March 2019

Information Technology
EMA/164023/2019

eAF Release Notes v1.23.1.2

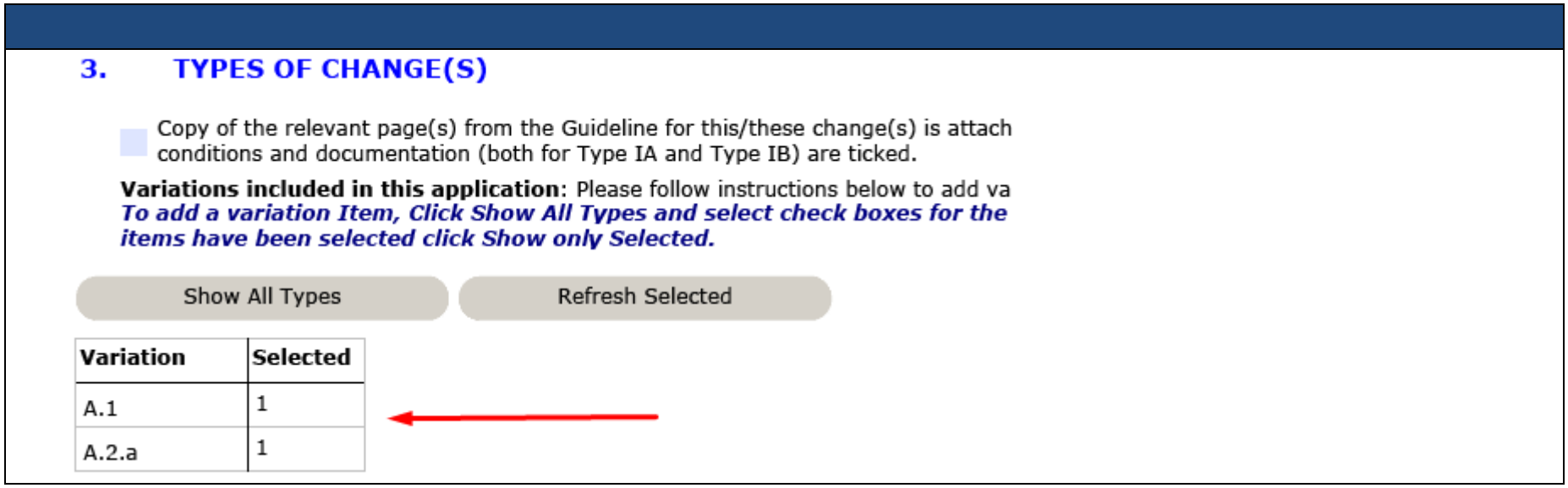
The scope of release v1.23.1.2 covers the following high priority fixes:

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.

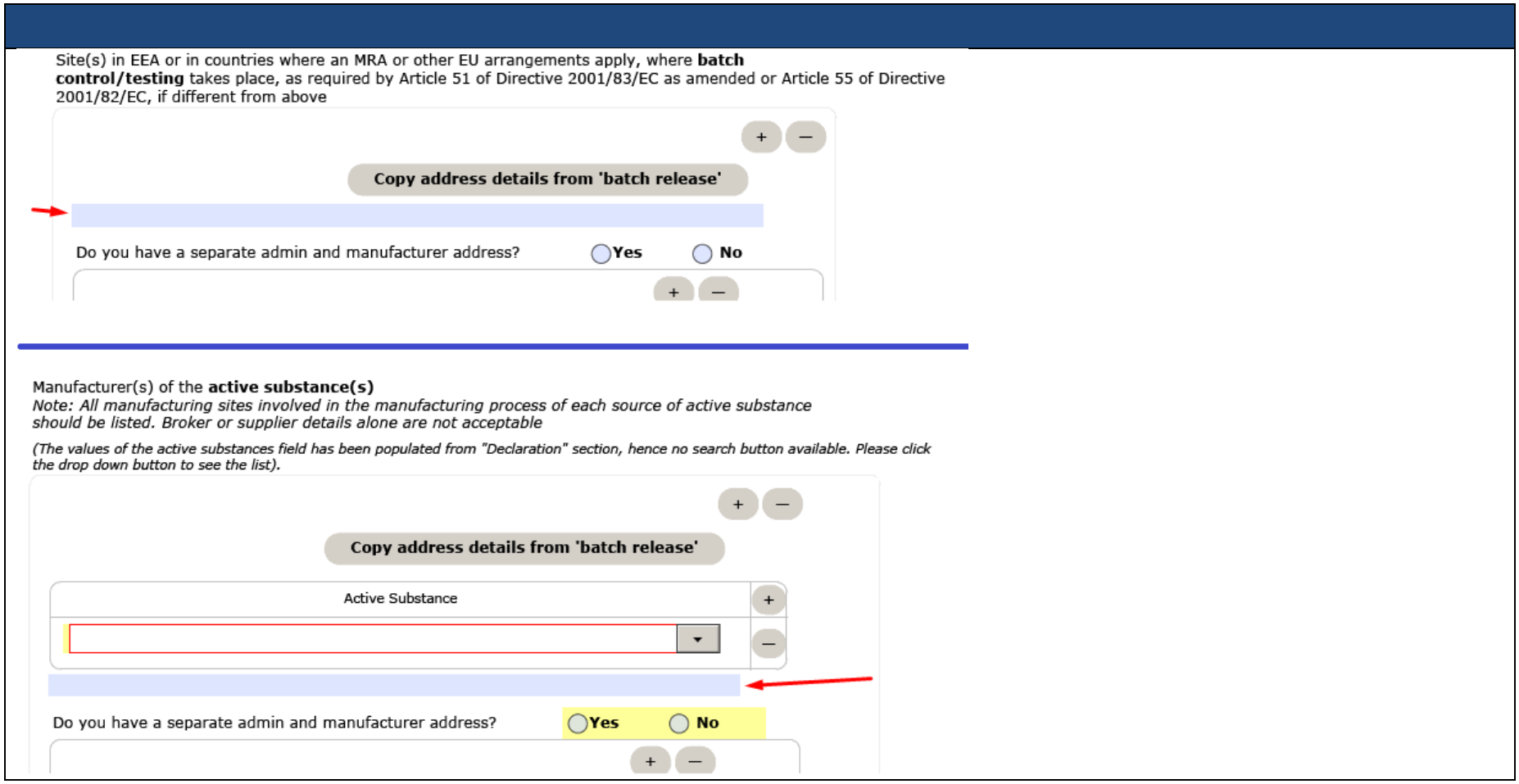
Variations included in this application: Please follow instructions below to add va
To add a variation Item, Click Show All Types and select check boxes for the items have been selected click Show only Selected.

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).



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 .