

January 9<sup>th</sup> 2021

### **IPFA position on acceptance criteria for Covid-19 vaccinated donors**

In anticipation of the regulatory approval for use of a number of Covid-19 vaccines and the commencement of national mass vaccination programmes the European Centre for Disease Prevention and Control (ECDC) has published its updated technical guidance - Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA - second update.

The guidance in respect of donor deferral following vaccination recommends:

- A minimum deferral of 4 weeks for investigational vaccines (clinical trials) of any type
- No deferral period for mRNA or protein vaccines
- A minimum of 4 weeks for viral vector-type vaccines when considered “attenuated virus” (as per Directive 2004/33).

<https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-supply-substances-human-origin-second-update.pdf>

On Dec 12th, 2020, the PEI published its recommendation concerning post vaccination donor deferral in line with the above stating that:

*“On the basis of the current state of knowledge, no donor deferral is required after vaccination with the SARS-CoV-2 vaccines under approval, which contain inactivated viruses or non-infectious virus components such as mRNA. All other default criteria set out in the Hemotherapy Directive remain fully applicable.”*

(in German: <https://www.pei.de/EN/medicine-safety/haemovigilance/guidelines/guidelines-node.html;jsessionid=12DF32D0B1D6547F1004A53F0749348D.intranet211> )

IPFA further understands that the US FDA responded to AABB and ARC that there is no requirement for deferral of donors vaccinated with either the Moderna or Pfizer Covid-19 vaccines (mRNA vaccine). and offered that a 14-day deferral is reasonable following a live-attenuated vaccine in any).

**Whilst IPFA strongly supports the above current recommendations it is also important to recognise the impact on the global blood and plasma supply of the Covid pandemic and accordingly advocates caution in the development of any future regulatory actions, based on the precautionary principle, concerning donor deferral which may further worsen plasma collection and consequently Plasma derived medicinal products supply.**