Supplementary Table 2. Legislation for post-market surveillance

|  |  |  |
| --- | --- | --- |
| **No.** | **Country/Region, document and release date** | **Post-market surveillance activities** |
| 1. | European UnionMedical Devices Regulation (MDR) (Regulation (EU) 2017/745) / Release date: May 2017 [38] | * **Medical device registry**

According to *Articles 28 and 29* of the MDR, each medical device produced must be registered in the Unique Device Identification (UDI) database. The UDI database ensures maximum availability of information regarding medical devices to all users of the database [38]. * **Adverse event reporting**

According to the MDR, sponsors should report certain adverse events and device deficiencies that occur during clinical investigations to the Member States in which those clinical investigations are being conducted and submit the reports to EUDAMED database. * **Medical device performance evaluation**

*Article 106* of the MDR on *Provision of scientific, technical and clinical opinions and advice* deems necessary to develop performance evaluation guidance for performance of conformity assessment in line with the state of the art with regard to clinical evaluation, performance evaluation, physico-chemical characterisation, and microbiological, biocompatibility, mechanical, electrical, electronic or nonclinical toxicological testing. * **Medical device classification**
* Class I - lowest risk
* Class IIa - low risk
* Class IIb - medium to high risk medical devices intended for long term use
* Class III - highest risk
 |
| 2. | United States of AmericaFederal Food, Drug, and Cosmetic Act, Section 522 [40]; | * **Medical device registry**

Medical device registries are not defined by this act, but by *Title 21 of the Code of Federal Regulation* [39] that requires each medical device to have its own UDI. * **Adverse event reporting**

Adverse event reporting is regulated by *Title 21 of the Code of Federal Regulation, section 803* that requires manufacturers, importers, and device user facilities to report device-related adverse events* **Medical device performance evaluation**

Performance evaluation procedure for post-market surveillance of medical devices is regulated by *Federal Food, Drug, and Cosmetic Act, Section 522*. Post-market surveillance is performed by the device manufacturer if the medical device is classified as:* Class II or III device that could cause serious adverse health consequences in case of failure.
* Class II or III device with widespread use in pediatrics.
* Class II or III device that is intended to be implanted in humans for longer than one year.
* Class II or III device that is intended for life-sustaining or life-saving use outside of medical facilities.

 * **Classification of Medical devices in the US:**
* Class I – Low risk (bandages, medical gloves, crutches, etc)
* Class II – Medium Risk (blood pressure monitors, surgical needles, surgical drapes, nebulizers, X-ray machines, etc.)
* Class III – High Risk (heart pacemakers, intra-aortic balloons, silicone gel-filled breast implants, automated external defibrillators, HIV diagnostic kits, etc.)
 |
| 3. | People's Republic of ChinaSupervision and Administration of Medical Devices as State Council Order Number 739 [68] | * **Medical device registry**

*Decree 4 CFDA from 2014* [41] regulates the registration process for medical devices and establishes a medical device registry. Additionally, *Order 739* [42], requires assigning a UDI to every medical device manufactured. * **Adverse event reporting**

In May of 2020, the NMPA issued an updated version of guidelines for adverse event reporting. These guidelines require medical professionals to report all adverse events that could have potentially lead to patient harm within 5 days of their occurence [41]. * **Medical device performance evaluation**

With the aim of making post-market surveillance more efficient, NMPA has expanded the inspection of medical devices to corresponding personnel and third parties when necessary, according to *Article 68 of Order 739* [68].* **Medical devices in China are categorized into three classes:**
* China Medical Device Class I – medical devices for which routine administration is adequate for safety and effectiveness.
* China Medical Device Class II – medical devices for which further control is required to ensure safety and effectiveness.
* China Medical Device Class III – medical devices with life support, and sustenance functions, including those pose a potential threat to patients’ health or are implanted into the human body.
 |
| 4. | JapanPharmaceuticals and Medical Devices Act (PMD Act) of November 2015 [43] | * **Medical device registry**

The PMDA in Japan requires all medical devices to be registered in PMDA database prior to marketing [43]. * **Adverse event reporting**

*Act 60.10 of Ministerial Ordinance No. 169* [44]regulates adverse event reporting by stipulating the obligation of medical device manufacturers and healthcare workers to report adverse events and initiate corrective actions. * **Medical device performance evaluation**

According to the *PMD Act of November 2015* [43]*,* an accredited certification body is to establish the rulebase for product inspection and apply for licencing. After obtaining the licence, the accredited body can perform third party performance evaluation. According to *Act 60 of Ministerial Ordinance No. 169* [37]*,* the manufacturer is obliged to perform corrective actions upon devices that do not pass conformity assessment. * **Medical device categories:**
* Class I - extremely low risk medical devices
* Class II - low risk medical devices
* Class III - medium risk medical devices
* Class IV - high risk medical devices
 |
| 5. | AustraliaChapter 4 of the Therapeutic Goods Act (TGA) 1989 [38], and the Therapeutic Goods (Medical Devices) Regulations 2002; last updated 23 July 2021[46] | * **Medical device registry**

According to *TGA*, all medical devices must be registered in the *Australian Register of Therapeutic Goods (ARTG)* [45]*.** **Adverse event reporting**

