APACMED POSITION PAPER ON

UNIQUE DEVICE IDENTIFIER (UDI) FOR MEDICAL DEVICES IN INDIA

Indian Medical Device industry have flourished over the years imbibing various positive changes and will continue to do. The Medical Device Rules, (2017) is another major step forward in this regard, under which, implementation of Unique Device Identifiers (UDI) for traceability of medical devices is also provisioned for. APACMed commends this initiative by government of India which will act as a key towards a single, globally harmonized identification system for medical devices in India.

The development and implementation of the UDI System are widely acknowledged globally as an effective means of ensuring timely access to complete, accurate and consistent information about medical devices which will help prevent ambiguity. The demand for improved traceability of medical devices in the supply chain is also growing and there is now a worldwide recognition that, in the interest of improved industry outcomes, the ability to unambiguously identify medical devices is essential.

Moreover, supply chain and patient safety issues are of utmost concern in the rapidly evolving healthcare sector. With a range of medical devices available in the market, traceability becomes a major issue resulting in improper product recalls, incomplete adverse event reporting, and counterfeit products. Therefore, medical device traceability is essential to ensure effective post-market safety-related activities in a globalised economy.

However, in the recent deliberations among the industry associations related to this, it have been highlighted that although the implementation of UDI for medical devices is indispensable and is a welcome move, there are certain concerns erupting from this which needs to be given heed.

In this regard, the Asia Pacific Medical Technology Association (APACMed) would like to highlight the following:

- There is no denying that COVID -19 has taken a toll on every industry and medical device industry is no exception to that, and hence concerns were erupting regarding the implementation date of UDI, which was earlier finalized as 1st January 2022. However, it is unanimously felt among member companies that not only should the implementation date be deferred but also be carried out in a phased manner. Here lessons need to be learned from global regimes like in US who have also implemented UDI in a phased manner to ensure effective implementation.

- In this context, APACMed recommends implementation of UDI in a phased manner, as per IMDRF guidelines - **for Class A & B Devices by September 2022 and for Class C & D Devices from September 2023 onwards**. This recommendation is made in line with the implementation time lines of G.S.R 102 (E). Phased timelines based on risk-class should apply to data submission compliance dates in addition to labelling compliance dates.

- Keeping the above imperatives in mind, APACMed requests the Ministry of Health & Family Welfare, Government of India to issue an amendment to the implementation timelines extending it **from January 2022 to September 2022, for Class A & B Devices and September 2023 for Class C & D Devices.** Subsequently, it is requested that CDSCO issues the guidance document on UDI implementation and expectation by November 2020, so that industry can prepare accordingly.

The above suggestions by APACMed are being made keeping in mind the importance of UDI implementation in medical device industry and the need to make it globally harmonized especially in the changing scenario while appreciating Government of India's efforts in initiating this process in India. Moreover,

As a regional association for medical technology, APACMed with our regional expertise, would welcome an opportunity to partner and work with Ministry of Health & Family Welfare, and CDSCO to contribute towards developing the UDI Guidance and Regulatory Roadmap to ensure seamless implementation of UDI in our country.

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