[redacted]

From: [redacted]
Sent: 19 March 2018 15:05
To: response
Cc: [redacted]
Subject: HKEX Consultation Feedback & Questions (from Sanwa Biotech Ltd Hong Kong)

To Whom it may concern,

As a Hong Kong based biotechnology startup in Hong Kong, for the last few years we had been carrying out R&D in Hong Kong towards our IVD product platform towards commercialization into both local & foreign market. We had studied the consultation paper would like HKEX to keep in mind of the constructive & broad base support to similar biotechnology companies like us in Hong Kong. After reviewing internally, we have the following concerns/questions we would like to bring to your notice:

According to paragraph 75(c),
"(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."
While medical devices under the current EU Medical Device Directive (93/42/EEC) are classified into Class I, Class IIa, Class IIb, and Class III medical devices, IVDs have a different classification system. Currently under the IVD Directive (98/79/EC), IVDs are classified as (1) General IVDs, and (2) IVDs in Annex II of the directive.
The current paragraph 75(c) fails to address the difference between the classification of medical device and IVDs under the current EU Directives.
Question 1: What is the IVD equivalence of a Class II medical device? Due to a lack of proper IVD classification in the current EU system, does the Exchange follow the Hong Kong MDCO, Department of Health guidance (GN-06) in which a Class B or Class C IVD would deem to be equivalent to a Class II medical device?

According to paragraph 76,
"At present the Exchange recognises the FDA, the CFDA and the EMA as Competent Authorities for the purpose of the new Biotech chapter. The Exchange may, at its discretion, recognise other national or supranational authorities as Competent Authorities in individual cases depending on the nature of the Biotech Product). The Exchange will seek the SFC's consent before making such a recognition."
EMA is the Competent Authorities of regulating pharmaceutical products only. For medical devices and IVDs, products are regulated by the Health Departments from individual EU country members, such as MHRA for the UK and ANSM for France. Once a product is registered in one of the EU country member, it will be recognised by the all EU countries and can be sold in any EU country.
The current paragraph fails to address whether a medical device/IVD product successfully registered in EU country member will be recognised by the Exchange.
Question 2: Will an IVD registered in an EU member country be recognised by the Exchange?

Question 3:
If an IVD is classified as:
EU – General IVD (paragraph 75c does not cover address this classification system)
HK – Class C

From our company perspective (a start-up located in Hong Kong),our product, due to being classified as general IVD, is not eligible for a CE certificate but can obtain a CE-mark through self-declaration route. The CE-marked product can be registered in EU and then be placed on the EU market legally. Does this product fulfil the requirements in paragraph 75c and 76?. This is an active and applicable market towards our company's business development plan.

At the same time, locally this product is classified as a Class C IVD in Hong Kong (which also is not covered by paragraph 75c). Despite Class C IVDs being the second-highest risk class products, Class C IVDs are not eligible for registration in Hong Kong (only the highest risk Class D IVDs are eligible). This product can still be placed on the Hong Kong market legally as there is no regulatory requirement for IVDs nor medical devices in Hong Kong. This means it has no effect

concerning our business operation/penetration locally. However, will this product, at discretion, be recognized by the Exchange?

Thank you for your kind attention.

Best,

Kelvin Chiu

Kelvin Chiu
CEO
Sanwa Biotech Ltd.