Bird & Bird & COVID-19 Medical Devices: Singapore

Emergency legislation / Regulatory relaxation during COVID-19 pandemic

Introduction

Background

Due to the COVID-19 pandemic, many countries have enacted emergency legislation removing certain regulatory barriers and exempting products from regulatory approval requirements. This allows unregistered products to be used or already registered products to be used for non-indicated conditions. The emergency legislation will define the products that are exempted and also from which provisions they have been exempted. There may also be an expiry date stated for the emergency legislation.

Europe

The European Commission has taken several measures in order to address the issues created by the Coronavirus crisis in the manufacture and supply chain of medical devices and In-vitro diagnostics.

As far as Medical devices are concerned, Member States can authorise derogations from conformity assessment procedures for medical devices, according to Article 11(13) of Directive 93/42 (MDD) and Article 59 of Regulation 2017/745 ("MDR").

In this regard, the EC published a Q&A on Conformity assessment procedures for protective equipment as well as a Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. According to the Recommendation, national competent authorities may authorise products that ensure an adequate level of health and safety in accordance with the essential requirements on the EU market, even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised.

In exceptional circumstances, products can be placed on the market even if the certification procedures have not been initiated and no CE marking has been affixed upon them, if the following cumulative conditions are fulfilled:

a the products are manufactured in accordance with one of the EN standards or in accordance with any of the other standards referred to in the WHO guidelines or a technical solution ensuring an adequate level of safety;

b the products are part of a purchase organised by the relevant Member State authorities;

c the products are only made available for the healthcare workers;

d the products are only made available for the duration of the current health crisis; and

e the products are not entering the regular distribution channels and made available to other users.

A draft proposal amending the MDR (and deferring the application of certain provisions) allows the European Commission to extend, in exceptional cases, the validity of a national derogations (under art. 11 MDD) for a limited period of time to the territory of the Union ('Union-wide derogation'). The Commission would thus be able to adopt Union-wide derogations in response to national derogations in order to address potential shortages Union wide of vitally important medical devices in an effective manner. This provision would be of immediate effect.

For IVD's, Art. 9(1) and 9(2) of Directive 98/79 ("IVDD") (and Article 54 of Regulation - "IVDR") provides equally for derogations from CE marking and conformity assessment procedures.

There is currently no pending draft proposal to defer the entry into force of some provisions of the IVDR including the powers for "Union-wide derogations".

The European Commission published however an Implementing Decision 2020/439 of 24 March 2020 on the harmonised standards for in vitro diagnostic medical devices drafted in support of the MDDD. These harmonised standards for in vitro diagnostic medical devices may not be used to confer presumption of conformity with the requirements of Regulation 2017/746.

Asia-Pacific ("APAC")

There is no single harmonised approach for medical device regulation in countries within the APAC region and each country has its own medical device registration system.

This means that during the COVID-19 pandemic, some countries in the APAC region have implemented emergency legislation to expedite the approval procedure for medical equipment used for the diagnosis or prevention of COVID-19, whilst others have not.

China, for example, has enacted extensive emergency legislation for expedited approval of manufacturing sites and medical devices for COVID-19. Provincial level legislation has also been enacted to enable the expedited approval of manufacturing sites and medical device products.

Hong Kong, with its current voluntary device registration process, has not enacted any specific COVID-19 related requirements, preferring to rely on its current system. Other countries, such as Australia and Singapore, have enacted emergency legislation that contains specific requirements for manufactures and importers to meet for the designated types of medical devices subject to the altered regulatory provisions.

Overall, there is a requirement to continually monitor this changing environment. The various provisions enacted are all valid for different periods and there is no coordinated approach to the issue across the APAC region.

This document does not constitute legal advice, if you require more information please feel free to reach out to the country contacts in this document.

