

Marketing authorisations – medicines for human use

Internal procedures in Luxembourg

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Decentralised procedures (DCP) and mutual recognition procedures (MRP)

Standard procedure

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
V5	Initial MA - Validation phase	maa.hum@ms.etat.lu	To market a multi-country pack that meets Luxembourg's language requirements, at least one of the member states in the procedure (RMS or CMS) must be FR, DE, BE, or AT. Please also refer to the Q&A on the 'country of origin' for the Luxembourg market and our guideline on multilingual/multi-country packaging.	na	na	Your application will be processed once the RMS creates the procedure in CTS and starts the validation phase. No dossier will be evaluated prior to procedure creation by the RMS.
V5	Initial MA - Assessment phase	maa.hum@ms.etat.lu	Apart from sending the respective eCTD sequence(s), there is no need to inform us about the response submission, as we track these through other channels. Please send an e-mail if there is a specific concern related to Luxembourg. There is no need to send reminders for CMS comments.	New MA – assessment phase - <DCP or MRP> – <Initial or line extension> - <name of product> - <n° of procedure>	Depending on the request.	Depending on the request.

V5	Initial MA - National phase with a multilingual/multi-country packaging	maa.hum@ms.etat.lu	<p>Send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product (SmPC) • Procedure number • RMS approval date • Multilingual/multi-country packaging (BE/LU, DE/LU, FR/LU or AT/LU, BENELUX) • Prescription status requested (not mandatory) • Contact details for all correspondence <p>Please note that we strongly encourage the use of the BE/LU pack (or BENELUX) as it includes 2 of the 3 official languages. The MAH must ensure that the health care professionals and patients can easily understand the information provided. The national expert commission can propose additional national measures if a risk for the patient is identified because of the languages used.</p> <p>The national phase should be submitted in parallel. LU does not review mock-ups, but they should remain available upon request.</p> <p>DE, AT, FR: The MAH is responsible of the compilation of the national requirement on the printed version. No combined version should be submitted; each competent national authority will approve its own product information.</p> <p>BE: Common product information for BE and LU should be submitted in parallel to FAMHP and DPM. Finalisation of the PI should be coordinated by the applicant.</p>	New MA - national phase - <DCP/MRP/RUP> – <Initial or line extension> – <name of product> - <n° of procedure>	<ul style="list-style-type: none"> • Proposed translation of the PI (SmPC, PIL, labelling) in at least one of the 3 national languages, with section 4.8 of SmPC and section 4 of PIL duly completed with LU contact point (see QRD appendix V on EMA website) and MA as specified in sheet n°2 and the guideline. 	<p>If the request is complete and acceptable, the prescription mode as well as potential restricted prescription and/or delivery conditions will be assessed by our "commission des experts" (monthly meetings on 1st Wednesday of the month).</p> <p>After the meeting, you will receive an official MA letter by e-mail (with digital signature).</p>
V5	Variation type IA and IB Notification 61.3	maa.hum@ms.etat.lu	<p>During the submission phase the eCTD sequence(s) need to be submitted via CESP. In general, no elements from the eCTD dossier should be provided via e-mail or other file sharing service.</p> <p>Following the EoP of the RMS, please send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product with strength(s) and pharmaceutical form(s) • Name of the MAH • Procedure n° (MR/DC) • Variation n° • Details of the variation (variation type and scope) • CESP n°(s) of the submitted dossier • LU MA n°(s) • LU national pack n°(s), if only certain national n°(s) are concerned • RMS approval date • Contact details for all correspondence <p>Note: the PoP must be submitted in the eCTD sequence.</p>	Variation <Ia/Ib> - <DCP/MRP/RUP> - <name of product> - <n° of procedure> - LU: <n° of LU authorisation>	<ul style="list-style-type: none"> • RMS approval email • Current/updated PI if applicable, in track mode. 	<p>No written approval will be sent (silent approval).</p> <p>A new MA will only be issued if the variation has an impact on the data provided in the official MA letter.</p>

