ANNEXES

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 78 to 81 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1. The post-market surveillance plan drawn up in accordance with Article 79.

The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 78.

(a) The post-market surveillance plan shall address the collection and utilisation of available information, in particular:
- information concerning serious incidents, including information from PSURs, and field safety corrective actions,
- records referring to non-serious incidents and data on any undesirable side-effects,
- information from trend reporting,
- relevant specialist or technical literature, databases and/or registers,
- information, including feedbacks and complaints, provided by users, distributors and importers, and
- publicly-available information about similar medical devices.

(b) The post-market surveillance plan shall cover at least:
- a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;
- effective and appropriate methods and processes to assess the collected data;
- suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;
- effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;
- **[**[X1]methods and protocols to manage the incidents subject to the trend report as provided for in Article 83, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;**]**
- methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
- reference to procedures to fulfil the manufacturers obligations laid down in Articles 78, 79 and 81;

— systematic procedures to identify and initiate appropriate measures including corrective actions;

— effective tools to trace and identify devices for which corrective actions might be necessary; and

— a PMPF plan as referred to in Part B of Annex XIII, or a justification as to why a PMPF is not applicable.

Editorial Information

X1 Substituted by Corrigendum to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Official Journal of the European Union L 117 of 5 May 2017).

2. The PSUR referred to in Article 81 and the post-market surveillance report referred to in Article 80.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, ANNEX III.