. For more detailed information, please visit the NoMA website:  <a href="http://www.legemiddelverket.no/templates/InterPage_66981.aspx?filterBy=CopyToGeneral">http://www.legemiddelverket.no/templates/InterPage_66981.aspx?filterBy=CopyToGeneral</a></p>
POLAND	<p>Requests for time slots in 2011 year should be submitted up to 31st of March 2010 only. For time slots DCP-Poland RMS in 2011, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products will contact applicants in June 2010.  <a href="http://www.urpl.gov.pl/pIRMS_DCP.asp">http://www.urpl.gov.pl/pIRMS_DCP.asp</a></p>
PORTUGAL	<p>To apply for a marketing authorisation through the Decentralised Procedure with PT as RMS, the Applicants need to inform INFARMED, IP and agree on a date for submission. Time slots should be requested about 6 months in advance of submission of the application, in accordance with the booking system available at INFARMED's website.</p> <p>Requests for a slot for duplicates and extensions can be made outside of the booking system established.</p> <p>More detailed information on the booking system can be found on the INFARMED website:  <a href="http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AUTORIZA_CAO_DE_INTRODUCAO_NO_MERCADO/PORTUGAL_COMO_ESTADO_MEMBRO_DE_REFERENCIA">http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AUTORIZA_CAO_DE_INTRODUCAO_NO_MERCADO/PORTUGAL_COMO_ESTADO_MEMBRO_DE_REFERENCIA</a></p>
ROMANIA	<p><a href="http://www.anm.ro/en/home.html">http://www.anm.ro/en/home.html</a></p>
SLOVAK REPUBLIC	<p><a href="http://www.sukl.sk/en/registration-of-medicinal-product/forms-and-instructions/sidc-as-rms-for-2011">http://www.sukl.sk/en/registration-of-medicinal-product/forms-and-instructions/sidc-as-rms-for-2011</a></p>
SLOVENIA	<p>Applicants wishing to apply for a marketing authorisation through the Decentralised Procedure with Slovenia as RMS need to inform the Agency for Medicinal Products and Medical devices of the Republic of Slovenia (JAZMP) at an early stage of their intentions and agree a date for submission. The JAZMP has a booking system in place and opens the window for requests twice a year for one month during which applicants are given the opportunity to submit requests for time slots for DCP applications with Slovenia as RMS. Requests for a time slot are made by using the CMDh request form. The request form should be sent to the following address: <a href="mailto:mrp_dcp@jazmp.si">mrp_dcp@jazmp.si</a>. More detailed information, including the next opportunity to submit DCP requests, can be found on the JAZMP website: <a href="http://www.jazmp.si/files/humana/Request_for_RMS.pdf">http://www.jazmp.si/files/humana/Request_for_RMS.pdf</a>.</p>
SPAIN	
SWEDEN	<p>Three times a year, the Medical Products Agency provides one month during which applicants are given the opportunity to submit requests for time slots for DCP applications with Sweden as RMS. Time slots should be requested about 6 months in advance of submission of the application, e.g. for applications that are to be submitted in July-October, the DCP request form should be submitted in February the same year. Bookings further in advance are not made. More detailed information, including the next opportunity to submit DCP requests, can be found on the MPA website <a href="http://www.lakemedelsverket.se/english/product/Medicinal-products/New-applications/DCP-with-Sweden-as-RMS/">http://www.lakemedelsverket.se/english/product/Medicinal-products/New-applications/DCP-with-Sweden-as-RMS/</a>.</p>

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<p style="text-align: center;"><b>UNITED KINGDOM</b></p>	<p>Applicants wishing to apply for a marketing authorisation through the Decentralised Procedure with UK as RMS need to inform the MHRA at an early stage of their intentions and agree a date for submission. The MHRA has a booking system in place, and advice on available 'slots' can be obtained by emailing <a href="mailto:MR-DCprocedures@mhra.gsi.gov.uk">MR-DCprocedures@mhra.gsi.gov.uk</a> with the product name, active substance, ATC code, its therapeutic area, the complexity of the submission (new drug, line extension, generic, etc.) and preferred submission date. MHRA has no cut-off date for booking of future 'slots'. Applicants are requested to notify MHRA of any proposed change to an agreed/confirmed date of submission as early as possible so that an alternative submission date can be agreed. Free 'slots' do become available at short-to-medium term notice due to cancellations or increase in MHRA resource. These free 'slots' are normally advertised for uptake on the MHRA website, although applicants are advised to always check with MHRA as booked capacity is constantly changing. More detailed information on the booking system can be found on the MHRA website.</p> <p><a href="http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplications/Otherusefulservicesandinformation/RequestsforMHRATOactasReferenceMemberState(RMS)/index.htm">http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplications/Otherusefulservicesandinformation/RequestsforMHRATOactasReferenceMemberState(RMS)/index.htm</a></p>