Baker McKenzie Wong & Leow.

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Medical Device Companies in Korea to Record Value Transfers to Healthcare Professionals from 1 January 2018

With the recent amendments to the Korean Medical Device Act ("**KMDA**"), medical device companies will have to record certain value transfers made to healthcare professionals ("**HCPs**") by way of expenditure reports effective from 1 January 2018. Accordingly, Korea's Ministry of Health and Welfare ("**MOHW**") has issued guidance on how medical device companies should prepare such expenditure reports for each type of value transfer.

Key points include, amongst others:

- Local companies which manufacture, import, sell or lease medical devices must prepare and retain expenditure reports. Overseas subsidiaries or overseas head offices have no such obligation, as the KMDA does not have extra-territorial effect, even if these overseas entities provide economic benefits to Korean HCPs.
- The obligation to record value transfers applies equally to a manufacturer, importer, and seller, and not just the party which holds the product authorisations for the medical devices.
- Companies are given 3 months from the end of their fiscal year to prepare expenditure reports, and the reports must include all value transfers made from 1 January 2018 to the date on which the company's fiscal year ends.
- All transfers of value (i.e. economic benefits) that are given to HCPs or returned to the company from HCPs must be recorded in the expenditure reports.
- HCPs may request for a report setting out a list of economic benefits provided to them from the company. Medical device companies should note that employers or supervisors of HCPs are not entitled to such reports.
- Types of value transfers to be recorded include the giving of product samples / free trials, sponsorship to attend academic conferences, clinical trial support, benefits provided to attendees of product presentations hosted by the medical device company, and compensation for post marketing studies.
- Supporting documents must also be retained by the medical device companies. It would suffice for the supporting documents to verify the information reflected in the expenditure reports, and no specific types of documentation is required.

CorpPass Required to Access the Health Sciences Authority's Portal from 1 January 2018

CorpPass is a corporate digital identity for businesses to transact online with government agencies. Companies transacting with the Health Sciences Authority of Singapore ("**HSA**") will require a CorpPass account to login to the HSA's e-services portal, PRISM and MEDICS, from 1 January 2018.

Any employee of a Singapore company who has been authorised to act as the company's CorpPass Administrator may set up the CorpPass account. Currently, CorpPass does not allow for foreign entities to register for an account. The director / secretary of the local company must give authorisation to apply for the CorpPass account, either by logging in online to verify the application, or by signing a letter of authorisation in the prescribed form.

Once the CorpPass account has been set up, the CorpPass Administrator may create multiple user accounts for employees of the company to transact with government agencies on behalf of the company. Apart from the change in login method, all other functions of the HSA's e-services remain unchanged.

More information about CorpPass for HSA e-services can be found on the HSA's website here.

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