V5	Variation type II	maa.hum@ms.etat.lu	<p>During the submission phase the eCTD sequence(s) need to be submitted via CESP. In general, no elements from the eCTD dossier should be provided via e-mail or other file sharing service.</p> <p>Following the EoP of the RMS, please send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product with strength(s) and pharmaceutical form(s) • Name of the MAH • Procedure n° (MR/DC) • Variation n° • Details of the variation (variation type and scope) • CESP n°(s) of the submitted dossier • LU MA n°(s) • LU national pack n°(s), if only certain national n°(s) are concerned • Total amount of fees paid (please refer to our webpage for information on how to pay the fees) • RMS approval date • Contact details for all correspondence <p>Note: the PoP must be submitted in the eCTD sequence.</p>	Variation II - <DCP/MRP/RUP> - <name of product> - <n° of procedure> - LU: <n° of LU authorisation>	<ul style="list-style-type: none"> • National form: "Formulaire (AMM) variation Type II" • RMS approval email • Current/updated PI if applicable, in track mode. 	<p>You will receive a signed copy of the Notification form as approval of the Type II variation.</p> <p>A new MA will only be issued if the variation has an impact on the data published on the official MA letter.</p>
V5	Renewal	maa.hum@ms.etat.lu	<p>During the submission phase the eCTD sequence(s) need to be submitted via CESP.</p> <p>Following the EoP of the RMS (MR/DC) or the Country of Origin (NP), please send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product with strength(s) and pharmaceutical form(s) • Name of the MAH • Procedure n° • LU MA n°(s) • CESP n°(s) of the submitted dossier • RMS approval date • Contact details for all correspondence <p>Note: the PoP must be submitted in the eCTD sequence.</p>	Renewal - <DCP/MRP/RUP> - <name of product> - <n° of procedure>	<ul style="list-style-type: none"> • RMS approval email (MR/DC) • Product information (SmPC, labelling, leaflet) 	You will receive a new MA letter by e-mail (with digital signature) within a few weeks.
V5	MAH transfer	maa.hum@ms.etat.lu	<p>Same procedure as for variation type IA</p> <p>A CESP Submission is recommended.</p>	MAH transfer - <DCP/MRP/RUP> - <name of product> - <n° of procedure> - LU: <n° of LU authorisation>	<ul style="list-style-type: none"> • A copy of the transfer agreement • A copy of the new product information • A copy of the approval of the country of origin if applicable 	You will receive a new MA by e-mail (with digital signature) within a few weeks.

V5	Change in multilingual/multi-country packaging	maa.hum@ms.etat.lu	<p>Changes to multilingual/multi-country packaging is possible from one country to another if the new country is part of the procedure and if the language comply with our regulation (BE, FR, DE, AT). Please send an e-mail to the PoC about the requested change.</p> <p>Please note that we strongly encourage the use of the BE/LU pack (or BENELUX) as it includes 2 of the 3 official languages. The MAH must ensure that the health care professionals and patients can easily understand the information provided. The national expert commission can propose additional national measures if a risk for the patient is identified because of the languages used.</p>	Change country of origin - <DCP/MRP/RUP> - <n° of procedure> - <name of product> - LU: <n° of LU authorisation>	• Current PI authorised in the new country of origin	The change will be made for all registered presentations. You will receive a confirmation by e-mail and an updated version of the MA letter by e-mail a few weeks later. As a result of this change, you must inform the Ministry of Health and Social Security - Department of Social Security, as this will have an impact on the price of the product (pharma@mss.etat.lu).
V5	Taxes	maa.hum@ms.etat.lu Bureau des amendes et recouvrements: Lux.ar@en.etat.lu	Please consult the document "Fees in relation to marketing authorisations in Luxembourg (human)" on our website. If you still have questions, please send a message to the PoC.	Fee question/information	na	na
V5	MA withdrawal	maa.hum@ms.etat.lu	<p>Before withdrawing an MA that is still declared as marketed, the MAH must submit a request to end commercialisation to the PoC (see section above). A public MA listing is available on our website to consult the market status.</p> <p>If the medicine is not marketed, send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product • Procedure number <p>note: for presentation withdrawal, please submit the relevant variation.</p>	MA withdrawal - <DCP/MRP/RUP> - <name of product> - <n° of procedure> - LU: <n° of LU authorisation>	• National form: "Formulaire AMM suppression" duly completed.	You will receive confirmation by mail and the final official withdrawal can be seen in the "Journal Officiel", Mémorial B.

