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# Client Alert: Iranian Food and Drug Organization Announces Restrictive Rules on Import of Health-related Products

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***The Iranian Food and Drug Organization (IFDA) announced new restrictive policies effective from beginning of the new Iranian calendar year 1397 (21 March 2018 – 20 March 2019), for foreign suppliers of health and medical related products including, in particular, over-the-counter and prescribed pharmaceuticals as well as certain FMCGs. It is currently unclear at this stage how these new restrictions will be practically implemented by the IFDA as sources unofficially confirmed that implementing regulations will still need to be drafted in the coming weeks.***

The restrictions, among other things, aim to prevent foreign suppliers from appointing different local importers for imports in the Iranian market. It requires that only a single local importer must apply for the import marketing authorization of all the products produced by the foreign supplier. Previously, the Ministry of Health authorized one importer per product (on some occasion each category of product) of the foreign supplier allowing the foreign supplier to appoint multiple importers for different products. It appears that under the new practice, if implemented, the importer will have the import right over all the products of the foreign supplier.

Under a new policy, foreign suppliers are encouraged to set up their directly owned offices and entities in order to take over the import marketing authorization from the local importers. It would seem that the contractual obligations towards local importers are not being considered by the IFDA which could potentially result in contracts being breached.

Such policy is not to be implemented under a mandatory basis but is aimed to encourage voluntary compliance through the offer of certain benefits to those companies that do comply. Such benefits include, among others, the approval of higher profit margins and market share (a policy arguably contrary to the current competition laws) as compared to those approved for Iranian importers. The Ministry of Health has announced that to the extent it deems the policy successful, the foregoing encouragement-based policy of the IFDA would become mandatory in the next Iranian calendar year of 1398 (21 March 2019 – 20 March 2019) and as such, should be closely monitored.

Moreover, in deviation from the previous policies, the IFDA has announced that it will not approve the transfer of import marketing authorizations of all health-related products, in particular, pharmaceuticals,

between local importers at the request of the foreign supplier unless (i) the request is made to transfer the marketing authorizations to an affiliated entity of the foreign supplier; or (ii) the previous importer consents to such transfer (a policy previously imposed on a limited category of products including food and beverages).

Lastly, the import of certain categories of cosmetics and hygiene products are generally prohibited to the extent that there are sufficient equivalent local products available. While this import ban had been recently imposed on the market, the range of the products impacted by such policy has substantially increased.

## Practical application

We have been informally advised by the IFDA that some of the above-said policies are still under review and it is unclear as of now to what extent they will be implemented. It is anticipated that certain exemptions from the policy will be applicable to more critical products such as foreign prescribed pharmaceuticals so as to not disrupt the market.

It is advisable that the impact of the implementation of the foregoing policies be closely reviewed for those foreign companies working with existing importers, those in the process of appointing a new importer or those who wish to replace existing importers. A potential restructuring may be required as a result of such new policies.

We are currently working closely with our clients in coordination with the IFDA on practical measures to adopt in order to prevent a substantial disruption of market supply and ways to adapt our clients' practices to comply with the new regulations once implemented.

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**If you would like more information about this topic then please contact us.**

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