Q1. How does the TFDA become aware of international medical device safety vigilance information?

A：In order to ensure the safety of medical devices marketed in Taiwan, the TFDA proactively monitors international medical device recalls issued by major health authorities overseas (including the US FDA, Health Canada, the UK's MHRA, Switzerland's Swissmedic, Japan PMDA, Australia TGA, etc.), as well as news covered by domestic and international media regarding medical device safety issues. The TFDA will immediately check to make sure if there are medical devices affected within its jurisdiction and take responsive measures in order to safeguard the medical device users in Taiwan.

Q2. Is there a legal basis for the TFDA to post summaries of international medical device vigilance information or send notices to medical institutions?

A：Article 37 of the Consumer Protection Act stipulates that, “If the municipal governments or the county (city) governments believe that goods or services provided by traders have caused or will cause material injuries or damages to consumers, and the situation is an emergency, then in addition to the actions to be taken pursuant to the preceding article, that governments shall publicize their names, addresses, goods or services through the mass media, or take other necessary actions.” In addition, based on Article 38 of the Consumer Protection Act, “If the central competent authority believes it necessary, the actions set forth in the preceding five Articles may also be taken.” According to applicable requirements of the Consumer Protection Act as mentioned above, the TFDA, to protect the safety of the general public in their use of medical devices, posts relevant international medical device safety vigilance information on TFDA official website (TFDA website homepage > business area > notification and safety monitoring > medical devices zone > safety and quality alerts) as soon as it is received, so that the general public would be promptly aware of information regarding medical device hazards.

Q3. What is the international safety information of medical device vigilance?

A：Upon investigating or receiving a manufacturer's report, a foreign health authority analyzes/evaluates the international safety information of medical device vigilance according to product hazards that have occurred or have not yet occurred and classifies/categorizes them according to risk. The content of the vigilance information usually involves a product recall or safety alert that provides advice about a marketed medical device (e.g., a system that has not been updated may inadvertently trigger an alarm, a battery may leak electricity, etc.). Through posting the announcement of product vigilance information on the official website of a foreign health authority, users within such authority's jurisdiction are informed of the product's potential health hazards, and actual occurrence of hazardous events can therefore be prevented.

For each class of recalls posted by the US FDA, its content includes removals from product channel, corrective/preventive measures, and so forth. In terms of correction and prevention, actions taken would include investigation of product issues, product modification issues, re-labeling of product information, and informing users of product issues, which are slightly different from the "recalls" as defined under Taiwan's domestic laws and regulations.

The US FDA has defined its classification of recalls as follows (website link：https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall)：

Class I recall：A situation where there is a reasonable chance that a product will cause serious health problems or death.

Class II recall：A situation where a product may cause a temporary or

reversible health problem or where there is a slight chance that it will cause serious health problems or death.

Class III recall：A situation where a product is not likely to cause any health problem or injury.

Medical device safety communication：A message or a letter that describes US FDA's analysis of a current issue and provides specific regulatory approaches and clinical recommendations for patient management.

Q4. Which international medical device recalls get posted on the TFDA website?

After investigation of the international medical device recalls mentioned below reveals that there might be domestic holders of related medical device licenses, the TFDA will request license holders to provide a Chinese translation summary for the product involved in the vigilance.

1. Class I medical device recalls announced by health authorities of any jurisdiction.
2. Medical device recalls issued by health authorities of any jurisdiction that involve product removals, or which are medical device recalls voluntarily reported by license holders and received by the TFDA, once such recalls are investigated and evaluated, recall actions must also be initiated for domestic medical devices.
3. Major safety information on vigilance of specific medical devices.
4. News events concerning domestic and international medical device safety issues.

Q5. What are domestically affected medical devices in an international medical device recall?

As long as the following principles are fulfilled, regardless of whether products within the approval scope of a specific medical device license have been marketed or the hazards indicated in an international recall have not yet occurred, this would constitute the so-called “domestically affected medical devices.”

1. Medical devices whose model numbers, specifications or specific lot numbers are included in the medical device license, as mentioned in an international recall and have been imported into Taiwan.
2. Products included in a medical device license held by the medical device firm that may be affected by an international recall, as determined by the TFDA.

Q6. In the event that a medical device license holder receives notice from TFDA's commissioned organization regarding a medical device recall, how should they reply?

In order to expedite the medical device recall process and shorten the required time for a manufacturer to reply, as with any medical device recall, once a potentially related medical device license in Taiwan is found, TFDA's commissioned organization will notify the license holder to log into the post market quality management system for medicinal products, medical devices, foods, and cosmetics to reply regarding the contents of the recall. For those who wish to apply for a system account, please refer to the TFDA website (www.fda.gov.tw/TC/siteList.aspx?sid=4273) for details.

Q7. If a medical device firm that holds a license fails to respond to a medical device recall upon receipt of an official notice, will it be punished?

According to Article 49 of the Medical Devices Act, upon the finding that a medical device is likely to cause harm to the health of human body, the holders of the medical device license or those who have completed the listing shall immediately and proactively report to the central competent authority and undertake corrective and preventive measures. Based on the same Act's Article 71, Paragraph 7, those who fail to conduct reporting or undertake corrective and preventive measures in accordance with the provisions shall be imposed a fine of not less than NT$20,000 but not more than NT$500,000.

When necessary, the TFDA may further activate the re-evaluation mechanism for medical device safety in accordance with Article 50 of the Medical Devices Act, mandate medical device firms holding the license of such product to make corrections within a time period. For those who fail to make corrections within a time period or if there is a serious safety concern, their licenses or listings may be cancelled.