Zero-day procedure

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
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V5	Request phase	maa.hum@ms.etat.lu info shortages@ms.etat.lu	<p>LU may contact MAH to inquire on the possibility to have a Zero-day procedure. MAH may also request such procedure but should first consult the CMDh guideline on the Zero Day procedure and the LU criteria.</p> <p>Decisions are made on a case-by-case basis, considering factors such as feasibility, shortages, unmet medical need, and the potential submission date. The submission should be done as soon as possible, no later than 8 weeks, unless some variations are ongoing.</p> <p>At least one of the following member states must already have the product registered: FR, DE, BE, or AT, to meet our language requirements. Applicants are reminded that this procedure is only to be used when a full timetable is not considered appropriate by the proposed CMS.</p> <p>See our Q&A for further information on the "country of origin" for the Luxembourgish market and our guideline on the multilingual/multi-country packaging.</p> <p>If Luxembourg Health Authority agrees with the D0 :</p> <ul style="list-style-type: none"> - LU will accept the assessment of the RMS or the National Competent Authority (in the instance of an MRP), without any comments or questions. - This addition will not affect renewal or PSUR timelines <p>Information required from MAH:</p> <ul style="list-style-type: none"> • Name of the product, dosage form, strength, active substance • The MR/DC Procedure number or national number • Current variation(s) under assessment • Brief dossier overview (eCTD modules, ERA, commitments, etc.) • Expected dossier submission date 	New MA - <D0 procedure> – request phase - <name of product> - <n° of procedure>	<ul style="list-style-type: none"> • The currently approved product information of the product. 	If the criteria are met and the dossier is acceptable for LU and the RMS should be contacted (see validation phase section).
V5	Validation phase	maa.hum@ms.etat.lu	<p>After the LU, the applicant should contact the RMS to agree on a submission date. The MAH must submit the dossier ASAP.</p> <p>In case, the RMS accepts and the procedure is started, note that in addition to sending the eCTD dossier via CESP, please send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product • Procedure number • CESP number(s) 	New MA - <D0 procedure> – validation phase - <name of product> - <n° of procedure>	No documents needed.	Your request will be treated (i.e. validation of your dossier), but you will not receive a dedicated confirmation e-mail.
V5	National phase	maa.hum@ms.etat.lu	<p>Same procedure as for DCP/MRP/RUP National Phase.</p> <p>Please note that a Day Zero procedure is concluded on the same day it started (i.e. following validation) by the RMS.</p>	New MA - <D0 procedure> – <Initial or line extension> – national phase - <name of product> - <n° of procedure>	Same procedure as for DCP/MRP/RUP National Phase.	Same procedure as for DCP/MRP/RUP National Phase.

Centralised procedures

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
V2	Initial - National phase	maa.hum@ms.etat.lu	<p>If the MAH or his representative wishes to commercialise the centrally authorised product in Luxembourg, please send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product • EU authorisation number • Multilingual/multi-country packaging (BE/LU, DE/LU, FR/LU or AT/LU, BENELUX) • Requested prescription status (not mandatory) • Contact details for all correspondence 	Request NN CP – <Initial or line extension> – <name of product> - <EU authorisation n°>	No documents needed.	<p>Applications for national registration and "national numbers" (NN) of centrally authorised medicines are processed on a monthly basis by our national "commission des experts". Meetings are usually held on the 1st Wednesday of the month. After the meeting and national registration in our database, we will inform you by e-mail about your NN for each pack. The electronic documentation will be sent by email the following month.</p> <p>With information of the NN, MAH or representative can proceed to price setting.</p>
V5	Variation type IA and IB	maa.hum@ms.etat.lu	<p>We do not have the resources to monitor all CP variations. Please inform us via e-mail for any change that impacts the packs and the presentations (e.g. deletion or addition of packs), and for any change that impacts the Luxembourgish "information on European MA" (document that is sent with initial registration).</p>	CP update – <name of product> - <EU authorisation n°>	<ul style="list-style-type: none"> • CHMP opinion • EC decision if available • Updated PI • etc. 	<p>We will inform you by e-mail when your request has been processed. If there is a change in our national database, you will receive an updated version of the MA documentation by e-mail.</p>
V2	Variation type II	maa.hum@ms.etat.lu	Same as for type I and notifications.	Same as for type I and notifications.	Same as for type I and notifications.	Same as for type I and notifications.
V2	Renewal	maa.hum@ms.etat.lu	There is no need to inform us about approved renewals for centralised procedures. We monitor these changes via EMA and the European Commission.	na	na	na

