New Guidance Released on Class B, C, and D Medical Devices in Vietnam

Hien Thi Thu Vu | Thomas J. Treutler
thuhien.v@tilleke.com | thomas.t@tilleke.com

Vietnam's Ministry of Health (MOH) has recently issued a very important notification and new regulations relating to the implementation of Decree No. 36/2017/ND-CP (Decree 36) on medical device management. The key notification was issued under Official Dispatch No. 7165/BYT-TB-CT dated December 14, 2017 (Dispatch 7165). The new implementing guidelines for Decree 36 were issued under Circular No. 46/2017/TT-BYT dated December 15, 2017 (Circular 46). These developments are crucial to the registration regime for medical devices in Vietnam.

Dispatch 7165

While not relating to Class A medical devices (which include, for example bandages, wheelchairs, reusable surgical instruments, medical gloves, etc.), Dispatch 7165 provides specific guidance on Class B, C, and D devices, as well as in vitro diagnostic (IVD) biologicals. Class B medical devices include items such as blood centrifuges, diagnostic ultrasound scanners, and infusion cannulas, while Class C medical devices include items such as diagnostic X-ray equipment, electrosurgical units, and urethral stents. Class D medical devices include items such as absorbable sutures, arterioscopes, implantable infusion pumps, dental implants, etc.

A marketing authorization (MA) license for Class B, C, and D medical devices will only be required from January 1, 2019 onwards. This means that the MA regime for Class B, C, and D medical devices will be delayed for one year from the original date set forth under Decree 36. This delay is likely spurred on due to the imminent delays in registering massive amounts of medical devices that have never been registered before, especially when infrastructure and proper resources need to be bolstered among the registration teams/office of the MOH to handle the huge workload. The early deadlines to register all devices were not practicable and were over-ambitious goals.

From now until January 1, 2019, some specific interim regulations set forth under the new Official Dispatch are as follows:

- Class B, C, and D medical devices which were included in the enclosed annex of Circular 30/2015/TT-BYT dated October 12, 2015 on promulgating the importation of medical devices (Circular 30) will continue to be governed by the regulations of Circular 30. This means the MOH is allowing these devices to be imported and circulated in Vietnam,

provided that these devices have import licenses as stipulated in Circular 30, and have been properly classified as Class B, C, or D medical devices by the authorized organizations.

- For Class B, C, and D medical devices which are not included in the enclosed annex of Circular 30, the MOH will allow these devices to be imported and circulated in Vietnam, provided that they have been properly classified as Class B, C, or D medical devices by the authorized organizations. For smooth customs clearance, in practice, these devices may also need a letter from the Department of Medical Equipment and Construction (DMEC) under the MOH to confirm that the imported medical devices are not included in the enclosed annex of Circular 30.

- The importation and circulation of IVD biologicals (e.g., microbiology reagents, histology reagents, etc.) require an MA license (as stipulated in Circular 44/2014/TT-BYT on drug registration) or an import license (as stipulated in Circular No. 47/2010/TT-BYT). IVD biologicals with MA licenses can be imported until the expiry date of their MA licenses. For IVD biologicals with import licenses that expire on December 31, 2017, their import licenses can be extended if the expiry date on their Letter of Authorization (LOA) remains valid after December 31, 2017 and the importer submits a written extension request for the import license to the DMEC, which will then review the request and approve the extension at its discretion.

Circular 46

Circular 46, which was just released, provides long-awaited implementing guidelines to Decree 36 and will enter into effect on February 1, 2018.

The Circular specifically states that Class C and D medical devices that are put into the human body are exempt from the requirement to submit summaries of clinical testing data and clinical testing research results. These medical devices include (1) medical devices in Annex I of the Circular (e.g., peritoneal dialysis catheters, cannulae, introducers, etc.), and (2) medical devices which are freely sold and have obtained certificates of free sale from a competent body of any of the countries and organizations which are set forth in Annex II of the Circular.

Class C or D IVD medical devices (e.g., HIV blood donor screening equipment, HIV blood diagnostic equipment, plasma bags, etc.) are also exempt from the requirement to submit test results if such medical devices have been freely sold and have obtained certificates of free sale from a competent body of any of the countries and organizations which are included in Annex II of the Circular. Annex II countries include Japan, Canada, the United States, and various European countries.

The Circular also includes a list (i.e., Annex III) of Class B, C, and D medical devices which may be traded like other normal goods, and imposes no requirements on the establishments trading them to declare their eligibility to trade in medical devices.

Additionally, the MOH issued guidance on presenting technical summaries, and requirements and terminology for Vietnamese to English translations for the LOA. A sample LOA is also promulgated under the Circular.

Technical summaries and English LOAs which were signed before the effective date of the Circular (February 1, 2018) will continue to be used; companies are not required to re-prepare these documents.

Hien Thi Thu Vu *is the Regulatory Affairs Manager at Tilleke & Gibbins in Vietnam. Hien, who has degrees in pharmacy and law, is also a registered patent attorney and member of the Hanoi Bar Association. She previously worked with Hoffman La Roche as a regulatory affairs team member, and has 15 years' experience in the legal field in regulatory affairs, patent litigation, and patent prosecution.*

Thomas J. Treutler *is Managing Director of Tilleke & Gibbins in Vietnam, and is a registered patent attorney and member of the California Bar Association. He has worked in Vietnam since 1993.*

Tilleke & Gibbins *has offices across Southeast Asia (Thailand, Vietnam, Indonesia, Cambodia, Myanmar and Laos), specializing in life sciences matters, and providing corporate, regulatory, and intellectual property services to major pharmaceutical companies. For further information, please contact Thomas at thomas.t@tilleke.com or Hien at thuhien.v@tilleke.com.*