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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Chile	**Agency Name:** Instituto de Salud Pública de Chile (ISP)	
Name of FRP: Priority Review: Simplified Registration 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?	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	Simplified Procedure is for the registration of Pharmaceutical Products (generics): - The simplified procedure allows for the omission of specific data regarding safety and efficacy of the pharmaceutical product filed for registration and it is permitted, in general, for pharmaceutical products containing the same active ingredient, in the same pharmaceutical dosage form and the same administration route as another product which currently has or had in the past a sanitary registration granted by the ISP and which has not been cancelled for public safety issues. - Specific therapeutic equivalence studies will be required for products containing active ingredients as per Decree No. 500 of 2012 of the MoH approving Technical Guideline No. 136 which establishes the active ingredients included in pharmaceutical products that must demonstrate therapeutic equivalence and its amendments. - For biological products, the generic pathway or simplified procedure for registration is prohibited. Nevertheless, for specific biotechnological products included in Technical Guideline No. 170, a biosimilar pathway is available, permitting the reduction or abbreviation of safety and efficacy data based upon head to head, stepwise comparability studies with the reference biotechnological product in all quality-characterization, non-clinical and clinical stages.	
Must the product address an unmet medical need or serious condition?	Yes	

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If a fee is required, what is the amount (in US$ equivalent)	GOVERMENT FEES IN USD FOR MARKETING AUTHORIZATION FOR: - GENERICS (Simplified Procedure) = USD 1600.	
Total target (agency) time for assessment (calendar days)	6 months (this is a legal deadline)	
Total target (company) time for responses to agency questions (If stated)	10 – 30 working days.	
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?	Click here to enter text.	
How many reference agency decisions are required?	Click here to enter text.	
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes at time of submission	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Certificate is for those products imported during any stage of the production process, issued by the corresponding health authority of the country where the manufacturing facilities are located certifying that the foreign manufacturer is duly authorized in their country and follows Good Manufacturing Practices in accordance with WHO recommendations. It also indicates that production areas or types of products are authorized for manufacturing, unless such information is included in the document such as marketing authorization certificate, pharmaceutical product certificate, marketing authorization certificate or official certification recommended by the World Health Organization issued by the authorities of the country of origin and duly legalized.	
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?	Click here to enter text.	

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How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- always
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?	- Any pharmaceutical product, whether imported or manufactured in the country, requires a sanitary registration (marketing authorization) in order to be distributed or used under any title in Chile (a pharmaceutical product may be exceptionally authorized by the ISP to be used temporarily without prior sanitary registration if an epidemic, emergency or catastrophe occurs, or if required for an urgent medical use or for scientific research or clinical trials). - In general terms, for the sanitary registration of a pharmaceutical product the applicant will be required to comply with general requirements including the submission of administrative information, technical information, pharmaceutical quality information and data on safety and efficacy of the product. Special requirements will also be applicable for fixed dose combination products, pharmaceutical combination products, phytopharmaceutical products; homeopathic products and biologicals. - Sanitary registrations for pharmaceutical products will last for a period of 5 years, which is renewable for equal and successive periods, if not cancelled. - The marketing authorization of generic drugs can be according to the ordinary approval procedure ("New Drug Application"), the simplified approval process ("Simplified Registration Procedure"), or the abbreviated approval process ("Short Registration Procedure"). The registration procedure will depend on the pharmaceutical product (NDA for new active ingredients, new doses or new routes of administration; Simplified procedure if there are any products already approved with the same ingredients in the same dose and with the same route of administration; and Short procedure if the Ministry of Health requests it either for the implementation of public health plans and programmes, or if the active ingredient is added to the National Formulary).
Date of this update	22 February 2020

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References	1. Drug Approval System of Chile. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwidoefV6OPnAhUEahQKHS-8CbwQFjAAegQIAhAB&url=http%3A%2F%2Fwww.nifds.go.kr%2Fbrd%2Fm_95%2Fdown.do%3Fbrd_id%3Dboard_mfds_411%26seq%3D22991%26data_tp%3DA%26file_seq%3D1&usg=AOvVaw0FnA8qPnPrraG_uAZVAvbt Accessed on 22 February 2020. 2. Regulatory, Pricing and Reimbursement. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-chile/ Accessed on 22 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.

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