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.

Decisions of the Technical Committee for Drug Control at its session on 02/04/2026

*- Approval to adopt the recommendations issued by the Human Pharmaceuticals Regulatory Affairs Department (General Administration of Human Pharmaceutical Registration) as follows: -

• First: Regarding products that have obtained approval to proceed with registration procedures according to Ministerial Decree No. 425 of 2015 and have not fulfilled the technical studies for the product, which are limited to the following:

- Group One: Companies that manufactured the pilot batch before 31/03/2025 and submitted the final registration file before 31/12/2025.

- Group Two: Companies that manufactured the pilot batch before 31/03/2025 but did not submit the final registration file before 31/12/2025.

- Group Three: Companies that manufactured the pilot batch after 31/03/2025 or have not manufactured it to date.

For Group One: Companies listed in this group must fulfill the technical studies for the files submitted before 31/12/2025 by a deadline no later than 31/05/2026. If the aforementioned date is not adhered to, the companies listed in this group are granted a maximum grace period of 18 months from the date of the Technical Committee for Drug Control, inclusive of any previous grace periods granted to the product, to fulfill registration requirements and submit the final registration file according to the implementation mechanism referred to in the Technical Committee's decision and in line with World Health Organization requirements and the decision of the Chairman of the Egyptian Drug Authority No. 450/2023. If not fulfilled within the granted

grace period, a list of the products shall be prepared and submitted to the Technical Committee for Drug Control for cancellation of these products.

For Group Two and Three: Companies listed in these groups are granted a maximum grace period of 18 months from the date of the Technical Committee for Drug Control, inclusive of any previous grace periods granted to the product, to complete registration procedures and submit the final registration file according to the implementation mechanism referred to in the Technical Committee's decision and in line with World Health Organization requirements and the decision of the Chairman of the Egyptian Drug Authority No. 450/2023. If not fulfilled within the granted grace period, a list of the products shall be prepared and submitted to the Technical Committee for Drug Control for cancellation of these products.

• **Second:** Regarding companies that obtained approval to proceed with product registration procedures during the first year of Ministerial Decree No. 645 of 2018 (third/fourth status) and have not submitted the final registration file to the Regulatory Affairs Department, companies are granted a one-month grace period from the date of the Technical Committee for Drug Control to submit a pledge, approved by the Chairman of the Board of Directors and bank-notarized, committing to submit the final registration file within a maximum period of 18 months from the date of the Technical Committee's approval, inclusive of any previous grace periods granted to the product according to the implementation mechanism referred to in the Technical Committee's decision and in line with World Health Organization requirements and the decision of the Chairman of the Egyptian Drug Authority No. 450/2023.

Cancellation procedures for these products shall proceed in the following cases:

- Failure to submit a pledge, approved by the Chairman of the Board of Directors and bank-notarized, within one month of the Technical Committee for Drug Control's approval to demonstrate seriousness in completing registration procedures.
- Failure to comply with submitting the final registration file as indicated above within a maximum period of 18 months from the date of the Technical Committee for Drug Control's approval.

• Third:

- For products that have received a preliminary registration notification and submitted the registration file before 31/12/2025:

Companies listed in this group must fulfill registration requirements for the files submitted before 31/12/2025 by a deadline no later than 31/05/2026. If the aforementioned date is not adhered to, companies listed in this group are granted a maximum grace period of 18 months from the date of the Technical Committee for Drug Control, inclusive of any previous grace periods granted to the product, to complete registration procedures and submit the final registration file according to the implementation mechanism referred to in the Technical Committee's decision and in line with World Health Organization requirements and the decision of the Chairman of the Egyptian Drug Authority No. 450/2023. If not fulfilled within the granted grace period, a list of the products shall be prepared and submitted to the Technical Committee for Drug Control for cancellation of these products.

- For products that have received a preliminary registration notification and have not submitted the registration file before 31/12/2025:

Companies are granted a maximum grace period of 18 months from the date of the Technical Committee for Drug Control, inclusive of any previous grace periods granted to the product, to complete registration procedures and submit the final registration file according to the implementation mechanism referred to in the Technical Committee's decision and in line with World Health Organization requirements and the decision of the Chairman of the Egyptian Drug Authority No. 450/2023. If not fulfilled within the granted grace period, a list of the products shall be prepared and submitted to the Technical Committee for Drug Control for cancellation of these products.

