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Government Proposes New Changes in Healthcare, Life Science and Trade Sectors Through the Draft Omnibus Law

The government has issued a draft of a new omnibus law, which addresses various issues, as we have discussed in our previous client alert here.

This client alert covers specific proposed key changes and implications in healthcare/life science and trade sectors set out in the draft of the job creation law ("**Draft**").

It remains to be seen how the government will implement the proposed efforts to make investing in Indonesia easier and the proposed liberalization of foreign investment restrictions here in the aforementioned sectors.

Implications for healthcare/life science and trade sectors

The affected regulations from healthcare/life science and trade sectors are:

(a) Law No. 36 of 2009 on Health

(b) Law No. 44 of 2009 on Hospitals

(c) Law No. 5 of 1997 on Psychotropics

(d) Law No. 35 of 2009 on Narcotics

(e) Law No. 33 of 2014 on Halal Product Assurance

(f) Law No. 18 of 2012 on Food

(g) Law No. 7 of 2014 on Trade

(h) Law No. 2 of 1981 on Legal Metrology

(i) Law No. 20 of 2014 on Standardization and Assessment of Compatibility

What the Draft says

Some notable relevant provisions under the Draft are as follows:

A. Healthcare and Pharmaceutical Sector

There are no significant changes in the healthcare and pharmaceutical sector but the Draft proposes to unify and simplify the regulatory process in this sector. As an example, the Draft proposes removing certain types of administrative sanctions and changing the licensing terminology to a more generic term, i.e., Business License (*Perizinan Berusaha*), which replaces the term of 'marketing authorization'.

Due to the change of the term (and subject to any implementing regulations), people can argue that marketing authorizations for pharmaceutical and/or medical device products would no longer be needed. As such, no sanction will be imposed on business actors if they sell pharmaceutical and/or medical device products without marketing authorizations, provided they manage to maintain their Business License. On the contrary, considering that marketing authorizations have always been very important for the government in managing technical compliance and ensuring consumer protection, we do not think that the government will simply waive the requirement to have marketing authorizations on a whim (i.e., this is the same with changes in other sectors relating to the marketing authorization). Perhaps the Draft uses Business License term generally as the reference to all licenses that business actors need to obtain, which may include marketing authorizations.

Likewise, the use of general term can cause ambiguity particularly from a drafting point of view. It would be unclear which license that business actors should obtain to carry out their activities or to avoid sanctions. Having said that, we learned that the government is aiming to regulate the technical matters more specifically in the implementing regulations of the amended laws.

The Draft also provides that the Central Government (not the regional or ministry level) will have authority over healthcare and pharmaceutical supervision and compliance.

On healthcare sector, we note that the Draft proposes moving detailed provisions on the determination of the number and types of healthcare services facilities to a government regulation. Currently, those provisions are regulated under certain laws and regulations.

There are no notable changes to the licensing requirements for drugs and medical devices (made locally or imported) as the businesses are still required to fulfil the Business License requirement from the Central Government, where a marketing authorization could still be a commitment to be fulfilled under the Business License.

B. Halal Product Assurance

- **Limitation of MUI's significance:** The Draft notably limits the power of the Ulema Council (*Majelis Ulama Indonesia* or "**MUI**") in the implementation of halal product assurance. For instance, the issuance of a *fatwa halal* and determination of halal status is no longer exclusive to MUI (i.e., the fatwa is required for the issuance of a halal certificate). Other legally incorporated Islamic organizations may also issue a *fatwa halal* and/or determine halal status. Further, the determination of halal status of a product must be in accordance with the standards of the Halal Product Assurance Implementing Board ("**BPJPH**"), as opposed to fully relying on MUI. The cooperation between BPJPH and MUI is also limited to determining halal status of products and must involve third party legally incorporated Islamic organizations.

