



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

March 2019

Information Technology
EMA/164023/2019

eAF Release Notes v1.23.1.2

The scope of release v1.23.1.2 covers the following high priority fixes:

1. EAF-3042 In Section 3, after clicking at the variation summary table and subsequently moving forward using 'tab' to move forward the form goes to infinite loop of error messages
2. EAF-3122 Section 2. Approved Manufacturers description fields under 'Batch control/testing' and 'Manufacturer(s) of the active substance(s)' are mandatory
3. SD-252458 When selecting 1.1.1 "Generic of a Centrally Authorised Medicinal Product" section 1.4.2 Article 10(1) generic application is automatically ticked. When selection is manually changed to 1.4.3 Article 10(3) hybrid application and the form is validated and signed the selection is automatically changed back to 1.4.2.

Additional details can also be found in the release notes available here: [eAF esubmission website](#).

1. EAF-3042 In Section 3, After click at a particular place form goes to infinite loop of error message box

In Variation form section 3, the summary variations table is updated automated with no user action.


3. TYPES OF CHANGE(S)

Copy of the relevant page(s) from the Guideline for this/these change(s) is attach conditions and documentation (both for Type IA and Type IB) are ticked.

Variations included in this application: Please follow instructions below to add va
To add a variation Item, Click Show All Types and select check boxes for the items have been selected click Show only Selected.

Show All Types Refresh Selected

| Variation | Selected |
|-----------|----------|
| A.1 | 1 |
| A.2.a | 1 |



2. EAF-3122 Clarification on new mandatory field in the renewal eAF v1.23.1.1

In Renewal form section 2,
the description field under button "Copy address details from 'batch release' " is not mandatory (batch control testing).
The description field under "Active Substance" sub-section is not mandatory(active substance manufacturer).

Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where **batch control/testing** takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above

+ -

Copy address details from 'batch release'

Do you have a separate admin and manufacturer address? Yes No

+ -

Manufacturer(s) of the **active substance(s)**
Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not acceptable
(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

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Copy address details from 'batch release'

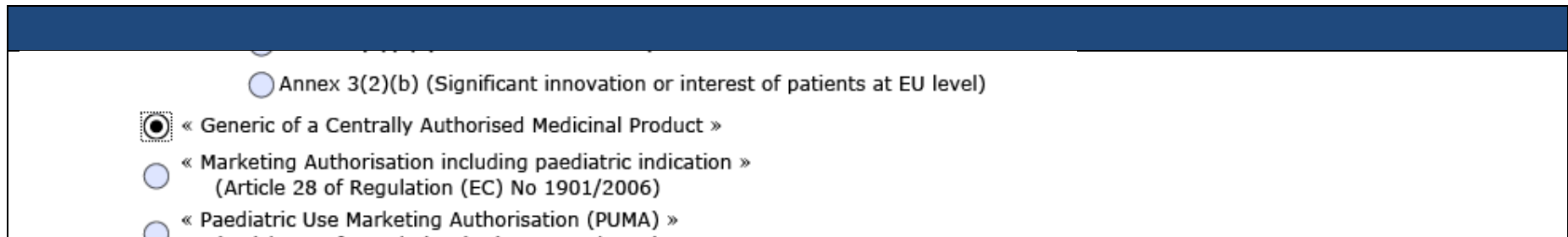
Active Substance

Do you have a separate admin and manufacturer address? Yes No

+ -

3. SD-252458 After validation, 1.4.2 Article 10(1) generic application is ticked

In Human form when clicking section 1.1.1 -> "Generic of a Centrally Authorised Medicinal Product", it does not automatically checks the section 1.4.2 .



The screenshot shows a form with a dark blue header bar. Below the header, there are four radio button options for selecting a medicinal product type. The first option is "Annex 3(2)(b) (Significant innovation or interest of patients at EU level)" with an unselected radio button. The second option is "« Generic of a Centrally Authorised Medicinal Product »" with a selected radio button (indicated by a dotted border around the button). The third option is "« Marketing Authorisation including paediatric indication » (Article 28 of Regulation (EC) No 1901/2006)" with an unselected radio button. The fourth option is "« Paediatric Use Marketing Authorisation (PUMA) »" with an unselected radio button.

- Annex 3(2)(b) (Significant innovation or interest of patients at EU level)
- « Generic of a Centrally Authorised Medicinal Product »
- « Marketing Authorisation including paediatric indication »
(Article 28 of Regulation (EC) No 1901/2006)
- « Paediatric Use Marketing Authorisation (PUMA) »