

Client Alert

August 2010

Vietnamese Government plans to simplify prioritized Ministry of Health procedures

On 2 June 2010, the Government of Vietnam issued Resolution No. 25/NQ-CP (the "**Resolution**") aiming to simplify 258 administrative procedures under the management of various ministries and branches. There are 18 procedures under the jurisdiction of the Ministry of Health which are deemed priority targets for simplification.

Administrative Procedures

1. Eight administrative procedures in the pharmaceutical sector:
 - (i) Granting an operation license for a foreign company trading in medicines and medical materials in Vietnam;
 - (ii) Issuing the purchase order for finished products without a register number for businesses eligible for export and import of finished products;
 - (iii) Registering new locally manufactured drugs;
 - (iv) Registering new foreign manufactured drugs;
 - (v) Registering medicines under license between local drug makers;
 - (vi) Granting a certificate of good storage practice (GSP);
 - (vii) Issuing a notice of receipt for medicine advertisement applications;
 - (viii) Issuing a notice of application for drug launch workshops;
2. Seven administrative procedures in the food sector:
 - (i) Certification of food safety and hygiene for high-risk foodstuff producers, processors and dealers;
 - (ii) Certification of meeting standards for common and locally made foodstuffs;
 - (iii) Certification of meeting standards for natural mineral water;
 - (iv) Certification of meeting product standards for imported food additives and food processing supportive substances;
 - (v) Certification of meeting standards for locally made infant nutrient foods;
 - (vi) Certification of meeting standards for imported infant nutrient foods; and

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- (vii) Issuing a receipt for food product advertisement applications.
- 3. One administrative procedure in the medical equipment sector:
 - (i) Granting import permits for medical equipment.
- 4. One administrative procedure in the medical examination and treatment sector:
 - (i) Issuing a receipt for advertisement registration in the medical examination and treatment sector.
- 5. One administrative procedure in the cosmetics sector:
 - (i) Granting receipts and sequence numbers for public notices of cosmetics imports.

We would like to highlight one important procedure which may directly affect the operation of a foreign pharmaceutical trading company in Vietnam.

Procedure for granting an operation license for a foreign company trading in medicines and medical materials in Vietnam

We would like to highlight one important procedure which may directly affect the operation of a foreign pharmaceutical trading company in Vietnam.

Pursuant to the Resolution, a foreign pharmaceutical company does not have to submit a certification of its existing bank account number in a local bank in the application dossier.

Furthermore, the requirement to submit summarized audit statements of the latest fiscal year (verified by an independent audit agency) shall be replaced by a requirement for written verification from the tax office where the company is registered, regarding fulfilment of all tax liability in the originating country for the 12 months prior to the month the operation license application is filed, with a notarized Vietnamese translation.

The Resolution also recommends allowing English language applications and removing requirements to include company background information.

One significant recommendation of the Resolution is that the approval timeline for an operation license should be reduced from three months to one month.

The Resolution also recommends removal of several inconveniences which foreign pharmaceutical companies have had to cope with for many years, including requirements on sending applications twice a year, two year validity terms for operation licenses and minimum turnover quotas for medicines and medicine materials in the latest year.

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