



## ***INDONESIA REVISES ITS IMPORT RULES AND REMOVES DE FACTO BAN ON IMPORT OF PHARMACEUTICAL PRODUCTS***

With the introduction of Regulation No. 39/2010 of 4 October 2010, the Indonesian authorities have changed their previous practice and now allow economic operators to import both finished goods for sale on the domestic market and raw materials for production, under the same legal entity. This comes after intense joint action by the EU Delegation and the European Chamber of Commerce towards the Indonesian Government.

In September 2009, the Indonesian Ministry of Trade issued Regulation No. 45/2009. This regulation imposed new conditions for imports, implying that a company could no longer import both finished products and raw materials for production under the same legal entity. As a consequence, in order to import both finished goods and raw materials, a company would have had to set up a new legal entity. The implementation of this policy would therefore have imposed significant costs and an additional administrative burden for foreign companies established in Indonesia, as well as for domestic companies.

Regulation No. 45 applied to all sectors. Nevertheless, it had a particularly negative impact on the pharmaceutical industry because of the overlap with the provisions of Decree 1010/2008. This Decree provided that pharmaceutical companies are allowed to import finished products only if they have production facilities in Indonesia. The practical effect of both decrees taken together was a de facto import ban on pharmaceuticals.

The EU delegation, jointly with the European Chamber of Commerce, held intense discussions with the Indonesian authorities, inter alia in the context of a newly established sectoral dialogue on pharmaceuticals and cosmetics. This led to Regulation No. 39/2010 of 4 October 2010, which will allow imports of both finished products and raw materials under the same import license and legal entity as of 1 January 2011. As a result, the de facto ban on the importation of pharmaceuticals will be removed.

Indonesia is an important and growing market for the EU pharmaceutical industry, given its increasing middle-class and health-insurance coverage. EU exports of pharmaceuticals to Indonesia amounted to nearly €124 million in 2009. Between 2005 and 2008, the Indonesian market for EU pharmaceuticals increased by 72%. The EU Member States that were mostly concerned by Regulation No. 45 were Germany, the United Kingdom and Belgium.

Despite the above-mentioned improvements, imports of both finished products and raw materials will only be possible under certain conditions. For example importers will have to be approved by the Ministry of Trade and will have to submit quarterly reports on the volume of imports. It should also be noted that the new Regulation is still facing resistance both from the Indonesian Parliament and the SME association who fear a "flooding of the market" with finished products.

The issuance of Regulation No. 39/2010 marks a significant success for joint market access work undertaken by the EU Delegation, Member States and the EU industry (under the umbrella of the European Chamber of Commerce). The Commission, Member States and European business will continue to monitor the situation closely.

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