November 2019

Information Technology
EMA/629064/2019

eAF Release Notes v1.23.1.4

The scope of release v1.23.1.4 covers the following high priority fixes:

1. SD-336020 eAF MAA - business rule validation error
2. SD-271393 Defect in eAF (MAA form) section 1.5

Additional details can also be found in the release notes accessed here: eAF esubmission website.

1. **SD-336020 eAF MAA - business rule validation error**

   In MAA Human form, section 2.1.2 (claim for new active substance, known active substance) is mandatory only if 1.4.1 or 1.4.5 is selected.

For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC :

- ○ Claim for new active substance(s)

  Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)

  - ☐ *please provide evidence and justification to support the claim of new active substance status in annex 5.23*

- ○ Known active substance

2. **SD-271393 Defect in eAF(MAA form) section 1.5**

In MAA Human form, section 1.5, there are now 2 exclusive groups, as follows:

group 1: user can select 1.5.1 or 1.5.2 or none.

group2: user can select 1.5.4 or 1.5.5. or 1.5.6 or none.