



30 August 2023  
EMA/102302/2005 v. 6.3  
Human Medicines Division

## Member states contact points for translations review

The Eudralink message should include at least the following information:

**Eudralink subject:** Post-opinion review – Day <...> – <Product name> – <EMA procedure number>  
– Deadline for comments: <...>

**Eudralink text:** Please find attached the product information for <Product name> in your national language.

<For PSUR: Period covered by the PSUR: <dd.mm.yyyy> - <dd.mm.yyyy> >

<Please note that due to the existence of usage patent(s) the Annexes reflect differences in SmPC/PL compared to the reference medicinal product> [only for generics/hybrids/biosimilars – delete if not applicable]

Comments in Word must be sent directly to <MAH translation contact point e-mail> with copy to the Agency <Product Shared Mailbox>.

Deadline for the linguistic review comments is: <...>

### Renewals, variations, referrals, annual re-assessments

Translations sent by Applicant/MAH to the Member States contact points and handled by procedure coordinator/Vet e-mail address

### Initial and line extension applications

Translations sent by Applicant/MAH to [QRD@ema.europa.eu](mailto:QRD@ema.europa.eu) with a copy to the product mailbox

Member states	Human	Veterinary
<b>Austria</b>	Translations reviewed by Germany	Translations reviewed by Germany
<b>Belgium</b>	Translations reviewed by France, Germany and the Netherlands	Translations reviewed by France, Germany and the Netherlands
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<b>Croatia</b>	<a href="mailto:qrd.hr@halmed.hr">qrd.hr@halmed.hr</a>	<a href="mailto:iva.g-zdunic@mps.hr">iva.g-zdunic@mps.hr</a>
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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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<b>Sweden</b>	RIC@lakemedelsverket.se	RIC@lakemedelsverket.se

\*German translations to be sent to both BfArM and PEI (Human) and to PEI and BVL (Veterinary)  
\*\* If applicable