APPENDIX 18 *CONFIRMATION OF QUALITY DOSSIERS WITH REFERENCE AGENCY'S APPROVAL*

The information requested in the Dossier Clarification Supplement ('supplement') in Appendix 18A serves to complement the technical dossier submitted in support of a NDA or GDA submitted via the abridged evaluation route. This will enable HSA to better leverage the assessment done by our reference agencies and optimises the regulatory review process.

Please complete and submit the supplement if your application fulfils all of the following:

- The registration application is for a NDA (chemical or biologic) or GDA;
- The application is submitted via the abridged evaluation route; and
- Approval has been obtained from at least one of HSA's reference agencies (EMA[1], FDA, Health Canada, MHRA[2], Swissmedic and TGA) not more than 5 years before the date of submission to HSA.

For products approved by more than one of HSA's reference agencies, you may confirm the CMC aspects against one of the reference agencies which has approved the same quality aspects (i.e. drug substance/ drug product manufacturing sites, drug substance/ drug product manufacturing process, drug substance/ drug product specifications, drug substance/ drug product container closure system and retest period/ shelf life) as proposed for registration in Singapore. This agency is referred to as the 'specified reference agency'.

If you are able to confirm that the CMC aspects proposed for registration in Singapore are the same as those approved by the specified reference agency, please indicate by checking the relevant checkboxes. If there are any differences concerning the CMC aspects listed in sections 3(a) and 3(b), please state these differences in section 3(c).

If you are unable to confirm whether the quality aspects proposed for registration in Singapore are the same as those approved by any reference agency, please indicate by checking checkbox (c) in Section 1.

[1] For products approved via the Centralised Procedure
[2] For products approved via the national procedure or where MHRA acted as the RMS for the MRP or Decentralised Procedures on or prior to 31 January 2020 when the UK has formally left the European Union

The supplement must be signed by a person who is authorised by the applicant (i.e. the company seeking product registration) to provide such confirmation on behalf of the company. Please submit the completed document in PRISM under 'Other Supporting Documents'.

REVISION HISTORY

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