FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Hong Kong	**Agency Name:** Department of Health (DH)	
Name of FRP: Registration of Advanced Therapy Products		
Is this FRP Proposed or Active? Proposed		
Date FRP was officially enacted: 10/18/2019		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☒	☒

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	Choose an item.
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	Hong Kong has proposed legislation to create a regulatory framework for **advanced therapy products (ATPs)**, such as interventions based on cells, genes and tissues. The plan is to amend existing laws to create licensing, labeling and record-keeping requirements for ATPs. NB: blood transfusion, cornea transplant and bone marrow transplant are not considered as ATPs.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	The application fee, currently at $1,100, to be paid via PRS 2.0 with credit card/PPS online payment services, or in person by cash or cheque along with the notification of payment. When an application is approved, you will be required to pay a registration fee of $1,370 per product. You will receive the Certificate of Drug/Product Registration when we have received the payment.
Total target (agency) time for assessment (calendar days)	Click here to enter text.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

Select one of the following (* see definitions at end of document)

Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**
☐	☐	☒

If this is a reliance or recognition pathway, what are the accepted reference agencies?	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,

FRPath.org Country and FRP Information Input Form	
	Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA. Approvals from the EU countries must be issued from the EMA.
How many reference agency decisions are required?	Minimum 1.
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Not applicable
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes. The applicant must submit official evidence of registration approval of the product (e.g. soft copy and original or certified true copies of free sale certificates) in two or more of the following countries[1]: 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 USA. [1] Approvals from the EU countries must be issued from European Medicines Agency (EMA).
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- Draft guidance is open for comment until 31 December 2020. Please send your views to the Drug Office of the Department of Health through email (pharmgeneral@dh.gov.hk), mail (Rm 1856, 18/F, Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong) or facsimile (3904 1224). - The technical requirements for The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Common Technical Document (CTD) Modules

FRPath.org Country and FRP Information Input Form	
	3 to 5 for pharmaceutical products apply to registration of ATP. - Relevant Risk Management Plan (RMP) approved by reputable regulatory authority(ies) is/ are required for the product along with information on whether any of the risk management plan activities and mitigation strategies will be implemented in Hong Kong.
Date of this update	27 October 2020
References	1. Asia Regulatory Roundup: Hong Kong Proposes Regulatory Framework for Cell and Gene Therapies. https://www.raps.org/news-and-articles/news-articles/2019/10/asia-regulatory-roundup-hong-kong-proposes-regula Accessed on 27 October 2020. 2. Pharmacy and Poisons (Amendment) Bill 2019 to regulate advanced therapy products. Accessed on 27 October 2020. 3. Regulation of Advanced Therapy Products. Accessed on 27 October 2020. 4. Guidance on Application of Certificate of Drug/ Product Registration — Advanced Therapy Products Version 1.0.1 (Draft for comment). Accessed on 27 October 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.

This FRP Information Input Form v3.3 is ©2020 FRPath.org and the Erudee Foundation.