

# Technical Update

November 2021



## 1. New regulations on management of medical devices ("MD")

On 8 November 2021, the Government enacted *Decree No. 98/2021/NĐ-CP* on management of medical devices ("**Decree 98**"). Decree 98 will come into effect on 1 January 2022 and replace *Decree No. 36/2016/NĐ-CP* dated 15 May 2016 (amended by *Decree No. 169/2018/NĐ-CP* and *Decree No. 03/2020/NĐ-CP*) ("**Decree 36**").

Some of the new highlights of Decree 98 are as follows:

- Amends the regulations on MD circulation by:
  - moving MD – Class B to the list of applicable standard declaration (along with MD – Class A) so that MD - Class B will no longer need to file its Certificate of Circulation Registration;
  - revising the validity of the MD's Certificate of Circulation Registration from five years to indefinite; and
  - providing express approval for MD – Classes C and D Certificate of Circulation Registrations within 10 working days on receipt by the Ministry of Health of a completed application dossier. This procedure will be applied where the MD has already been licensed for circulation in certain countries, such as United States of America, Canada, and Japan, or has been commercially circulated in Vietnam under the form of an Import License, circulation number, or Certificate of Circulation Registration.
- Extends the validity of the MD *Import License* until the end of 31 December 2022.
- Supplements the procedure for MD's price declaration to enhance its transparency in trading and bidding:
  - The price of MD must be declared before circulation in Vietnam and must be updated in case of price variation. The entity declaring the applicable standards (in the case of MD - Classes A and B) or holding the Certificate of Circulation Registration (in the case of MD - Classes C and D) ("**Marketing Authorization Holder**") is responsible for implementing or appointing a distributor to declare and update the MD price upon changes.
  - The MD tender winning price of public medical establishments must be publicized.
- Narrows down and simplifies some administrative procedures in the field of MD, for instance:
  - Classification of MD: The classification of MD will be carried out by the Marketing Authorization Holder and no longer by the MD classification establishments.
  - Advertisement of MD: It removes the procedures for confirming MD advertising contents. Instead, the Marketing Authorization Holder or an authorized organization will be responsible for publicly posting the intended content and the form of the advertisement on the MD management portal before implementing the advertisement.
  - Announcement of satisfaction of MD trading conditions: It simplifies the procedures for announcing the satisfaction of MD production, trading, and consultation for MD technique. Once the state management authority receives the dossier for declaration, it will publicize the dossier on the MD management portal without issuing a confirmation document, and the enterprise can immediately operate such activity upon submitting the dossier for declaration.
- Supplements the regulations on MD clinical study activities, including requirements for MD to be clinically studied, the clinical study facility, and the procedures for approval of a MD clinical study.

## **2. Draft Circular on guidelines for foreign exchange management in respect of foreign loan borrowing and repayment of the enterprises**

The State Bank of Vietnam ("SBV") is drafting and collecting opinions on a Circular to replace *Circular 03/2016/TT-NHNN* dated 26 February 2016 proving guidelines for some contents of foreign exchange management in respect of foreign loan borrowing and repayment of the enterprises (amended by *Circular 05/2016/TT-NHNN* and *Circular 05/2017/TT-NHNN*) ("Circular 03").

The draft Circular clarifies and supplements existing regulations on foreign loan borrowing and repayment to ensure consistency with other relevant legal documents (e.g. Circular No. 06/2019/TT-NHNN on foreign exchange management of foreign direct investment activities in Vietnam), notably as follows:

- Extends the deadline for the borrower to complete the payment of an overdue short-term loan from 10 days to 30 days commencing from the first anniversary of the initial capital drawdown. In this case, the short-term loan will not be given a renewal contract and requested to register with SBV.
- Supplements the subjects of registration of foreign loans and registration to amend foreign loans in respect of entrusting subject specifically defined in the re-lending entrust agreement between credit institutions, foreign bank branches and non-resident entrusting party.
- Expands cases where the registration to amend foreign loans are not required, including where the modification of an interest and fee payment plan does not result in changing the principle and method of determining interest and fee (i.e. the parties amend the deadline and repayment schedules but do not modify the total amount of interest and fees to be paid). In such cases, the borrower only needs to notify the SBV in writing within 30 days.
- Supplements and clarifies the regulations on the borrower's account for performing foreign loans:
  - Where the currency of the loan is different from the currency of the direct investment capital account ("DICA"), the borrower is permitted to open a foreign borrowing and foreign loan repayment account to implement the foreign loans at the bank where the borrower opened its DICA.
  - In order to repay the loan with an outstanding principal at the first anniversary of the initial capital drawdown which is considered as medium/long-term loan but not subject to loan registration, the borrower, being a foreign invested enterprise, is not required to use its DICA to repay debts.
  - In case the bank providing account services to borrower cannot provide the confirmation for the loan due to its termination of operation or such foreign loan withdrawal, repayment is not required to be conducted via the foreign borrowing and foreign loan repayment account, the borrower can provide other alternative documents to prove its foreign loan withdrawal, repayment status.
- Supplement the regulations related to the lender's account for performing foreign loans opened within the territory of Vietnam:
  - In respect of the lender's VND account: The lender of the VND loan of the microfinance project can opt to use VND account; the lender in other VND loans are required to open a VND account to perform related transactions.
  - In respect of the lender's foreign currency account: Where using a foreign currency account of non-residence opened at a commercial bank to perform foreign loan, the lender must comply with the provisions on foreign exchange restriction within the territory of Vietnam.
- Changes the frequency of the borrower's periodic reports on short, medium and long-term foreign loans from quarterly to monthly, in the form of an online report.

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