-For products that have received a preliminary registration notification and were granted an 18-month grace period to submit the CTD file, which expired on 12/02/2026:

These products shall be cancelled for non-compliance with the granted grace period. Companies are granted a grace period of 30 days from the date of the cancellation issuance to submit a new registration application according to the decision of the Chairman of the Egyptian Drug Authority No. 450 of 2023, while retaining their place in the generics pool and the possibility of benefiting from previous technical studies, provided that proof of production is submitted.

- Compliance with the application of the rules is mandatory.

• Fourth: Approval to adopt the following implementation mechanism for submitting the final registration file in the CTD format in line with World Health Organization requirements:

First: Manufacturing the production/pilot batch using an active substance with a DMF file. The company must adhere to the following:	
Quality File (Module 3)	Bioequivalence/Bioavailability File (Module 5)
The company is committed to manufacturing two additional batches using the same specifications, manufacturing method, and the same active substance supplier used in the previously produced batch. Accelerated stability studies for 6 months and long-term stability studies for 12 months shall be conducted on the second and third batches.	The results of the bioavailability/bioequivalence studies conducted on the previously produced batch will be evaluated according to the requirements of the Bioavailability and Bioequivalence Unit.
Second: Manufacturing the production/pilot batch using an active substance without a DMF file. The company must adhere to the following:	
Quality File (Module 3)	Bioequivalence/Bioavailability File (Module 5)
The company is committed to manufacturing 3 pilot/production batches using a supplier with a DMF. Accelerated stability studies for 6 months and long-term stability studies for 12 months shall be conducted on the three batches.	The company must contact the Bioavailability/Bioequivalence Unit to determine the status of the previously conducted study.

Decisions of the Technical Committee for Drug Control at its session on 09/04/2026

- The decision of the Technical Committee for Drug Control at its session on 26/02/2026 is amended to read as follows: The decision of the Technical Committee at its session on 12/02/2026 regarding products containing the substance Anidulafungin with Tween 80 or Polysorbate 80 is updated so that the decision includes the following: "Companies are granted a grace period to implement the decision ending on 12/08/2026 or until packaging materials (containing the warnings before their update) are exhausted, whichever is sooner."

- Note: The Technical Committee decided on 12/02/2026, based on what was presented regarding Tween 80: The decision of the Technical Committee at its session on 04/10/2018 is 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 insert and on the outer packaging of the product: 'Do not use in newborns less than one month of age'." This is in light of the decision of the Scientific Committee for the Evaluation of Medical Products for Pediatric Diseases at its session on 26/10/2025.

- Regarding products containing "Glucose and Sodium Chloride Solution for IV Infusion":** A warning in clear font and a different color shall be placed on the outer packaging ("Used With Caution In Pediatrics") for registered products for all packages of different sizes, based on the decision of the Scientific Committee for the Evaluation of Medical Products for Pain and Anesthesia at its session on 12/03/2026, with mandatory compliance with the application of the rules.

- Note: It was presented to the Scientific Committee for the Evaluation of Medical Products for Pain and Anesthesia at its session on 12/03/2026, which recommended the following: Approval of the product in the submitted package from a scientific standpoint for the following reasons:

1. It reduces the occurrence of overdose compared to larger volume packages.
2. It reduces the possibility of using the same package for more than one patient.

- With the recommendation to place a warning in clear font and a different color on the outer packaging ("Used with caution in Pediatrics"). This recommendation applies to registered products for all packages of different sizes.

Decisions of the Technical Committee for Drug Control at its session on 23/04/2026

- The decision of the Technical Committee for Drug Control at its session on 23/04/2026 is amended to read as follows:

1. Registered medicinal products containing Betahistine:

The Committee approved the temporary limit for N-Nitroso Betahistine impurity proposed by the Nitrosamine Impurities Committee, provided that the daily intake does not exceed 120 ng/day, in line with the limit adopted by France.

The Committee also approved the extension of the implementation period proposed by the Nitrosamine Impurities Committee until the end of November 2026. During this period, the concerned products may continue to be manufactured, provided that the level of N-Nitroso Betahistine impurity does not exceed 120 ng/day.

