General Decisions of the Technical Committee for Drug Control Regarding the Egyptian Drug Authority Website

Decisions of the Technical Committee for Drug Control at its session on 12/02/2026

* - Not approving the reception of new products containing (Calcium carbonate + Famotidine + Magnesium Hydroxide) in the pharmaceutical dosage form of Effervescent Granules, based on the decision of the Scientific Committee for Medical Products for Liver and Digestive System Diseases at its session on 15/12/2025, and the Scientific Committee for Medical Products for Internal Medicine Diseases at its session on 02/02/2026.

- Note: -

- The Scientific Committee for Medical Products for Liver and Digestive System Diseases at its session on 15/12/2025 recommended to disapprove the product scientifically, as the company did not provide a scientific justification demonstrating the therapeutic advantage of the proposed dosage form over the dosage form of the reference product (Chewable tablet), in addition to the availability of multiple alternatives in the Egyptian market with the same therapeutic purpose.

- The Scientific Committee for Medical Products for Internal Medicine Diseases at its session on 02/02/2026 recommended to disapprove the product scientifically, as the dosage form does not offer a therapeutic advantage over the alternatives available in the Egyptian market for the same therapeutic purpose, in addition to the following:

1. The reference dosage form (Chewable tablet) is easier to use.
2. The presence of Calcium carbonate in the dosage form (Effervescent Granules) may increase the occurrence of Gastric Distension & Bloating, which may conflict with the therapeutic purpose presented by the company.

* - Not approving the reception of new products containing (Clindamycin + Clotrimazole) in the pharmaceutical dosage form Vaginal dosage form, based on the decision of the specialized Scientific Committee for Obstetrics and Gynecology Diseases at its session on 21/01/2026.

- **Note**: -
- The Scientific Committee for Medical Products for Obstetrics and Gynecology Diseases at its session on 21/01/2026 recommended to disapprove the product for the following reasons:
- There are no recent scientific studies confirming the safety and efficacy of the two substances together as a Fixed dose combination in the treatment of Mixed Vaginitis.
- According to the protocols followed in the treatment of Mixed Vaginitis, the committee finds that:
- Combining two substances Clindamycin (Antibacterial) & Clotrimazole (Antifungal) as a Fixed dose combination provides a broad-spectrum treatment that may lead to misuse in pathological conditions that do not require the use of both substances together.
- The treatment may require other active substances besides these two.

* - Approval to complete the registration procedures for products containing Tirzepatide in the submitted pharmaceutical dosage form Single dose prefilled syringe, with the commitment to

fulfill the requirements of the Quality Committee at its session on 14/01/2026, provided that the decision applies to generic products under registration.

- **Note**: -

- The Quality Committee at its session on 14/01/2026 decided the following:

The proposed pre-filled syringe presentation of Tirzepatide can be considered acceptable on the condition of the following recommendations:

1- The primary container closure system (glass syringe) should be comparable to the glass syringe that is encased in the single-dose prefilled pen (Autoinjector) presentation of the reference product. It is recommended that the needle not come in contact with the drug product.

2- The manufacturing process should be similar to the reference product with studying the effect of critical steps (e.g. plungering) on the stability of the product.

3- The photostability should be investigated and the prefilled syringe should be packaged with appropriate light-protective measures and labeled accordingly.

*** - Concerning the substance Tween 80:** The decision of the Technical Committee at its session on 04/10/2018 is to be updated to include "Products containing Anidulafungin with Tween 80 or Polysorbate 80 may be used for children starting from one month of age, provided that the following warning is written in the package leaflet and on the outer packaging of the product: Do not use for newborns less than one month of age," based on the decision of the Scientific Committee for Medical Products for Pediatric Diseases at its session on 26/10/2025.

- Note: -

- The Technical Committee decided on 04/10/2018, based on what was presented: To cancel the decisions of the Technical Committee at its sessions on 12/04/2012 and 26/11/2015 and to approve the recommendation of the Pediatrics Committee at its session on 03/07/2018, with the review of doses according to age and ensuring that the percentage of Dioxan does not exceed the permissible limit according to pharmacopoeias.

- **The Scientific Committee for Medical Products for Pediatric Diseases recommended at its session on 26/10/2025:** According to scientific references and reference countries, products containing Anidulafungin, which also include Tween 80 or Polysorbate 80, are used for children starting from one month of age. Accordingly, the committee recommends using products containing Anidulafungin with Tween 80 or Polysorbate 80 for children starting from one month of age, provided that the following warning is written on the package leaflet and the outer packaging of the product: Do not use for newborns less than one month of age.