V5	Change in multilingual/multi-country packaging	maa.hum@ms.etat.lu	<p>Please send an e-mail to the PoC informing about the requested change, with the following information:</p> <ul style="list-style-type: none"> • Name of the product • EU authorisation number • Former and new multilingual/multi-country packaging (need to comply with the national language) <p>Please note that we strongly encourage the use of the BE/LU pack (or BENELUX) in Luxembourg as it includes 2 of the 3 official languages. The MAH must ensure that the health care professionals and patients can easily understand the information provided.</p> <p>The national expert commission can propose additional national measures if a risk for the patient is identified because of the languages used.</p>	Change country of origin - <name of product> - <EU authorisation n°> - LU: <n° of LU authorisation>	na	The change will be made for all registered presentations. You will receive a confirmation by e-mail. As a result of this change, you must inform the Ministry of Health and Social Security - Department of Social Security, as this will have an impact on the price of the product (pharma@mss.etat.lu).
V2	MA withdrawal	maa.hum@ms.etat.lu	There is no need to inform us about approved renewals for centralised procedures. We monitor these changes via EMA and the European Commission.	na	na	na

National procedure

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
V5	Initial - general note	maa.hum@ms.etat.lu	PLEASE NOTE: National MA procedure is only acceptable in case there is no other MA in another country. As in Luxembourg we only have products with multicountry packaging due to the size of the market on our market there is already an MA in this country and consequently, MRP or RUP is mandatory. Please note that in some cases, we may accept a Zero Day procedure (see section above).	na	na	na
V5.1	Variation type IA	maa.hum@ms.etat.lu	<p>During the submission phase the eCTD sequence(s) need to be submitted via CESP. In general, no elements from the eCTD dossier should be provided via e-mail or other file sharing service.</p> <p>Please send an e-mail to the PoC with the following information:</p> <ul style="list-style-type: none"> • Name of the product with strength(s) and pharmaceutical form(s) • Name of the MAH • Variation n° (super-grouping or var.nr. of country of origin) • Details of the variation (variation type and scope) • CESP n°(s) of the submitted dossier 	Variation IA - <name of product> - NP - <n° of LU authorisation>	<ul style="list-style-type: none"> • RMS approval if applicable (super-grouping) • Country of origin approval 	<p>For type IA variations, no written approval will be sent (silent approval).</p> <p>A new MA will only be issued if the variation has an impact on the data published on the official MA letter.</p>

			<ul style="list-style-type: none"> • LU MA n°(s) • LU national pack n°(s), if only certain national n°(s) are concerned • RMS approval date if applicable (super-grouping) • Country of origin approval date • Contact details for all correspondence <p>Note: the PoP must be submitted in the eCTD sequence.</p>			
V5	Variation type IB	maa.hum@ms.etat.lu	<p>Under Article 20 of the Variation Regulation, a MAH must submit the same type IB/II variation (or group of variations) across several MAs, in a single worksharing application, with the Country of Origin and LU included in the same procedure.</p> <p>During the submission phase the eCTD sequence(s) need to be submitted via CESP. In general, no elements from the eCTD dossier should be provided via e-mail or other file sharing service.</p> <p>Note: the PoP must be submitted in the eCTD sequence.</p> <p>For national closure the same procedure as for type IB in DCP/MRP/RUP procedures applies.</p>	Variation IB - <name of product> - NP - <n° of LU authorisation>	Same procedure as for DCP/MRP/RUP. EoP of the worksharing	<p>For type IB variations, no written approval will be sent (silent approval).</p> <p>A new MA will only be issued if the variation has an impact on the data published on the official MA letter.</p>
V5	Variation type II	maa.hum@ms.etat.lu	<p>Under Article 20 of the Variation Regulation, a MAH must submit the same type II variation (or group of variations) across several MAs, in a single worksharing application, with the Country of Origin and LU included in the same procedure.</p> <p>During the submission phase the eCTD sequence(s) need to be submitted via CESP. In general, no elements from the eCTD dossier should be provided via e-mail or other file sharing service.</p> <p>Note: the PoP must be submitted in the eCTD sequence.</p> <p>For national closure the same procedure as for type II in DCP/MRP/RUP procedures applies.</p>	Variation II - <name of product> - NP - <n° of LU authorisation>	Same procedure as for DCP/MRP/RUP. EoP of the worksharing	<p>You will receive a signed copy of the national form as approval of the Type II variation.</p> <p>A new MA will only be issued if the variation has an impact on the data published on the official MA letter.</p>
V4	Renewal	maa.hum@ms.etat.lu	<p>Same procedure as for DCP/MRP/RUP.</p> <p>However, in a national procedure, approval letter from the country of origin needs to be submitted.</p>	Renewal - <name of product> - NP - <n° of LU authorisation>	<ul style="list-style-type: none"> • approval of the country of origin • Product information (SmPC, labelling, leaflet), with section 4.8 of PIL duly completed with LU contact point (see QRD appendix V on EMA website). 	You will receive a new MA letter by e-mail (with digital signature) a few weeks.
V5	MA withdrawal	maa.hum@ms.etat.lu	<p>Same procedure as for DCP/MRP/RUP.</p>	Withdrawn - <name of product> - <n° of procedure> - LU: <n° of LU authorisation>	na	You will receive confirmation by mail and the final official withdrawal can be seen in the "Journal Officiel", Mémorial B.

