[redacted]

From: [redacted]
Sent: 05 March 2018 18:51
To: response
Subject: Commentary on HKSE's Consultation Paper of companies from the emerging and innovative sectors

Dear HKSE Officer

As a reflection to the Consultation Paper of companies from the emerging and innovative sectors., we would like to share two points

1. **AS an industrial participant, we have the concerns of Clinical Trial requirement for Medical Devices. Not all Class II Devices, per FDA requirements, needs Clinical Trial. There's various degree of intensity in Clinical Evaluation activities per outlined by different Regulatory authorities.**

2. We believe that Medical Device Clearance needs to be further address

a) EUROPE: On the regulatory authorities, "EMA" European Medicines Agency" doesn't address European Medical Device's approval. Usually, this is the duty of Conformity Assessment Body on Assessment of the Medical Device to the European's Medical Device Regulations. In our everyday terms, these are the TUV's (TUV Rheinland, TUV SUD) and SGS (Of Switzerland) Notified Bodies from Europe that we know.

b) note that in Hong Kong, the Registration is still Voluntary for medical devices and other competent authorities: markets does it mean other authorities are allowed? e.g. EU's CE, Canada, Australia, Japan.

"CONSULTATION PAPER: A LISTING REGIME FOR COMPANIES FROM EMERGING AND INNOVATIVE SECTORS"

https://www.hkex.com.hk/-/media/HKEX-Market/News/Market-Consultations/2016-Present/February-2018-Emerging-and-Innovative-Sectors/Consultation-Paper/cp201802.pdf?la=en

Before we want to explore our concerns, we would like to input based on the following:

Of the following section:

P.5 DEFINTION:

"Regulated Product": A Biotech Product that is required by applicable laws, rules or regulations to be evaluated and approved by a Competent Authority based on data derived from clinical trials (i.e. on human subjects) before it could be marketed and sold in the market regulated by that Competent Authority

CHAPTER 2: BIOTECH COMPANIES

Proposals

75. With regards to paragraph 74(a) above, the Exchange would consider the following to demonstrate that a Regulated Product has developed beyond the concept stage

P.25 (c) Medical devices (including diagnostics) In the case of a Core Product that is a medical device (which includes diagnostic devices), the applicant must demonstrate that:

(i) The product is categorised as Class II medical device (under the classification criteria of the relevant Competent Authority) or above;
(ii) it has completed at least one clinical trial on human subjects (which will form a key part of the application required by the Competent Authority or the Authorised Institution);
and

(iii) either the Competent Authority or the Authorised Institution has endorsed or not expressed objection for the applicant to proceed to further clinical trials; or the Competent Authority has no objection for the applicant to commence sales of the device.

We believe as an industrial participant, we have the concerns, not all Class II Devices, per FDA needs Clinical Trial

1. Not all medical devices need clinical trial. In the industry, there's clinical evaluation. The regulation authorities, such as US's FDA decides what are the needed schemes to fulfill such clinical evaluation. Yes, we would like to repeat not ALL MEDICAL DEVICES PRODUCTS, EVEN US FDA CLASS II products needs Clinical trials. The following example, of "CAPITAL EQUIPMENTS" in hospitals, these are not small devices.

I) Magnetic Resonance Imaging Systems (MRI)
7. Clinical Images You should provide sample clinical images to support the ability of your system to generate diagnostic quality images.
For newly introduced systems, you should provide sample clinical images for all pulse sequences.
21 CFR 892.1000: Magnetic resonance diagnostic device. Classification. Class II.

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM454613.pdf

II) Emission Tomography Devices:
This includes Single Photon Emission Tomography (SPECT) imaging systems and their accessory devices, 511 keV Ultra-High Energy collimators (UHEC), Attenuation Correction Devices (ACD), Positron Emission Tomography (PET) imaging systems and their accessories, Coincidence Imaging Devices (CID), and Nuclear Tomography Systems (NTS) and its accessories.

> **IV. Regulatory Requirements**
>
> Under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act of 1976, all Emission Computed Tomography (ECT) and their accessory devices may be cleared by 510(k) process, when the device shows substantial equivalence to the legally marketed predicate devices. All Emission Computed Tomography devices and accessories are currently classified as Class II devices with a Product Code of 90-KPS. Nuclear Tomography Systems are classified Class II with a product code of JWM.

As for Clinical Evaluation, it asks for Clinical Images, not a FULL SCALE Clinical Trial
see "Clinical Images: Submit sample images from three different organs, such as brain, lung, and heart, obtained on each system used with the collimator."

//Note: note Clinical Trial, has been mentioned, it's basically a representative sample set of Clinical Image, to represent the Image quality, is sufficient for the US FDA Filing.

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073794.htm#11

CHAPTER 2: BIOTECH COMPANIES
2. "EMA" European Medicines Agency
So what is the Medical Device equivalent for Europe?
The guidance's mentioned of EMA, represent only Medicines, as its name suggests. "EMA" European Medicines Agency" doesn't address European Medical Device's approval. Usually, this is the duty of Conformity Assessment Body on Assessment of the Medical Device to the European's Medical Device Regulations
http://www.doks.nbog.eu/Doks/NBOG_BPG_2017_1_rev1.pdf
In layman's term, that is Europe's CE program. **In our everyday terms, these are the TUV's (TUV Rheinland, TUV SUD) and SGS (Of Switzerland) Notified Bodies from Europe that we know.**

TÜV SÜD Product Service GmbH Zertifizierstellen
http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.nb&refe_cd=EPOS_43445
TÜV Rheinland LGA Products GmbH
http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.nb&refe_cd=EPOS_43519
b) note that in Hong Kong, the Registration is still Voluntary for medical devices
http://www.mdco.gov.hk/english/faq/faq.html
c) Regulated Products" "FDA, CFDA, EMA or any other national or supranational authority which the Exchange recognises as a Competent Authority on a case by case basis"
- does it mean other authorities are allowed? e.g. EU's CE, Canada, Australia, Japan.

much thanks,
Nick