



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

<sup>1</sup>17 March 2020  
EMA/95063/2016 rev. 4  
Human Medicines Evaluation Division

## Contact details of national competent authorities for requests of translation exemption falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages

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<sup>1</sup> Changes implemented in:

**Rev.4:** HR, CS, CY, HU, IE, IT, NO, PL, SL, ES, SV details updated (17 March 2020)

As of 1.2.2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period, i.e. until 31.12.2020.

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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Member State	Contact point
<b>Austria</b>	<a href="mailto:basg@basg.gv.at">basg@basg.gv.at</a>
<b>Belgium</b>	[For cases of shortages] <a href="mailto:industry@afmps.be">industry@afmps.be</a> [For all other request] <a href="mailto:FAGG_CP_RAP@fagg.be">FAGG_CP_RAP@fagg.be</a>
<b>Bulgaria</b>	<a href="mailto:rozalina.kulaksazova@bda.bg">rozalina.kulaksazova@bda.bg</a> (FAO Ms Rozalina Kulaksazova)
<b>Croatia</b>	<a href="mailto:ana.kontek@halmed.hr">ana.kontek@halmed.hr</a> (FAO Ms Ana Kontek)
<b>Czech Republic</b>	<a href="mailto:Frantisek.Pavlik@sukl.cz">Frantisek.Pavlik@sukl.cz</a> (FAO František Pavlík) and CC to <a href="mailto:QRD@sukl.cz">QRD@sukl.cz</a>
<b>Cyprus</b>	<a href="mailto:szeitouni@phs.moh.gov.cy">szeitouni@phs.moh.gov.cy</a> (FAO Mrs. Stephanie Zeitouni)
<b>Denmark</b>	[Request to be addressed to the Head of Unit at] <a href="mailto:dma@dkma.dk">dma@dkma.dk</a> (FAO Deirdre Mannion, Head of Unit)
<b>Estonia</b>	<a href="mailto:documentation@ravimiamet.ee">documentation@ravimiamet.ee</a>
<b>Finland</b>	<a href="mailto:mrp@fimea.fi">mrp@fimea.fi</a>
<b>France</b>	<a href="mailto:dajr@ansm.sante.fr">dajr@ansm.sante.fr</a>
<b>Germany</b>	<a href="mailto:article63@bfarm.de">article63@bfarm.de</a> [For vaccines/biological medicinal products]: <a href="mailto:Dominique.Westphal@pei.de">Dominique.Westphal@pei.de</a> (FAO Ms Dominique Westphal) and CC to <a href="mailto:QRD@pei.de">QRD@pei.de</a>
<b>Greece</b>	<a href="mailto:thkousteni@eof.gr">thkousteni@eof.gr</a> (FAO Theoni Kousteni)
<b>Hungary</b>	<a href="mailto:varga.zoltan@ogyei.gov.hu">varga.zoltan@ogyei.gov.hu</a>
<b>Ireland</b>	<a href="mailto:eanna.forde@hpra.ie">eanna.forde@hpra.ie</a> (FAO Éanna Forde)
<b>Iceland</b>	<a href="mailto:ima@ima.is">ima@ima.is</a> <a href="mailto:dagbjort@ima.is">dagbjort@ima.is</a>
<b>Italy</b>	<a href="mailto:it-h.qrd@aifa.gov.it">it-h.qrd@aifa.gov.it</a> and CC to <a href="mailto:legge189.uae@aifa.gov.it">legge189.uae@aifa.gov.it</a>
<b>Latvia</b>	<a href="mailto:maiija.cirkina@zva.gov.lv">maiija.cirkina@zva.gov.lv</a> (FAO Maija Cirkina)
<b>Lithuania</b>	<a href="mailto:vaidaribokaite@vvkt.lt">vaidaribokaite@vvkt.lt</a> (FAO Vaida Ribokaite)
<b>Malta</b>	<a href="mailto:helen.vella@gov.mt">helen.vella@gov.mt</a> (FAO Ms Helen Vella) [or as alternate contact] <a href="mailto:emma.cassar-buontempo@gov.mt">emma.cassar-buontempo@gov.mt</a> (FAO Ms Emma Cassar Buontempo)

Member State	Contact point
<b>Netherlands</b>	<a href="mailto:NLtranslationexemptionCP@cbg-meb.nl">NLtranslationexemptionCP@cbg-meb.nl</a>
<b>Norway</b>	<a href="mailto:pi@noma.no">pi@noma.no</a>
<b>Poland</b>	<p>[Request to be addressed to the Head of Agency at]</p> <p><a href="mailto:pl@urpl.gov.pl">pl@urpl.gov.pl</a></p> <p>[or alternatively to]</p> <p>Łukasz Burda – <a href="mailto:Lukasz.burda@urpl.gov.pl">Lukasz.burda@urpl.gov.pl</a></p> <p>Anna Wachnik-Święcicka – <a href="mailto:Anna.wachnik@urpl.gov.pl">Anna.wachnik@urpl.gov.pl</a></p>
<b>Portugal</b>	<a href="mailto:infarmed@infarmed.pt">infarmed@infarmed.pt</a>
<b>Romania</b>	<a href="mailto:adina.preda@anm.ro">adina.preda@anm.ro</a> (FAO Ms Alexandrina Preda)
<b>Slovak Republic</b>	<a href="mailto:petra.docolomanska@sukl.sk">petra.docolomanska@sukl.sk</a> (FAO Petra Dočolomanská)
<b>Slovenia</b>	<a href="mailto:srz-h@jazmp.si">srz-h@jazmp.si</a>
<b>Spain</b>	<p><a href="mailto:grd@aemps.es">grd@aemps.es</a></p> <p>[or alternatively to]</p> <p><a href="mailto:crecuero@aemps.es">crecuero@aemps.es</a> (FAO Cristina Recuero Carretero)</p>
<b>Sweden</b>	<a href="mailto:ric@lakemedelsverket.se">ric@lakemedelsverket.se</a>
<b>United Kingdom</b>	<a href="mailto:patient.information@mhra.gsi.gov.uk">patient.information@mhra.gsi.gov.uk</a> (FAO Ms Jan McDonald)