FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Chile	**Agency Name:** Instituto de Salud Pública (ISP CHILE)	
Name of FRP: Sanitary Registration of Orphan Medicines		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 2/5/2015		
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?	At the time of the 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	Orphan pharmaceutical product or orphan drug: that drug intended for the diagnosis, prevention or treatment of a rare disease or a disease whose etiology has an equivalent frequency.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Click here to enter text.
Total target (agency) time for assessment (calendar days)	Review times: 6 – 12 months.
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?	Agencies such as the FDA and / or EMA.
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?	Choose an item.

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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?	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. At the time of entering the registration application, the interested party must duly substantiate that it is an orphan drug, through certificates issued by health authorities such as the FDA or EMA, accrediting the orphan drug status for the reference drug, or that the medication is on the list of orphan drugs prepared by the Ministry of Health for this purpose.
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?	- It is established that the products whose sanitary registration is granted must be the object of special Pharmacovigilance measures, in application of the provisions of article 218 of DS No. 3/2010 of the Ministry of Health. Said measures will be indicated and based on the resolution that grants the sanitary registry, must include at least the sending of Periodic Safety Reports and the presentation of a Risk Management Plan, all in accordance with the provisions of General Technical Standard No. 140 "On the National Pharmacovigilance System of Pharmaceutical Products for Human Use" (Res. Ex. Minsal Nº381 / 2012).
Date of this update	31 May 2020
References	1. Approves recommendations on sanitary registration of orphanic medicines. Accessed on 31 May 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.