Pharmaceutical Certificates of Origin Required in the GCC

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The importation of pharmaceutical products into Gulf Corporation Council ('GCC') states can be complicated. In previous Law Update articles, we have written extensively on the topic of obtaining product registration approvals. In this article we address the requirement to have a certificate of origin ('COO') and examine the variations in practice across GCC states.

A significant percentage of the pharmaceutical products imported into the GCC come from Europe and comply with the European requirement to have a COO. In Europe, the country of origin is determined by applying European Directive No. 952/2013 ('**European Code**') as follows:

goods, the production of which involves more than one country or territory shall be deemed to originate in the country or territory where they underwent their last, substantial, economically-justified processing or working, in an undertaking equipped for that purpose, resulting in the manufacture of a new product or representing an important stage of manufacture;

The accepted methodology to determine the foregoing is the 'last/final customs tariff code change along the entire value chain of a certain product'. For pharmaceutical products, the last customs tariff code change is a change occurring on a bulk drug product level.

So the question is, could a European product, which already carries a COO, be sufficient to comply with the equivalent GCC requirements? The answer is both 'yes' and 'no', depending upon the local requirements of the country of import. In the GCC, some states follow the European approach, but insert a few unique differences. Unfamiliarity with these differences in either law, procedure, interpretation, or local approach can lead to products being held at customs and, in some cases, being returned to the home port.

GCC Common Customs Law

Customs procedures in the GCC states follow a regional common customs law. The Common Customs Law of the GCC Member States ('GCC Common Customs Law') was adopted by the Supreme Council at the 20th Session (Riyadh, 27-29 November 1999) and implemented only as a reference law for one year from the date adopted by the Supreme Council. It was intended to be revised in the light of the comments received by the Secretariat General from each member state in an attempt to have the law compulsorily implemented by all the customs administrations of the GCC. The GCC Common Customs Law was re-published in 2008, with the only substantive changes being made to the introductory narrative.

According to Article 25 of the GCC Common Customs Law, '[i]mported goods are subject to the proof of origin according to the rules of origin adopted within the framework of the international and regional economic agreements in force'. The phrase, 'within the framework of the international and regional economic agreements', references the rules of origin requirements found in Annex K, Chapter 1 of the Revised Kyoto Convention on the Harmonisation and Standardisation of Customs Procedures, as amended ('Revised Kyoto Convention'), which prescribes that where two or more countries have taken part in the production of the goods, the origin of the goods should be determined according to the substantial transformation criterion. Therefore, both the European Code and the GCC Common Customs Law follow the same basic principles.

A number of states in the GCC (and wider region) are signatories to the Revised Kyoto Convention, which aims to standardise customs procedures and ensure that they are consistent with the practices of international trade, including the United Arab Emirates ('UAE'), Kingdom of Saudi Arabia ('KSA'), Qatar, Oman, and Bahrain. With regard to these countries, the rules regarding COO should be the same as for the European Code; however, this is not the case. (Kuwait is not a signatory to this convention.)

The Revised Kyoto Convention prescribes that where two or more countries have taken part in the production of goods, the origin of the goods should be determined according to the substantial transformation criterion. In applying the substantial transformation criterion, use should be made of the World Customs Organisation's International Convention on the Harmonized Commodity Description and Coding System ('Harmonised System'). Each signatory state should follow the methodology set out in the Harmonised System when examining what constitutes a substantial transformation of goods. The recommended practice detailed by the Revised Kyoto Convention, Annex K, Chapter 1, is as follows:

- 'operations which do not contribute, or which contribute to only a small extent, to the essential characteristics or properties of the goods, and in particular operations confined to one or more of those listed below, should not be regarded as constituting substantial manufacturing or processing:
- operations necessary for the preservation of goods during transportation or storage;
- operations to improve the packaging or the marketable quality of the goods or to prepare them for shipment, such as breaking bulk, grouping of packages, sorting and grading, repacking;
- simple assembly operations; and
- mixing of goods of different origin, provided that the characteristics of the resulting product are not essentially different from the characteristics of the goods which have been mixed.'
- GCC customs authorities should also accept COO forms in the format and of the size laid out in the Revised Kyoto Convention. The following table confirms how the law is currently applied across the GCC states.

Other Matters to Consider

The balance of power – imports and distributor arrangements:

Once the issue of COO is resolved, each importing GCC state will then only permit imports from a company which is duly authorised to bring the products into the country. As a general rule, in order to import and distribute medical products in any of the GCC states, the importing company must be a locally established company. It is possible for a company owned by both a local shareholder and a foreign shareholder to apply for registration to import and distribute products. However, foreign producers with no established corporate presence will need to either establish a company with the necessary licence, or engage a distributor, or agent, which is already registered with the various competent authorities in the country into which the products are to be imported.

Conclusion

The importation procedures and the price of many pharmaceutical products are controlled at both the GCC and local member state. It remains the case across the GCC that local ministries of health (the bodies which register the products), typically permit only one distributor per product to be registered. This stringent and often lengthy process of product registration – including product evaluation, establishing pharmacovigilance systems, obtaining product labelling and COO compliance, and other matters – assists the regulator in tracking products being brought in-country, which, in-turn, reduces the risk of counterfeit products finding their way onto the shelves or parallel imports flooding the market. It also prevents and minimizes the risk of fraud and abuse within the supply-chain by those companies engaged in anti-competitive practices. These control

mechanisms are expected to strengthen over time.

GCC State	GCC Common Customs Law	Revised Kyoto Convention	Variation
UAE	✓	Instrument of accession	Local variation of procedure may affect imports into various Free Zones.
KSA	✓	Instrument of accession	None
QATAR	✓	Instrument of accession	None
OMAN	✓	Signatory	None
KUWAIT	✓	N/A	The applicable Kuwaiti laws provide that the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid. Therefore, in Kuwait, the COO is linked to the site of the manufacturer.
BAHRAIN	✓	Instrument of accession	The country of origin is the country in which the Certificate of Pharmaceutical Products ('CPP') has been issued. The CPP should be legalised from the batch releaser country, which is considered the country of origin even if the bulk pharmaceutical active ingredients were manufactured elsewhere and only packed in the batch releaser country.