FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Turkey	**Agency Name:** Turkish Drug and Medical Device Institution (TITCK)	
Name of FRP: TITCK Priority Assessments		
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	- Applications relating to first generic products or products of which generic is authorized but not on the market, - Applications relating to biosimilar products, - Applications relating to innovative products, - Applications relating to transferring the production of imported medicines to our country, - Applications for locally manufactured products for exportation purposes , - Applications relating to products which cause serious public health problems in case they are not ready for use including vaccines or those which are included in the Agency's foreign medicine procurement list on the date of application, - Applications relating to products of companies which are benefited from the governmental incentives in the fields of R&D, manufacturing and marketing, - Special import permit applications, - Applications relating to the Good Manufacturing Practices (GMP) audit, - Applications relating to products which have strategic importance in terms of country policies.
Must the product address an unmet medical need or serious condition?	Negotiable
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)	According to TITCK regulations, the overall approval target timeline is 210 calendar days, 180 calendar days for a

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	prioritized accelerated review and 150 calendar days for highly prioritized products. However, *prioritized accelerated review* and *highly prioritized* are not defined in the regulation. Nevertheless, the draft updated registration regulation provides more clarity on those definitions. In any case, the actual approval timelines are much longer in practice than those stated in the TITCK regulation. The TITCK review process consists of the following common steps: validation of the submitted dossier, scientific assessment, company response and final authorization.
Total target (company) time for responses to agency questions (If stated)	If the submission is found to be inadequate the applicant has to complete the deficiencies in 30 days. In the second pre-assessment step the revised dossier is evaluated in 30 days. If the dossier still lacks the necessary information the application is rejected by the Agency.

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?	No
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Submission of a Certificate of Pharmaceutical product (CPP) with an application is not required; however, evidence of approval in another country is required for final authorization by the TITCK.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, it 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?	Evidence of approval in another country is required for final authorization by the TITCK.
How are queries to the companies sent?	
Are external reviewers (e.g. non-	Yes- always

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agency) involved in the assessment?	
Post-authorization study commitments	Choose an item.
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- It is necessary to apply for prioritization in order to prioritize a product. However, Prioritization Commission may put some products on its agenda without prioritization request (application) if deemed necessary. - TITCK's queries are not sent in batches; however information on whether they are sent as they arise or at specified times during the assessment was not found.
Date of this update	4 JANUARY 2020
References	1. Mashaki Ceyhan E, Gürsöz H, Alkan A, Coşkun H, Koyuncu O, Walker S. The Turkish Medicines and Medical Devices Agency: Comparison of Its Registration Process with Australia, Canada, Saudi Arabia, and Singapore. *Front Pharmacol*. 2018;9:9. Published 2018 Jan 25. doi:10.3389/fphar.2018.00009 2. TURKISH MEDICINES AND MEDICAL DEVICES AGENCY GUIDELINE FOR WORKING PRINCIPLES AND PROCEDURES OF HUMAN MEDICINAL PRODUCTS PRIORITY ASSESSMENT COMMISSION. https://titck.gov.tr/storage/legislation/QgR2Se2X.pdf Accessed on 4 January 2020. 3. Turkish Medicines and Medical Devices Agency Marketing Authorization Procedure. 4. DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF Accessed on 4 January 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.