Notice to Applicant

Rules for registering biological products under the fast-track registration pathway

2026

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List of abbreviations:

ACWY	Meningococcal Meningitis vaccine (serotype A,C,W,Y)
DT	Diphtheria -tetanus
DTP	Diphtheria -tetanus- Pertussis
DTP-HB-Hib	Diphtheria-Tetanus-Pertussis-Hepatitis B vaccine- Haemophilus influenza
EMA	European Medicines Agency
FDA	Food And Drug Administration
HBsAg	Hepatitis surface Antigen
MMR	Measles Mumps Rubella

Introduction:

The fast-track prioritizes the marketing authorization of products that meet the required criteria. This system enables the Central Administration for Biological and Innovative Products and Clinical Studies to issue marketing authorization licenses within a shorter timeframe than stipulated in the regulations and rules governing the normal marketing authorization track of biological products. Resources are allocated and review priorities are established for these products by all relevant departments, ensuring that the final marketing authorization license is issued within maximum of **90 WDs**.

Definitions:

Prequalified vaccines: Vaccines that are included in the list of prequalified products published on the World Health Organization website

Vaccine deficiency: The strategic stock is insufficient to meet the needs of the vaccine for three months, according to the need of Ministry of Health

Biological products deficiency: The strategic stock is insufficient to meet the needs of the product for three months, according to the report of shortage administration at EDA

Mandatory vaccinations: Vaccinations used in the Expanded Program on Immunization to vaccinate children under two years of age against infectious diseases.

School children's vaccinations: Vaccinations target school-aged children.

Traveler vaccinations: Vaccinations used to immunize travelers to countries with infectious diseases.

Unmet medical/patient needs: The product either treats or prevents a condition with no current therapy

OR in case there are available therapies, that product submitted for marketing authorization through fast track shows some advantage over available therapy, such as:

- Showing superior effectiveness, or improved effect on serious outcomes.
- Avoiding serious side effects of an available therapy.
- Improving the diagnosis of a serious condition where early diagnosis results in an improved outcome.
- Decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment.
- Ability to address emerging or anticipated public health needs.

Key criteria:

The fast-track marketing authorization pathway is based on granting special priority in the marketing authorization procedures for biological products that meet the criteria of this system, in accordance with public health priorities and requirements. This pathway applies to the following biological products:

- **Mandatory vaccinations included in the Expanded Program on Immunization:** For example, but not limited to, Oral polio vaccine, tuberculosis vaccine, measles, mumps, and rubella (MMR) vaccine, diphtheria, tetanus, and pertussis (DTP) vaccine, hepatitis B vaccine for infants, pentavalent vaccine (DTP-HB-Hib).
- **School child vaccinations:** For example, Meningococcal vaccine (A,C) and diphtheria-tetanus (DT) vaccine for children.
- **Traveler vaccinations:** For example, Cholera, typhoid fever, quadrivalent meningococcal vaccine (A, C, W, Y), seasonal influenza vaccine, and yellow fever vaccine.
- **Therapeutic serums:** For example, snake venom antiserum, anti-scorpion serum, Rabies immunoglobulin, tetanus antitoxin (1500 IU and 30,000 IU), diphtheria antitoxin.
- **Other vaccines:** For example, Rabies vaccine.
- **Other cases, in accordance with the decision of the Technical Committee for Drug Control**
  - Products intended for treatment of a serious life threating condition.
  - The product demonstrates the potential to address unmet medical / patient needs.

Steps for Implementing the fast-track marketing authorization procedure:

- After the issuance of the inquiry approval and fulfillment of the key requirements, the applicant may submit a request to transfer the application to the fast-track marketing authorization pathway, subject to payment of the prescribed service fee.
- The registration administration shall communicate with the shortages administration to obtain information regarding the strategic stock level of the product.
- The Registration administration shall decide on applications submitted under the fast-track marketing authorization pathway without the need for referral to the Technical Committee. Specialized scientific committees may be consulted, where necessary, to provide an assessment of the importance of the submitted products.
- Upon approval by the registration administration to proceed under the fast track marketing authorization pathway, the company shall submit a request via email to schedule an appointment for dossier submission at: bioreg.rec@edaegypt.gov.eg Such request must be submitted within a maximum of **15 WDs** from the date of approval for registration through the fast-track pathway.
- An appointment for dossier submission shall be scheduled within a maximum of **3 WDs** from the date of receipt of the company's request.
- All remaining registration procedures and steps shall be conducted in accordance with the Regulatory Guideline for the Implementation of Egyptian Drug Authority Chairman Decision No. 343/2021 (Code: EDREX.GL.Bioinn.001), provided that all registration process is completed within **90 WDs.**

References:

- Egyptian Drug Authority Chairman Decision No. 343 of 2021 issuing rules for registering biological products.

History table

Version No	Issue date	Summary of changes
3	7/7/2026	Rephrasing and updating the Steps for Implementing the fast-track registration procedure