

Response to consultation paper: Biovigilance responsibilities of sponsors of biologicals

I note that the paper treats biologicals more like devices than medicines including identifying serious threats to public health and near serious adverse events and proposing reporting timelines of

- 48 hours for serious threats to public health
- 10 days for serious adverse events
- 30 days for near serious adverse events

Current post-marketing PV guidelines for medicines have a

- 72 hour reporting time frame for significant safety issues
- 15 day time frame for serious adverse events

I suggest that the reporting time frame for biologicals be kept the same as for medicines i.e. 72 hours and 15 days. My understanding is that in the EU that there are no plans to make the reporting timeframes for biologicals different to those for medicines as in the recent update there was no change to reporting timelines (P II B2) (see link below)

[EMA](#)

*Product- or population specific considerations II: Biological medicinal products*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2016/08/WC500211728.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/08/WC500211728.pdf)

I also note that while reference is made in the consultation paper to reporting in special situations for SAS and Authorised Prescriber (see section 10) the reporting requirement and time frames for biologicals are not specified within the SAS or Authorised Prescriber guidelines. Is the plan to keep the requirements for biologicals consistent with those for medicines and devices?

A minor point to note in Section 6 is that 2 slightly references are made to reports from the world-wide literature i.e. 'reports in the world-wide scientific and medical literature' and 'reports in world-wide literature of adverse reactions that occurred in Australia'. It should be made clear that only 'literature reports of adverse reactions that occurred in Australia' will be required consistent with the similar requirement for medicines.