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Question & Answer

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QUESTION

Could you please confirm that when a new working seed is established only a notification is necessary or if this is not the case what variation category would be required? There is no change in the manufacturing process. A new working seed based on the approved master seed and seed lot system is produced and tested as described in the marketing authorization dossier.

ANSWER

It is indicated in Annex I, Title II of Directive 2001/82/EC as amended that, whenever possible, production of a vaccine shall be based on a seed lot system which is established at the manufacturers. When necessary, a working seed is derived from the master seed and is used as starting micro-organism/cell to produce the final vaccine.

Production and testing of master seed and working seed are described in the marketing authorisation dossier. For the master seed a manufacturing record and the test results are presented. A protocol of manufacturing and testing is also provided for a working seed.

A new working seed must be established from time to time as they do not last indefinitely. Production of new working seeds are performed on a routine basis and do not impact on the final product. Provided production and tests performed do not change with respect to the procedures, techniques and specifications defined in the dossier, the change of a working seed does not require a variation and can be handled as a notification, if required.

The protocols of production and testing of a new working seed are necessary to ensure a consistent batch testing and release procedure by the competent OMCL. Therefore, these protocols should be submitted for batch release of the first batch manufactured from the new working seed, if required by an OMCL/Member State. However, if there are any changes compared to the production and testing methods as described in the dossier arising from the establishment of a new working seed, these should be communicated via a variation procedure.

To summarize, a routine change in a working seed which does not change any of the specifications of the final product may be dealt with as a notification, if required, and no data are to be provided during the notification process. Member States that request the protocols of a new working seed for batch release will ask the marketing authorisation holder to submit this information in the submission for official batch release of the first batch using the new working seed in the respective countries.