FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Algeria	**Agency Name:** Agence Nationale des Produits Pharmaceutiques (ANPP)	
Name of FRP: Autorisation Temporaire d'Utilisation (ATU)		
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?	Choose an item.
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	All products
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Marketing approval fees for new drugs, biologics, and medical devices are fixed as part of Finance Law. They depend of the product type, importance and origin (imported or locally manufactured). As at July 2019, the current authorization fees are ranging between 100.000 DZD and 1.000.000 DZD (approx. 835 to 8.350 USD).
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?	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	Negotiable

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Product) required for approval?	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	No, the CPP is required.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	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 needs to have been marketed in another country. Foreign marketing authorizations are recognized and required for imported products under provisions of Decree No 92-284 dated of 6 July 1992, published in the Official Gazette, and related to registration of pharmaceutical products for human use. The foreign market authorization applicant in Algeria has to designate a reference market abroad (referred at as country of origin). In addition, a valid Certificate of Pharmaceutical Product issued by the competent regulatory authorities of country of origin in the format recommended by the World Health Organization + copy of valid marketing authorization in country of origin and/or CE marking certificate (for medical devices) are required as part of initial submission dossier and for the 5-year renewal.
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?	- To obtain market authorization for new drugs, biologics and medical devices in Algeria, submission of application to Ministry of Health is required, and must be accompanied by a submission dossier that includes clinical data. - Ongoing regulatory reform related to the establishment of the ANPP is likely to enter in application during the 2020-2021 biennium. The transfer process is gradual and follows a stepwise approach. The Decree No 19-190 dated of 3 July 2019, setting out missions, organization and operating of the National Agency for Pharmaceutical Products (ANPP), has been published in the Official Gazette No 43 dated of 7 July 2019. The headquarters of the ANPP was set in Algiers, while

	regional annexes of the agency may be created by order of the Minister of Health. Furthermore, activities related to products assessment, registration of drugs, and homologation of medical devices, have already been transferred from DGPES to ANPP. - There are currently no specific regulations for the authorization of orphan drugs in Algeria. The regulatory framework for the authorization, pricing, and reimbursement remains the same as for the other drugs. - There are neither specific regulations for similar biotherapeutic products in Algeria for the moment, nor this term is used in legal provisions prior to Article 210 of the Health Law No 18-11, dated of 2 July 2018 and published in the Official Gazette. - In practice, existing similar biotherapeutic products were approved according to the regulatory framework applicable to other drugs, on the basis of application including manufacturing and quality control data, and where mandatory, non-clinical and clinical comparative data with the reference biotherapeutic product. - The market authorization holder is obliged to notify any identified event related to the product safety that occurred locally or abroad, including those supposedly attributable to vaccination, and must report regularly or upon request to the National Center for Pharmacovigilance and Materiovigilance ("CNPM" – "Centre National de Pharmacovigilance et de Matériovigilance"), created by Decree No 98-192 dated of 3 June 1998 and published in the Official Gazette. - A temporary authorization for use ("ATU" – "Autorisation Temporaire d'Utilisation") may be exceptionally issued by Ministry of Health for non-registered products, when the latter are prescribed as part of the management of serious diseases in situations where there is no equivalent treatment in the national territory, and have proven their therapeutic benefit.
Date of this update	23 MARCH 2020
References	1. Regulatory Reforms: Algeria. https://pharmaboardroom.com/legal-articles/regulatory-reforms-algeria/ Accessed on 23 March 2020. 2. Biosimilar and Biologics: Algeria.

https://pharmaboardroom.com/legal-articles/biosimilars-and-biologics-algeria/ Accessed on 23 March 2020.
3. Marketing, Manufacturing, Packaging & Labeling, Advertising. https://pharmaboardroom.com/legal-articles/marketing-manufacturing-packaging-labeling-advertising-algeria/ Accessed on 23 March 2020.
4. Pharma Legal Handbook: Algeria. https://pharmaboardroom.com/wp-content/uploads/2019/12/PLH_ALGERIA_Final-new-exhibits01-10.pdf Accessed on 23 March 2020.
5. Regulatory, Pricing & Reimbursement Overview. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-overview-algeria/ Accessed on 23 March 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.