V5	Change in country of origin	maa.hum@ms.etat.lu	It is not possible to change the country of origin in a national procedure. The MA holder must submit a new MA application via MRP or RUP for a procedure which includes the new country of origin as RMS or CMS.	na	na	na
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Traditional herbal medicinal products

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
V4	Request phase	maa.hum@ms.etat.lu	As mentioned in our legal basis, it is possible to register herbal medicines at national level through a simplified national authorisation.	Herbal - <name of product> - initial request	Please send us the following elements: <ul style="list-style-type: none"> • The complete eCTD dossier (via CESP) including PoP, PoD (if applicable), national texts (ideally, please submit these documents also separately by e-mail). • The Belgian MA (or other country of origin) • The assessment report (if available). 	We will assess your application for the national phase is complete. If it is not, we will send you a list with the necessary additional information/documents. When the dossier is complete, the product will be assessed by our "commission des experts" (monthly meetings on 1st Wednesday of the month). In case of positive opinion, you will receive an official MA letter by e-mail (with digital signature).

Derogations

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
V5	Derogations to the MA	regulatorydpm@ms.etat.lu	Please refer to the regulatory team.	na	na	na

Commercialisation and market

Version	Step in procedure	Point of contact (PoC)	Procedure	Subject to be used in the e-mail	Documents to be attached	Outcome
V5	Export, Certificate of pharmaceutical product	inspections.dpm@ms.etat.lu	Please send an e-mail to the PoC with the request and the respective documents. Certificates are only issued for medicines with a MAH in Luxembourg.	CPP - <name of product> LU: <n° of LU authorisation>	<ul style="list-style-type: none"> • WHO template (other templates may be acceptable on a case-by-case decision) • Annexes to the template (last approved SmPC, leaflet, labelling) 	The processing time is approximately one month. The CPP will be sent by post.
V5.1	Start of commercialisation	maa.hum@ms.etat.lu	We do not have a dedicated form for the declaration of start of commercialisation. Please send an e-mail with the following information (include a table or similar) to the PoC: <ul style="list-style-type: none"> • MAH • Name of product • Active substance • Strengths and pharmaceutical forms • Corresponding authorisation number (LU - 10 digits) for NAPs and European number for CAPs • Packaging sizes • National registration numbers (LU - NN 7 digits) 	Start of commercialisation – <name of product> - LU: <n° of authorisation>	No documents needed.	Your request will be processed but you will not receive a dedicated confirmation e-mail.
V4	End of commercialisation	infoshortages@ms.etat.lu	Please refer to the procedure described on the 'Shortage/Marketing Status' webpage of the website.	na	na	na
V2	Shortage	infoshortages@ms.etat.lu	Please refer to the procedure described on the 'Shortage/Marketing Status' webpage of the website.	na	na	na
V5	Shortage with request for derogation to MA	infoshortages@ms.etat.lu regulatorydpm@ms.etat.lu	Please refer to the procedure described on the 'Shortage/Marketing Status' webpage of the website. For MA derogation, please refer to section "Derogation".	na	na	na
V5	Price fixation	pharma@mss.etat.lu	The Ministry of Health and Social Security – Department of Social Security is the competent authority for price setting. After marketing authorisation, the MSS establishes an official price upon request, which must occur before submitting a reimbursement request dossier. For details on the procedure, please contact the MSS.	na	na	na

V2	Reimbursement	Caisse nationale de la santé (CNS)	The competent authority for reimbursement of medicinal product is the National Health Fund (CNS). Please contact the CNS for the exact procedure.	na	na	na
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