HKAPI 香港科研製藥聯會
The Hong Kong Association of The Pharmaceutical Industry
ROOM 906-7, 9/F., K. WAH CENTRE, 191 JAVA ROAD, NORTH POINT, HONG KONG
TEL: (852) 2528 3061/2 FAX: (852) 2865 6283 WEBSITE: www.hkapi.hk

HKAPI responses to Department of Health's Proposal of New Principles for the Acceptance of NCE Applications

1. Background

Currently, official evidence of registration approval of a new chemistry entity ("**NCE**") application in two or more of the 32 reference countries[1] must be provided by the applicant in order for its application to be accepted by the Department of Health ("**DH**"). Recently, DH has received enquiries on whether NCE applications of public health perspective but without official evidence of registration in two of more reference countries will also be accepted.

2. DH's Proposal

To protect public health, DH is now considering the following proposal of new principles for the acceptance of NCE applications, that if an above-mentioned application at issue fulfills the following criteria, it should also be accepted:

1) there is a local unmet medical need for the product with public health perspective;
2) the product must be registered in at least one of the reference countries and/or registered in the country of origin; and
3) the product is promulgated by reputable international health agencies on human or veterinary medicines, including the World Health Organization (WHO), World Organization for Animal Health (OIE), Food and Agriculture Organization of the United Nations (FAO), etc.

In addition to the currently required documents for NCE registration, it is also proposed that an assessment report prepared by a local expert with fellowship or equivalent qualification (preferably to be independent) on the safety and efficacy of the product shall also be included in the application.

[1] The 32 reference countries are Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and US.

3. HKAPI's Comments

3.1 On the First Proposed Criterion – "*there is a local unmet medical need for the product with public health perspective*"

At this phase, HKAPI recommends aligning the definition of "local unmet medical need with public health perspective" with that of "communicable diseases of public health importance" as classified by DH's Centre of Health Protection ("**CHP**") and published in public information platform, i.e. any disease that might become pandemic and cannot be treated effectively by any currently available drug or treatment option in Hong Kong. This list of communicable diseases is updated according to Hong Kong's situation by the six scientific committees of CHP[2]

Moving forward, HKAPI recommends, referring to Singapore's mechanism for priority review[3], that DH considers, at the next phase, to broaden the above-suggested definition to include also non-communicable diseases such as cancers, based on local public health priorities.

3.2 On the Second Proposal Criterion – "*the product must be registered in at least one of the above reference countries and/or registered in the country of origin*"

To deter applicants from taking advantage of the "or" clause here, HKAPI suggests adding the following sentence at the end of this proposed criterion: "*In case the product is only registered in the country of origin, the applicant*

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[2] They are Scientific Committee on AIDS and STI, Scientific Committee on Emerging & Zoonotic Diseases, Scientific Committee on Enteric Infections and Foodborne Diseases, Scientific Committee on Infection Control, Scientific Committee on Vaccine Preventable Diseases and Scientific Committee on Vector-borne Diseases.

[3] The drug must be intended for the treatment of a **serious life-threatening condition** and demonstrates the **potential to address local unmet medical needs**, as defined by:
(i) the **absence of a treatment option**; or
(ii) the lack of safe and effective alternative treatments, such that the drug would be a **significant improvement compared to available marketed products**, as demonstrated by
(A) evidence of **increased effectiveness** in treatment, prevention, or diagnosis; or
(B) elimination or a **substantial reduction of a treatment-limiting drug reaction**.
Drugs that fulfill the above criteria may be considered for priority review.

must provide justification for not registering it in any of the reference countries."

In addition, HKAPI has a query whether DH would consider an application if the product's country of origin is not a member of the Pharmaceutical Inspection Co-operation Scheme ("**PIC/S**"). If yes, DH needs to have measures or criteria to ensure the quality of the drugs being manufactured by non-PIC/S member countries.

3.3 On the Third Proposed Criterion – "*the product is promulgated by reputable international health agencies on human or veterinary medicines, including the World Health Organization (WHO), World Organization for Animal Health (OIE), Food and Agriculture Organization of the United Nations (FAO), etc.*"

Given that DH's own judgment on the necessity to approve the registration of a particular drug in the event of a pandemic disease outbreak is the most crucial, HKAPI suggests the satisfaction of this criterion be made optional rather than compulsory, and this criterion shall only apply to communicable diseases. Hence, HKAPI suggests amending the wordings to **"***the product for communicable diseases is promulgated by reputable international health agencies on human or veterinary medicines, including the World Health Organization (WHO), World Organization for Animal Health (OIE), Food and Agriculture Organization of the United Nations (FAO), etc.*"

3.4 On the Proposed Additional Requirement – "*an assessment report prepared by a local expert with fellowship or equivalent qualification (preferably to be independent) on the safety and efficacy of the product shall also be included in the application*"

HKAPI is of the opinion that it is unrealistic to ask the applicant himself to provide the assessment report prepared by a local expert of its choice and expect such expert, who is a service provider to the applicant's company in writing up the report, to be totally independent and totally unbiased.

To ensure that the safety and efficacy of the product are reviewed independently, HKAPI suggests that the Pharmacy and Poisons Board of Hong Kong ("**PPB**") invites a local expert of its choice to review the application.

If deemed necessary, PPB could ask pharmaceutical companies to provide their or their appointed expert's opinion of the product, or even request the applicant to have experts to present data at PPB's review meeting and address potential questions.

4. <u>Other Comments by HKAPI</u>

- Sufficiency and availability of the applicant's submitted application documents should be evaluated on a case by case basis, allowing more room for flexibility when the unmet medical need situation becomes out of control.

- When a product has fulfilled the proposed criteria, an ad hoc PPB meeting shall be convened to evaluate the application, to shorten review timeline by giving such application an expedite consideration.

- A special importation process based on PPB's endorsement shall be in place, instead of letting the applicant wait in the normal application queue for obtaining product license.

- Due to system limitation and incompatibility, the usual requirement for electronic submission for this type NCE application shall be scrapped.