

Variations Checklist

To be attached to the application/worksheet by Info Man for completion by Validators.

Application number:

Check Points:

- Application form completed correctly
- UK annex form submitted and completed
- If extension, check that they have declared that it is to be rolled back *(on UK Annex)*
- If worksharing, check #270666 for CMDv notification
- For grouped variation, are stem numbers same?
- If grouped variation, is it in accordance with Annex III, 1234/2008
- Stem number: _____
- Other concurrent applications checked *(renewals, other variations)*

- Indicated request for Partnership Initiative? YES:
NO:
- **IF NO:**
Suitable for Partnership Initiative? YES:
NO:
- **IF YES:**
Contacted applicant to enquire if they would like to use Partnership Initiative?
- Completed Partnership Initiatives spreadsheet? DM5 #250186

- Conditions met in accordance with Notice to Applicants (NtA)
- Relevant documents supplied in accordance with NtA
- Expert report (Type II only)
- CV of expert (Type II only)
- No data. Signed statement cross referring to previously submitted data or letter of access submitted

- Active Substance Master File (ASMF) *(open part in application is same version as manufacturers' parts)*
- ASMF number: _____
- ASMF location *(registry or assessor office)* _____

- Reduced fee? *(i.e. copycats and identical data)*
- Completed reduced fee spreadsheet DM5 # 225458

- Co-ordinator allocated *(Not applicable for ATC variations)*

- Deferred(see LMS notes)

Outcome:

- Pass
- Fail
- Withdrawn
- Approved (Type IAs only)
- Rejected (Type IAs only)

Data and file marked forward to: _____

<u>Admin Info:</u>	
Harmonised product that affects the SPC?	<input type="checkbox"/>
Have they stated they DO NOT want Joint Labelling?	YES: <input type="checkbox"/> NO: <input type="checkbox"/>
Type IA – does the change affect the memo and LMS?	YES: <input type="checkbox"/> NO: <input type="checkbox"/>
Partnership Initiative	YES: <input type="checkbox"/> NO: <input type="checkbox"/>