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New Decree on Administrative Penalties in Vietnam Healthcare Sector

Vietnam's efforts against the outbreak of COVID-19 in the country have been largely successful, and despite two distinct spikes of local transmission, in both cases the spread was halted relatively quickly. As these complications from the COVID-19 pandemic have been playing out in Vietnam throughout 2020, it became clear that effective and strong enforcement of healthcare regulations, especially those related to disease control, was crucial.

On September 28, 2020, the government of Vietnam took action on this by issuing Decree No. 117/2020/ND-CP ("Decree 117"), which provides penalties for administrative violations in the healthcare sector. Some provisions of Decree 117—mostly those related to disease control and epidemic situations—took effect immediately, with the remainder taking effect on November 15, 2020. The decree, which was based on a draft proposed by the Ministry of Health, replaced Decree No. 176/2013/ND-CP on the same matter.

Decree 117 sharply escalates the penalties for some violations that have been proliferating amid the COVID-19 pandemic, while some other penalties remain unchanged or are slightly amended.

The main administrative penalties under Decree 117 are reprimands and fines. Depending on the severity of the violation, violators may also be subject to additional penalties such as suspension of a certificate of eligibility for pharmaceutical business (CEPB), a license for healthcare operation, or other licenses and practicing certificates for up to 24 months; confiscation of illegal items; suspension of operations for up to 24 months; or deportation. Furthermore, remedial measures such as forced return of illegal earnings, compulsory quarantine and medical examination, public correction, or compulsory payment of treatment fees may also be applied.

Some key highlights of Decree 117 are discussed below.

- ▶ In relation to disease control, the maximum fine for failure to comply with quarantine is doubled to VND 20

million (USD 855) for infected people of type-A contagious diseases, and VND 10 million (USD 427) for those who are not infected but are asked to quarantine. Failure to declare one's contagious disease to a doctor could be subject to a fine up to VND 3 million (USD 130), which is 10 times higher than the penalty provided in the repealed decree. These penalties took effect on September 28, 2020.

- ▶ Exploiting an epidemic situation by price gouging of medicine or medical supplies is subject to a fine of up to VND 30 million (USD 1,300) for individuals or VND 60 million (USD 2,600) for companies and organizations. Violators may also be forced to suspend operations (which includes CEPB suspension for pharmaceutical business entities) for up to 24 months, and any illegal earnings will have to be returned to the buyers or sellers.
- ▶ The decree also provides a number of new penalties for the pharmaceutical sector. A fine of up to VND 10 million (USD 427) is imposed for various violations in pharmaceutical practice, such as being the chief pharmacist at two or more pharmaceutical business entities simultaneously, or practicing pharmacy not in accordance with the scope of practice stipulated in the relevant certificate. Engaging in the sale of pharmaceuticals without a CEPB or at an address different from the one stated in the CEPB is subject to a fine of up to VND 120 million (USD 5,155). The operations of the violator may also be suspended for up to nine months.
- ▶ Borrowing or lending a CEPB is punishable by a fine of up to VND 60 million (USD 2,600) and suspension of the CEPB for up to 24 months.
- ▶ Foreign-invested entity (FIE) importers that conduct activities directly related to drug distribution (except for drugs manufactured in Vietnam by the FIE importer) could be subject to a fine of up to VND 160 million (USD 6,900).
- ▶ For a drug that has been granted a marketing authorization in Vietnam, failure to notify the relevant authority of the recall of that drug in any country other than the country issuing the certificate of pharmaceutical product could subject the violator to a fine of VND 140 million (USD 6,000). The same fine is also applicable to submission of drug registration documents that are not based on actual research or manufacturing data. Remedial measures include compulsory recall of the drug and recommending that the relevant authority revoke the marketing authorization.
- ▶ Decree 117 also introduces some provisions on violations relating to the use and sale of liquor and beer. Employing minors in advertisements for liquor and beer is subject to a fine of up to VND 40 million (approximately 1,700). Selling or providing liquor and beer to minors is subject to a fine of up to VND 3 million (USD 130) for individuals or VND 6 million (USD 260) for companies and organizations.

Altogether, Decree 117 sharply escalates the penalties for some violations that have been proliferating amid the COVID-19 pandemic, while some other penalties remain unchanged or are slightly amended. Multinational pharmaceutical companies should note, in particular, the new penalties applicable to FIE importers, as drug distribution remains a sensitive area in Vietnam, and enforcement can be unpredictable. 🚫