PRESS RELEASE

PROCEDURE FOR AUDIT POSTPONEMENT AND REMOTE AUDITS OF PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 7 April 2020

In response to the COVID-19 pandemic and following their position paper of 24 March 2020, EXCiPACT asbl has issued a new procedure for audit postponement and the use of remote audits of pharmaceutical excipients suppliers.

The procedure is published as an Annex to the 2017 edition of the "EXCiPACT Certification Standards for Pharmaceutical Excipient Suppliers" and can be downloaded from the Homepage of their website www.excipact.org .

It affects only those Pharmaceutical Excipient manufacturers and distributors who are already EXCiPACT certified. Re-certification or surveillance audits may be impossible due to the strict travel ban and safety rules in place affecting both Certification Body auditors and staff from Excipient manufacturers and distributors to help them to remain or renew their certification.

The procedure describes alternative options to maintain or to renew the Certification of Pharmaceutical Excipient manufacturers and distributors. It indicates the conditions and time-periods which are acceptable to postpone a re-certification or surveillance audit or to replace it by a remote audit. It has been communicated to each EXCiPACT Registered Certification Body for implementation in their internal procedures.

These new audit requirements shall remain valid while the COVID-19 pandemic containment measures are in place in the affected world regions and until local regulation travel restrictions are suspended, and that physical (on-site) audits return to normal.

EXCiPACT Certification audits (i.e. those required for a first certificate) are out of scope of this procedure.

Notes for the Editor

EXCiPACT asbl provides management oversight for the voluntary, independent, high quality international EXCiPACT Certification Scheme that provides for independent third-party GMP and/or GDP certification of manufacturers, suppliers and distributors of pharmaceutical excipients worldwide. The Scheme ensures patient safety through supplier quality while minimising the overall costs for assessing the excipient supply chain. It has been operational since early 2013 since when there has been considerable interest among pharmaceutical excipient suppliers, their customers and regulators. For further information see www.excipact.org or contact info@excipact.org