Appendix 5: Definitions related to conformity assessment

The relevant definitions in the European Regulations, which relate to conformity assessment, were reviewed and compared to the definitions in the Australian Regulations. Where there are mismatches or an absence of a comparable definition, a proposal, with a justification, is provided below. Where the term is mentioned in the Australian Regulations, and the general meaning is well understood in the Australian context, and therefore there does not appear to be a necessity to explicitly define the terms, they have not been included as part of the consultation. Additional definitions that relate to other parts of the Australian Regulations will be included in upcoming consultations.

EU Regulation	Australian definition	Proposal for amendments
'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, **in the context of a clinical investigation, whether or not related to the investigational device.**	No equivalent definition. However, the term is mentioned in the Regulations.	**Propose to adopt the intent of this definition with modification.** Justification: Whilst the term 'adverse event' in its general meaning is understood in the Australian context, there is sometimes confusion about when an incident relating to a medical device is considered an 'adverse event'. We propose that the latter part of the EU definition (in bold) not be included as those terms are not used in the Australian context.
'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.	No equivalent definition. The term 'post-market surveillance' is referred to in the Regulations in the Requirements for Australian conformity assessment bodies. Here the term is equated to the post-marketing requirements in Schedule 3 of the Regulations.	**Propose to adopt the intent of this definition with modification.** Justification: Whilst the term 'post-market surveillance' in its general meaning may be understood in the Australian context, defining it will aid in providing further clarity on the post-market requirements of manufacturers. Modifications will be needed to remove reference to 'other economic operators' as this is not a term used in the Australian Regulations.
'Information society service' means any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services	No equivalent definition.	**Propose to adopt the intent of this definition.** Justification: This is a new feature in the European Regulations which clarifies the regulation of direct to consumer testing over the internet and other services provided by electronic means which are more difficult to

		categorise under the Australian Regulations.