Singapore

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for hand sanitisers, masks, thermometers, protective gear, respiratory devices, and diagnostic test-kits for COVID-19. • Import of Hand Sanitisers, Masks, Thermometers and Protective Gear: Health Products (Import, Wholesale and Supply of Medical Devices — Exemption) Order 2020. See link here • HSA's Regulatory Position on Respiratory Devices: Supply for Management of COVID-19 Patients. See link here. • HSA Expedites Approval of COVID-19 Diagnostic Tests in Singapore via Provisional Authorisation. See link here.
2	**Do the emergency provisions have an expiry date?**	No, but the Health Sciences Authority of Singapore has indicated that the Provisional Authorisation for Diagnostic Tests is merely an interim measure in response to the current public health need for timely detection of COVID-19 infections.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes Hand sanitisers, masks, thermometers, protective gear for medical professionals and respiratory devices.
4	**Do the emergency provisions stipulate which IVDs are included?**	Yes Tests intended for the detection and/or diagnosis of COVID-19 infection.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes Health Sciences Authority of Singapore ("HSA").
6	**What are the products exempted from?**	Hand sanitisers: Approval need not be obtained for import Masks, thermometers and protective gear for medical professionals: License need not be obtained for import, but notification must be given of the intention to import for commercial use or beyond a certain quantity. Information on the brand and quantity of the devices must be provided to HSA, and importers must maintain proper sales and distribution records. Respiratory devices: HSA-registered anaesthesia machines with facilities capable of providing controlled ventilation or assisted ventilation as emergency ventilators for COVID-19 patients may be used as ventilators without approval from HSA. Upgrades or modifications to HSA-registered ventilators may be done prior to HSA approval, as long as these changes do not affect performance specifications and the requisite safety standards continue to be met. Information on modifications need only be submitted on a 6-month basis. Diagnostic test-kits: HSA has set up a provisional authorisation process intended for detection and/or diagnosis of COVID-19 infection, allowing test-kits which have received such authorisation to be supplied to healthcare institutions, private hospitals, medical clinics and clinical laboratories in Singapore.
7	**Are exempted products required to meet GMP?**	Most of the listed products are exempted from the regulatory requirements, and therefore there is no requirement to provide

		evidence that the product meets GMP. However, upgrades or modifications to HSA-registered ventilators must meet the requirements of the Health Products (Medical Devices) Regulations 2010. As the stated products are exempted from the regulatory requirements, there is no requirement to provide evidence that the product meets GMP.
8	**Are there specific procedures to be followed?**	Yes. Import of surgical masks and thermometers for personal use: Import of surgical masks, thermometers and/or protective gear for medical professionals for commercial or other purposes Notification to HSA for upgrades or modifications to respirators Provisional authorisation for diagnostic test kits: hsa_md_info@hsa.gov.sg
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. For forms, please refer to the link above. For email to HSA seeking provisional authorisation, the following information must be included:- • A brief description of the test (test design, target biomarker, device technology, description of key functional elements, specifications, composition, accessories) • Intended purpose of the test • Information for Users (IFU) for the test • Summary of analytical validation (e.g. Limit of Detection, inclusivity, cross-reactivity, precision, interfering substances, Hook effect) and clinical data collected for the test where available • Summary of any planned or ongoing validation including clinical studies
10	**Are there any additional requirements that must be met for a product to be supplied?**	No
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes Importers of masks, thermometers and protective gear for medical professionals must **maintain proper distribution and sales records** according to the template form on the HSA website (https://www.hsa.gov.sg/announcements/regulatory-updates/import-of-hand-sanitisers-masks-thermometers-and-protective-gear). Where necessary, for example if certain brands of thermometers are recalled, **HSA may require these records to be submitted for review**. Local dealers of upgraded or modified ventilators are subject to **post-market duties and obligations** as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010, including **reporting of adverse events arising from the use of these medical devices, reporting of Field Safety**

		Corrective Actions and recalls related to these devices. Where provisional authorisation of diagnostic test kits is sought, **periodic reports on specific data on the safety and/or performance of these tests will be required to be submitted to HSA post authorisation**, to assure the continued performance of these devices. If any safety or performance issues are observed, **HSA will require relevant follow up actions at the manufacturer's end**.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	No
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No, there is no specific legislative protection for products imported and supplied under the emergency provisions.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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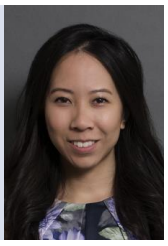

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By combining this talent with exceptional legal expertise and deep industry knowledge, our advice is always informed, up to date, focused and relevant.

With over 240 experts globally and a wealth of hands-on experience from working inside life sciences companies and regulatory bodies, clients choose us as their strategic partner to guide them through some of their most complex legal challenges.

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