FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Israel	**Agency Name:** Ministry of Health (MOH) Pharmaceutical Division	
Name of FRP: Abridged Procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: Click here to enter a date.		
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?	Before the marketing authorisation submission	
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	Under the Ministry of Health (MOH) Procedures, generic versions of "chemical"/"small molecule" medicinal products are generally registrable based on bioequivalence studies and are generally exempted from producing pre-clinical and clinical data. An applicant for the registration of a generic product is not privy to any information contained in the Drug Master File of the innovative product and relies only on the fact of registration of the innovative product. In general, a generic product is registrable in Israel only if its innovative version is registered and on the market in Israel. However, under the MOH Procedures, the MOH can approve the registration of a generic product based on its innovative version where the registration of the innovative product has expired or the innovative product has been discontinued in Israel. In addition, where the innovative product has been discontinued in all of the recognised countries, the MOH can approve the registration of a generic product based on another generic version that is marketed in Israel. The MOH will consider a product as generic if it comprises the same active pharmaceutical ingredients (API) as the innovative product (with the same strength and dosage form), even if the generic API is in a different form (different salt, ester, ether, isomer or mixture of isomers) from the innovative product. However, if there is a material difference in characteristics that impact safety or efficacy, the applicant for the registration of the generic product must establish to the MOH that the difference does not in fact prejudice the safety or efficacy of the product.	

FRPath.org Country and FRP Information Input Form	
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	The main fees are as follows: • The fee to obtain a Quality Control Certificate for the medicinal product is ILS16,326 [USD 4,740] and the renewal fee is ILS6,651 [USD 1,931]. • The fee for registering a pharmaceutical product on the Israel Drug Register is ILS6,022 [USD 1,748] and the renewal fee is ILS1,875 [USD 545].
Total target (agency) time for assessment (calendar days)	180 days (excluding periods of time in which the applicant responds to a MOH letter of deficiencies) for new medicinal products that are already registered or received a positive opinion by one of the following regulatory agencies: • The Food and Drug Administration. • The European Medicines Agency. • The Swiss Agency for Therapeutic Products (Swissmedic). **Generic products that file for registration in Israel after receiving marketing authorisation from the Food and Drug Administration or by the European Medicines Agency, must be registered by the MOH within 70 days (as opposed to the standard examination period which is 270 days) (*section 47A(a2)(2), Pharmacists Ordinance*).
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?	- The Food and Drug Administration. - The European Medicines Agency. - The Swiss Agency for Therapeutic Products (Swissmedic).
How many reference agency decisions are required?	1
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes at time of submission
Can an alternate form of	An application for an imported product must be filed together with

FRPath.org Country and FRP Information Input Form	
reference documentation to the CPP be used? If so, what types of documents?	a Certificate of Pharmaceutical Product (CPP) issued by a recognized country no sooner than two years before the application date. The CPP must indicate that the pharmaceutical product is authorized for marketing in the recognized country. However, according to a recent MOH Procedure which modifies previous requirements, the CPP need not normally indicate that the pharmaceutical product is actually on the market in the recognized country (unless the application is for a generic product under the 70 days registration track, in which case a CPP issued by the Food and Drug Administration or the European Medicines Agency must be filed, indicating that the pharmaceutical product is actually on the market). In addition, as part of the registration process the applicant must obtain a Quality Control Certificate for the medicinal product, testifying that the product is of suitable quality for medical use. An application for the grant of the Certificate must be filed to the Files Assessment Department of the Institute for Standardisation and Control of Pharmaceuticals at the Pharmaceutical Division. An application to obtain marketing authorisation for the first batch of the registered product must be filed to the Pharmaceutical Control Section at the Pharmaceutical Division and to the Institute for Standardisation and Control of Pharmaceuticals.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this process is not through a Regional Regulatory Initiative.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, the product has to have been marketed in another country. With respect to imported pharmaceutical products, the product must be authorized for marketing in a recognized country (US, Canada, a pre-2004 EU country, Switzerland, Norway, Iceland, Australia, New Zealand and Japan).
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?	4-5 years
Any other details you wish to provide?	- Under Israeli legislation, the authorisation process for marketing medicinal products consists of two parts: (i) Registration of the medicinal product in the Israel Drug Register; (ii) Grant of marketing approval for the first batch of the product that is marketed in Israel for the first time. - The registration of the medicinal product must be under the

FRPath.org Country and FRP Information Input Form	
	name of an Israeli resident or a corporation registered in Israel (registration holder). - The MOH must be satisfied that the Registration Holder has in place a pharmacovigilance (PhV) system. - Before filing an application for registration for a new medicinal product and the start of the 180 days period, the applicant must file with the MOH an application for a preliminary assessment of the product, and obtain approval to file the main application. Under the MOH Procedures, the MOH strives to complete the preliminary assessment within five business days. However, it is possible to file the application for a preliminary assessment to the MOH only on one specific day per month (as of 2019). - Pharmaceutical products are registered in Israel for an initial period of about five years and are then renewed for additional consecutive periods not exceeding ten years each. An application for renewal must be filed to the MOH by the appointed pharmacist of the Israeli registration holder no later than 30 days prior to the expiry of each registration. Each renewal is subject to MOH discretion (which, of course, must be reasonable).
Date of this update	4 February 2020
References	1. Medicinal product regulation and product liability in Israel: overview. https://uk.practicallaw.thomsonreuters.com/w-016-6339?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1 Accessed on 4 February 2020 2. Pharmaceutical drug Products registration/submission in Israel. https://bio-chem.co.il/en/blog/pharmaceutical-drug-products-registrationsubmission-in-israel/ Accessed on 4 February 2020 3. State of Israel Ministry of Health, Pharmaceutical Division. https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx Accessed on 4 February 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.