



EXCiPACT Position Paper

Excipient manufacturer and distributor certification with regards to the COVID-19 outbreak

Brussels, March 2, 2020

This position paper indicates how EXCiPACT-Registered Certification Bodies can address some of the impacts arising from the current coronavirus crisis.

Since the beginning of 2020, a global infection risk was detected, caused by a new coronavirus called COVID-19. The infection is now impacting all five continents and has caused thousands of deaths. In order to mitigate the further spread of the virus, some governments are imposing travel restrictions and making recommendations to limit travel to when it is only absolutely necessary.

As far as the EXCiPACT Certification Scheme is concerned, some surveillance audits and re-certification audits may have been planned in some of the regions where a travel restriction is in place or has been recommended by National authorities. In such cases, EXCiPACT asbl will allow EXCiPACT-Registered Certification Bodies to postpone any affected audit by up to 3-Months without jeopardizing the current certification status.

If such exception is required, the Certification Body must inform EXCiPACT asbl administration (info@excipact.org) if a surveillance or re-certification audit is postponed and give an indication of the revised audit date.

If the 3-months allowance period must be further extended, the decision to maintain the EXCiPACT Certification status must be taken on case by case basis by direct communication between the Certification Body and EXCiPACT asbl.

This is a rapidly evolving situation and EXCiPACT asbl will update this position paper and republish it on our website as necessary.

A handwritten signature in black ink, appearing to read "Iain Moore".

Iain MOORE
President, EXCiPACT asbl

A handwritten signature in black ink, appearing to read "A. Bécart".

ALAIN BÉCART
Quality MANAGER, EXCiPACT ASBL