  ***Note**: For context, currently MUI has the power to issue certificates for halal auditors and for the accreditation of Halal Examination Bodies (Lembaga Pemeriksa Halal or "**LPH**") in addition to determining halal status through fatwa halal. The proposed change in the Draft might be a response from the government to MUI's recent attempt to challenge BPJPH's authority to issue halal certificates[1]. The new certification system will not work without MUI's cooperation to issue fatwa halal, and this is why BPJPH has not issued any halal certificate. By making the authority to issue fatwas non-exclusive, the government could began to implement the halal certification process under the current law even if MUI is not cooperative.*

- **Use of halal raw materials guarantees certification by BPJPH:** BPJPH may directly issue halal certificates for products that are made from halal certified raw materials, if the materials have fulfilled halal production process standards based on the inspection by LPH. Currently, products with halal-certified raw materials are still required to undergo a halal certification process. If the new provisions were adopted, business actors that have already used halal-certified raw materials would get a valuable commercial benefit as they could save costs and time when obtaining halal certificates for their products.

- **Simplification of regulatory process and requirements:** In general, the Draft proposes to simplify the regulatory process and requirements in this sector, such as by generalizing administrative sanctions. In the current law, several violations are subject to different administrative sanctions, and some may even be imposed without any verbal/written warning. We also note that under the Draft, BPJPH has the right to take over the halal certification process if LPH, MUI or a legally incorporated Islamic organization does not finish within the timeline. Further, the Draft limits the time for halal auditors to finish their inspection/examination. These new provisions would give more

[1] https://www.hukumonline.com/berita/baca/lt5d53e60da9064/sertifikasi-halal-beralih--mui-persoalkan-uu-jaminan-produk-halal/

certainty to business actors as the Draft shortens the regulatory process. For renewal of halal certificates, the Draft proposes that BPJPH may directly issue renewals of halal certificates for products if business actors provide statement that there is no change to the content of the certified product.

- **Micro and small business are now subject to halal certification**. Nevertheless, the Draft requires micro and small business actors to obtain a halal certificate, which in our opinion is not very practical as this would potentially increase the price of their products (i.e., which are mostly day-to-day products), and would be potentially harmful for micro and small business actors in Indonesia.

C. Hospital Sector

There are no significant changes in the hospital sector, but the Draft generally proposes to unify and simplify the regulatory process in this sector, such as by deleting certain types of administrative sanctions and changing the licensing terminology to Business License.

The Draft also provides that the Central Government (not the regional or ministry level) will have authority over supervision and compliance of hospitals. Further, we can still see the classification of hospitals in the Draft although it is not described in a detailed manner as the current law provides. In the current law, hospitals that do not comply with general requirements (such as the location, buildings, facilities and equipment) will not be granted licenses, or their licenses will not be renewed or will be revoked (if they have obtained the licenses). Under the Draft, the failure to meet these requirements will only lead to administrative sanctions. Yet, it is still unclear whether those requirements are still prerequisites for the establishment of hospitals.

It also remains to be seen whether the foreign investment restriction in the hospital sector will be amended.

D. Food Sector

We are seeing proposals to unify and simplify the provisions in line with proposals to the other (including health) sectors, such as (i) the use of the term Business License and (ii) the Central Government (not the regional or ministry level) having the authority to regulate, implement and supervise the food business.

More specifically, the Draft seems to provide more flexibility for businesses to import food because it removes the notion in the current law that import of food will only be conducted if the domestic production and national food reserves are not enough. The Draft states that import of food is one of the main sources to fulfil consumption needs and food reserves. Nevertheless, the Central Government still plays an important role in determining domestic consumption needs and sets out policies and regulations on food import for the benefit of farming sustainability.

There are no notable changes on the requirement for processed food (made locally or imported), as businesses are still required to fulfil the Business License requirement from the Central Government, where a marketing authorization could still be a commitment to be fulfilled under the Business License.

E. Trade Sector

The Draft unifies and simplifies regulatory processes in the trade sector to be in line with the other sectors. One example is removing certain types of administrative sanctions and changing the licensing terminology to introduce the term Business License. The Draft also requires businesses to obtain a Business License from the Central Government, not from the Ministry of Trade. The Draft does not include specific proposals to liberalize investment in the trading sector. We may see further implementing regulations from the Central Government in the near future.

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