

**To:** KONIG Helena (TRADE); 4.1(b)

**Subject:** Report of the meeting on IDN with Medicines for Europe and Fresenius-KABI, 19 October 2017

Fyi

On 19 October 2017, DG TRADE 4.1(b) ) met " Medicines for Europe", representing generics in the pharmaceutical industry, and Fresenius-Kabi. Fresenius-Kabi, in particular, represents a 5 bn US dollar- business with most sales taking place abroad (3 Bn US dollars). It owns a subsidiary and has a joint venture in Indonesia. It employs about 300 people in Indonesia.

Fresenius-Kabi's representative showed a deep understanding of Indonesia's dynamics and stressed that it is difficult , in general, to point to trade restrictive legislation as barriers are built through practice (N.B. this confirms our experience in all fields).

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## DETAIL

MfE pointed to the main following elements (N.B. also conveyed via the questionnaire addressed to stakeholders when the negotiations for an EU-IDN FTA were launched):

- IDN represents an interesting market due to its size and the Government's intention to extend health insurance to all. However, it is difficult for foreign industries to sell or invest *in loco* due to numerous trade barriers. On the other hand, tariffs are low and there are reportedly no intention to increase them.
- Halal legislation has the potential to become one of the main barriers. IDN will soon implement the framework law No 33/2014 (in 2019) and the establishment of an *ad hoc* agency (BHJPH) is evidence of that. Though not directly placed under the Ministry of religious affairs , its highest officials are former members thereof. The halal legislation is reported to impose mandatory certification and mandatory labelling for halal certified products and for non-halal products. While halal certification will be reportedly mandatory only for those who wish to be certified, non-halal ingredients must clearly be indicated on the label. MfE drew attention to the need to avoid an halal logo on the package (as a marking of 'non halal' would in practice mean that this product would no longer be bought). For active pharmaceutical ingredients (APIs), it is impossible to trace the origin in order to ensure compliance with halal requirements. This affects all pharmaceutical producers, local and foreign. Important to note that both generic industry

(MfE) as well as EFPIA are equally concerned by this. 4.2

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- It is uncertain whether the industry will continue to either produce or sell pharmaceuticals in Indonesia. Legal uncertainty affects the industry's decision to place new products on the market due to costly, lengthy authorization processes. The Government's practice mainly limits people's access to pharmaceuticals, as most medicinal products are of imported origin in Indonesia. Potential uneven application of the law is a threat, in particular for foreign manufacturers.
- Labelling rules (fully integrated to the product, in Bahasa) require costly, resource intensive compulsory labelling on the imported product, no stickers or possibility to relabel in-country are allowed.
- Procurement rules have an implicit bias towards buying from 100% domestic companies (rather than from JVs based in Indonesia)
- 4.1(a) and 4.2

We agreed to continue our exchanges.

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