*Chapter 5.7 of TGA* [45]reqiures distributors or users of medical devices to report adverse events or near adverse events to the TGA Incident Reporting and Investigation Scheme (IRIS).* **Medical device performance evaluation**

With the aim of ensuring medical device safety, post-market clinical follow-up studies are required by the *TGA*. A PMCF study is a study carried out following marketing authorisation to answer specific questions (uncertainties) relating to safety, clinical performance and/or effectiveness of a device when used in accordance with its labelling* **Medical device classification**

Classification of medical devices by the *TGA* is almost identical to the classification in the EU.  |
| 6. | United KingdomUK Medical Devices Regulation (UK MDR) 2002 - Section 48: Post-market surveillance [40]  | * **Medical device registry**

UK MDR 2002 requires manufacturers to register medical devices with the *Medicines and Healthcare products Regulatory Agency* [47]. The data from the registries is used to strengthen post-market surveillance.* **Adverse event reporting**

*Article 50.2 of the UK MDR* [47]*,* requires reporting of adverse events regardless of their severity to the MHRA with an aim of enhancing the MHRA’s ability to identify MD issues and taking appropriate corrective actions. According to *Article 51.2* [47]*,* manufacturers are obliged to submit field safety notices (FSNs) to help ensure consistency of reporting across the country. * **Medical device performance evaluation**

*Article 48* [47]defines the necessity of post-market performance follow-up (PMPF) for IVD medical devices with an aim of continuous monitoring of MDs. This would enable proactive collection and evaluation of performance and relevant scientific data from the used IVD and estimation of the expected lifetime.* **Medical device classification**
* Class I - generally regarded as low risk
* Class IIa - generally regarded as medium risk
* Class IIb - generally regarded as medium risk
* Class III - generally regarded as high risk
 |
| 7. | SwitzerlandMedical Device Ordinance (MedDO) /  August 2020 [48] | * **Medical device registry**

MedDO requires all medical devices to be assigned with a UDI. Switzerland MD registration procedure is in accordance with EU registration procedure [48]. * **Adverse event reporting**

Medical device manufacturers in Switzerland are obliged to report adverse events to Swissmedic in accordance with the *EU MDR* [38]. * **Medical device performance evaluation**

Performance evaluation of MDs in Switzerland is done in accordance with the *EU MDR* [38]*.* |

Supplementary Table 1. List of reviewed journal articles

|  |  |  |  |
| --- | --- | --- | --- |
| **Ref.****No.** | **Ref.** | **Topic** | **Category** |
| 1. | [35] | Establishing a National Medical Device Registry in Saudi Arabia: Lessons Learned and Future Work | Medical device registry |
| 2. | [36] | Research methodology and practical issues relating to the conduct of a medical device registry |
| 3. | [37] | Informed consent and compulsory medical device registries: ethics and opportunities |
| 4. | [52] | Implementing the new European Regulations on medical devices-clinical responsibilities for evidence-based practice: a report from the Regulatory Affairs Committee of the European Society of Cardiology | Adverse event reporting |
| 5. | [53] | Regulation and safe adoption of new medical devices and procedures |
| 6. | [54] | Reporter's occupation and source of adverse device event reports contained in the FDA's MAUDE database |
| 7. | [55] | The data extraction and longitudinal trend analysis network study of distributed automated postmarket cardiovascular device safety surveillance | Performance evaluation |
| 8. | [56] | Post-market clinical research conducted by medical device manufacturers: a cross-sectional survey |
| 9. | [57] | Improving the Methods for the Economic Evaluation of Medical Devices  |
| 10. | [58] | Security and privacy qualities of medical devices: an analysis of FDA postmarket surveillance |
| 11. | [59] | Testing of mechanical ventilators and infant incubators in healthcare institutions  |
| 12. | [60] | Testing of anesthesia machines and defibrillators in healthcare institutions in Bosnia and Herzegovina  |
| 13. | [69] | The current situation and development of medical device testing institutes in China |
| 14. | [75] | Prediction of medical device performance using machine learning techniques: infant incubator case study |
| 15. | [80] | Testing of therapeutic ultrasound in healthcare institutions in Bosnia and Herzegovina |
| 16. | [84] | EU post-market surveillance plans for medical devices.  |
| 17. | [85] | Improved clinical investigation and evaluation of high-risk medical devices: the rationale and objectives of CORE-MD (Coordinating Research and Evidence for Medical Devices)  |
| 18. | [86] | A Comprehensive Analysis of Postmarket Surveillance Study Orders: Device Characteristics, Study Statuses, Outcomes, and Potential Contributions  |
| 19. | [87] | Model competencies in regulatory therapeutic product assessment: Health Canada's good review guiding principles as a reviewing community's code of intellectual conduct |
| 20. | [88] | An example of US Food and Drug Administration device regulation: medical devices indicated for use in acute ischemic stroke  |
| 21 | [89] | Post-marketing surveillance and vigilance for medical devices: the European approach  |
| 22. | [90] | Approval of high-risk medical devices in the US: implications for clinical cardiology  |
| 23. | [91] | Post-market clinical research conducted by medical device manufacturers: a cross-sectional survey  |