FRPath.org
Where the Roads to Accelerated Assessments Converge

| *FRPath.org Country and FRP Information Input Form* | | |
|---|---|---|
| **Country:** Ukraine | **Agency Name:** State Service of Ukraine on Medicines and Drugs Control (SMDC) | |
| **Name of FRP:** Authenticity 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?** | 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** | All products (as long as they meet the criteria for the "authenticity" procedure). | |
| **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)** | The duration of the procedure for registration under "authenticity" procedure is **5 working days**. This period does not include:<br>- the period of consideration of the Application and the registration form;<br>- payment of the government levy and receiving the payment confirmation;<br>- final actions after expert evaluation (verification/proofreading of drafts of the registration certificate and its addenda);<br>- the period of signing the Order of the MOH on the registration of the medicinal product.<br>The above actions take an average of 1 to 2 months, and accordingly extend the resulting period for registration. | |
| **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** | Click here to enter text. | |

| *FRPath.org Country and FRP Information Input Form* | |
|---|---|
| **pathway, what are the accepted reference agencies?** | |
| **How many reference agency decisions are required?** | Click here to enter text. |
| **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 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. |
| **How are queries to the companies sent?** | Choose an item. |
| **Are external reviewers (e.g. non-agency) involved in the assessment?** | Yes- as needed |
| **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?** | - In 2015, in order to combat corruption, centralized purchases of medicinal products and medical devices were transferred to specialized international organizations that carry out procurement. These organizations include specialized funds, organizations and mechanisms of the Organization United Nations, the International Dispensary Association, the Crown Agents, the Global Drug Facility, the Partnership for Supply Chain Management, the NATO Support and Procurement Agency, which provide the governments and/or central government with services in the organization and conduct of procedures for the procurement of medical products, medical devices and related services.<br>- To implement the possibilities of such purchases, the simplified registration procedure was adopted (called the "authenticity" procedure). This |

| | |
|---|---|
| | registration procedure makes it possible to register the medicinal product as soon as possible. At the same time, a specialized expert evaluation of the registration dossier is not carried out, and the SEC conducts an audit of the accuracy of the translation of the instruction for use and the availability of the necessary documentation (completeness of the dossier).<br>- For the registration of a medicinal product by the "authenticity" procedure, the Applicant must comply with the requirements for the management of the safety of the medicinal product, namely, to assign a contact person responsible for pharmacovigilance in Ukraine, to establish and maintain a pharmacovigilance system throughout the validity of the registration certificate.<br>- **Important features of the procedure:**<br>1. The registration certificate does not allow importation for other purposes, except for purchase by international specialized organizations. That is, such a certificate does not give the right to import the medicinal product for retail sale, participating in other purchases, etc.<br>2. The procedure does not imply any changes to the registration certificate, or re-registration.<br>3. Labeling of the package of the medicinal product, as well as the instruction is carried out in the original language.<br>4. The set of documentation that must be submitted for state registration should include, in addition to other documents, an assessment report for the medicinal products drawn up by a competent regulatory authority of the country where this medicinal product is registered or issued by the WHO if the medicinal product is pre-qualified. For many medicinal products registered more than 15 years ago this requirement can be quite a significant problem. |
| **Date of this update** | 19 JANUARY 2020 |
| **References** | 1. Abridged registration procedures. https://cratia.ua/en/state-registration-medicines-and-active-pharmaceutical-ingredients/abridged-registration-procedures Accessed on 18 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.