



EXCiPACT Position Paper

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

Brussels, March 24th, 2020

This document updates the position paper issued on 2nd March 2020. ([Download](#))

Developments in the battle against COVID-19 have intensified rapidly. Recent epidemiological data has indicated the fight will last for some considerable time, especially in Europe. In light of this situation EXCiPACT has agreed to extend the postponement interval from 3 months to **6 months** for a scheduled audit which is affected by the travel ban and other restrictions. This brings the EXCiPACT Certification Scheme fully into line with the IAF ID3 Guidance¹ on dealing with extraordinary circumstances that may affect certification activities.

As mentioned in the original paper, 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.

EXCiPACT is working with Certification Bodies and its members to identify what steps could be taken to continue the Certification Scheme should the 6-month delay in scheduled audits be insufficient. Certification Bodies are also evaluating their options for ISO Certificate audits, including how modern technology can be used to conduct an audit with the auditor located off-site.

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 blue ink, appearing to read 'Iain Moore'.

Iain MOORE
President, EXCiPACT asbl

A handwritten signature in blue ink, appearing to read 'Alain Bécart'.

ALAIN BÉCART
Quality MANAGER, EXCiPACT ASBL

¹ International Accreditation Forum (IAF) Informative Document for Management of Extraordinary Events or Circumstances Affecting Accreditation Bodies, Certifying [Assessment] Bodies and Certified Organisations (IAF ID3 2011)