Decisions of the Technical Committee for Drug Control at its session on 26/02/2026

* - Disapproval of completing the registration procedures for products under registration containing the following combination:
(Tablet contains: Alendronic acid (as alendronate monosodium monohydrate) 70 mg / Soft gelatin Capsule Contains: Alfacalcidol 1 mcg)
And their cancellation and deletion from the boxes and the Egyptian Drug Authority database according to the rules, and not approving the reception of new products containing this combination in this pharmaceutical dosage form, based on the decision of the Scientific Committee for Medical Products for Rheumatology, Rehabilitation, and Orthopedic Surgery at its session on 16/02/2026.

- **Note**: -

- The Scientific Committee for Medical Products for Rheumatology, Rehabilitation, and Orthopedic Surgery at its session on 16/02/2026 recommended to disapprove the product scientifically, as the dose of Vitamin D varies from one patient to another depending on the patient's condition, in addition to the availability of alternatives for each substance individually in the Egyptian market.

* - Not approving the reception of new products and disapproval of completing the registration procedures for products under registration containing Dantron, and deleting them from the boxes and canceling them from the Egyptian Drug Authority database, applying the rules, in affirmation of the decision of the Scientific Committee for Medical Products for Pediatric

Diseases at its session on 13/01/2026 and the Committee for Liver and Digestive System Diseases at its session on 09/02/2026.

- Note: -

- The Scientific Committee for Medical Products for Pediatric Diseases at its session on 13/01/2026 recommended to disapprove the submitted combination scientifically for use in children for the following reasons:

1. According to scientific references, studies conducted on laboratory animals have proven that the use of Dantron is associated with the occurrence of Adenocarcinoma in the intestines and liver tumors, and the risk of similar effects in humans cannot be ruled out.
2- The existence of alternatives in the Egyptian market that have proven efficacy and are safer.

***The Scientific Committee for Medical Products for Liver and Digestive System Diseases at its session on 09/02/2026 recommended** to disapprove the submitted combination scientifically for the following reasons:

1- According to scientific references, studies conducted on laboratory animals have proven that the use of Dantron is associated with the occurrence of Adenocarcinoma in the intestines and liver tumors, and the risk of similar effects in humans cannot be ruled out.
2- The existence of alternatives in the Egyptian market that have proven efficacy and are safer.
3- The potential for misuse of Dantron in the treatment of constipation.

*** - For products containing Bilastine:** The warning in the Technical Committee's decision at its session on 04/04/2019 is to be updated to read "Do not use for children under 4 years of age and those weighing less than 16 kg," and this is to be written on the outer packaging and in the package leaflet based on the decision of the Scientific Committee for Medical Products for Pediatric Diseases at its session on 13/01/2026. Companies are granted a grace period of up to six months from the date of the committee to implement the decision, in case any company requests to benefit from this decision after being given an implementation period. The Technical Committee for Drug Control affirms that the Central Administration of Inspection on Pharmaceutical Institutions must take all necessary measures to ensure that no company provides its product with both the old packaging (containing the warnings before updating) and the new packaging (containing the warnings after updating) at the same time in the local market.

- Note: -

- The Scientific Committee for Medical Products for Pediatric Diseases recommended at its session on 13/01/2026 the following: Based on the practical experience of using the product in the Egyptian market, the safety and efficacy of using Bilastine in children has been proven, provided that the use is for children from 4 years of age who weigh not less than 16 kg, according to the reference country Canada. According to the growth rates of children in Egypt, a weight of 16 kilograms is appropriate for a child aged 4 years and not for a child aged 2 years.

* - The decision of the Technical Committee at its session on 12/02/2026 regarding products containing Anidulafungin with Tween 80 or Polysorbate 80 is to be re-updated so that the decision includes the following: "Companies are granted a grace period of up to six months

ending on 12/08/2026 to implement the decision, in case any company requests to benefit from this decision after being given an implementation period. The Technical Committee for Drug Control affirms that the Central Administration of Inspection on Pharmaceutical Institutions must take all necessary measures to ensure that no company provides its product with both the old packaging (containing the warnings before updating) and the new packaging (containing the warnings after updating) at the same time in the local market."

- Note: -

- The Technical Committee decided on 12/02/2026, based on what was presented regarding the substance Tween 80: To update the decision of the Technical Committee at its session on 04/10/2018 to include "Products containing Anidulafungin with Tween 80 or Polysorbate 80 may be used for children starting from one month of age, provided that the following warning is written in the package leaflet and on the outer packaging of the product: Do not use for newborns less than one month of age," based on the decision of the Scientific Committee for Medical Products for Pediatric Diseases at its session on 26/10/2025.

- The Technical Committee decided on 04/10/2018, based on what was presented: To cancel the decisions of the Technical Committee at its sessions on 12/04/2012 and 26/11/2015 and to approve the recommendation of the Pediatrics Committee at its session on 03/07/2018, with the review of doses according to age and ensuring that the percentage of Dioxan does not exceed the permissible limit according to pharmacopoeias.

- The Scientific Committee for Medical Products for Pediatric Diseases recommended at its session on 26/10/2025: According to scientific references and reference countries, products containing Anidulafungin, which also include Tween 80 or Polysorbate 80, are used for children starting from one month of age. Accordingly, the committee recommends using products containing Anidulafungin with Tween 80 or Polysorbate 80 for children starting from one month of age, provided that the following warning is written on the package leaflet and the outer packaging of the product: Do not use for newborns less than one month of age.

Decisions of the Technical Committee for Drug Control at its session on 12/03/2026

* - Disapproval of completing the registration procedures for products under registration containing Carbamazepine in the pharmaceutical dosage form IV injection, their cancellation and deletion from the boxes and the Egyptian Drug Authority database according to the rules, and not approving the reception of new products, based on the decision of the Scientific Committee for Medical Products for Psychiatric and Neurological Diseases at its session on 04/03/2026.

- Note: -

- The Scientific Committee for Medical Products for Psychiatric and Neurological Diseases recommended at its session on 04/03/2026 to disapprove the product for the following reasons:

1- Failure to provide recent studies proving the efficacy and safety of Carbamazepine in this pharmaceutical dosage form.

2- The availability of alternatives in the Egyptian market in the IV injection pharmaceutical dosage form used for the same therapeutic purpose as an Anti-Epileptic.

Decisions of the Technical Committee for Drug Control at its session on 26/03/2026

* - Disapproval of completing the registration procedures for products under registration containing (Diosmin + Tranexamic Acid), their cancellation and deletion from the boxes and the Egyptian Drug Authority database, applying the rules, and not approving the reception of new products based on the decision of the Scientific Committee for Medical Products for Obstetrics and Gynecology Diseases at its session on 10/03/2026.

- Note: -

- The Scientific Committee for Medical Products for Obstetrics and Gynecology Diseases at its session on 10/03/2026 recommended to reject the product scientifically for the following reasons:

- The only study submitted by the company is insufficient to prove the efficacy of the proposed combination.

- There is no therapeutic role for the substance Diosmin in the proposed combination for the treatment of Abnormal Uterine Bleeding according to the adopted treatment protocols.

* - Not approving the reception of new products containing (Diphenhydramine Hydrochloride + Oxeladin Citrate + Guaiphenesin), based on the decision of the Scientific Committee for Medical Products for Chest Diseases at its session on 09/02/2026, and the Scientific Committee for Medical Products for Pediatric Diseases at its session on 10/03/2026.

- Note: -

- The Scientific Committee for Medical Products for Chest Diseases at its session on 09/02/2026 recommended to disapprove the product scientifically for the following reasons:

1- According to scientific references, the substance Oxeladin belongs to the therapeutic group of Centrally acting cough suppressant (that crosses the blood brain barrier). It exists in a single form according to the scientific reference France, and the reference daily dose does not exceed 50 mg. However, in the product's leaflet, it ranges between 90-120 mg daily, which increases the occurrence of serious side effects for this substance.

2- According to treatment protocols, the dose of the substances Diphenhydramine Hydrochloride and Guaiphenesin in the presented concentrations are less than the therapeutic doses.

3- There is no scientific justification for combining Oxeladin, which is used to treat dry cough, with Guaiphenesin, which is used to treat cough accompanied by phlegm.

***The committee recommends registering the substance Oxeladin individually according to the scientific reference France, due to the need for a Central Acting Cough Suppressant in the Egyptian market.**

- The Scientific Committee for Medical Products for Pediatric Diseases at its session on 10/03/2026 recommended to disapprove the submitted combination scientifically for the following reasons:

1- There is no scientific justification for combining Oxeladin, which is used to treat dry cough (Cough suppressant), with Guaiphenesin, which is used to treat cough accompanied by phlegm (Expectorant).

2- According to treatment protocols, the dose of the substances Diphenhydramine Hydrochloride and Guaiphenesin in the presented concentrations are less than the therapeutic doses.