In addition, samples shall be collected from the active pharmaceutical ingredient (API) available at the manufacturing companies. Samples shall also be re-collected from previously manufactured batches as well as from batches manufactured during the extension period. Such sampling shall be conducted at pharmaceutical manufacturing sites, distribution companies, and pharmacies, and the collected samples shall be tested in accordance with the applicable regulations.
Furthermore, these medicinal products shall be subject to close pharmacovigilance monitoring. The matter shall be re-submitted to the Technical Committee for Drug Control during the extension period should any findings warrant further review, in accordance with the applicable regulations.
The concerned companies shall ensure that, for any batches manufactured after the expiry of the extension period, the level of N-Nitroso Betahistine impurity does not exceed 26.5 ng/day.

2. Betahistine-containing medicinal products under registration:

For medicinal products containing Betahistine that are currently under registration, the level of N-Nitroso Betahistine impurity shall not exceed 26.5 ng/day, in accordance with the requirements of the U.S. Food and Drug Administration (FDA).

Decisions of the Technical Committee for Drug Control at its session on 05/05/2026

- The decision of the Technical Committee for Drug Control at its session on 05/05/2026 is amended to read as follows:

The Committee approved the update of the reference country selection criteria for biological medicinal products and human medicinal products, whereby the reference countries shall be those having National Regulatory Authorities (NRAs) responsible for the regulatory, oversight, and enforcement activities related to biological and pharmaceutical products, provided that they meet at least one of the following reference recognition criteria:

1- ICH Founding Regulatory Authority.
2- ICH Standing Regulatory Members.
3- Regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement.
4- Regulatory authority that is WLA as listed by WHO (for the approved function & scope).
5- WHO prequalification process.

-List of National Regulatory Authorities (NRAs) and their classifications according to the above-mentioned reference recognition criteria:

NRA/Country	Criteria	Regulatory Functions	Scope
United States of America (USFDA)	ICH Founding Regulatory Authority	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**

EMA (Europe) Products with EMA CPP	ICH Founding Regulatory Authority	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
NRA/Country	**Criteria**	**Regulatory Functions**	**Scope**
Japan (PMDA/MHLW)	ICH Founding Regulatory Authority	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
England (MHRA)	WLA	1.Registration and marketing authorization 2.Vigilance 3. Licensing establishments 4.Regulatory inspection 5.Laboratory testing 6.Clinical trials oversights 7.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
Canada (Health Canada)	ICH Standing Regulatory Members	1.Registration and marketing authorization 2.Vigilance 3.Market surveillance and control 4.Licensing establishments 5.Regulatory inspection 6.Laboratory testing 7.Clinical trials oversight 8.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
Switzerland (Swissmedic)	ICH Standing Regulatory Members	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA)	**Medicine Vaccine biotherapeutics**
Australia (TGA) & New Zealand	Regulatory authority associated with an ICH	1.Registration and marketing authorization 2.Vigilance	**Medicine Vaccine biotherapeutics**

	member through a legally-binding, mutual recognition agreement with EU member states, England and Canada	3.Market surveillance and control 4.Licensing establishments 5.Regulatory inspection 6.Laboratory testing 7.Clinical trials oversights 8.Regulatory Authority (RA) lot release	
NRA/Country	**Criteria**	**Regulatory Functions**	**Scope**
Republic of Korea (MFDS)	**WLA**	1.Registration and marketing authorization 2.Vigilance 3.Market surveillance and control 4.Licensing establishments 5.Regulatory inspection 6.Laboratory testing 7.Clinical trials oversights 8.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
Singapore (HAS)	**WLA**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversights	**Medicine & biotherapeutics**
Austria (BASG), France (ANSM), Germany (BfARM/ PEI), Iceland (IMA), Ireland (HPRA), Italy (AIFA), Luxembourg (MoH), Belgium (FAMHP), Norway (NOMA), Denmark (DKMA), Finland (FIMEA), Portugal (INFARMED), Sweden (SMPA), Spain (AEMPS), the Netherlands (CBG MEB).	**WLA**	**Approved Function**	**Approved Scope**
New Countries			

NRA/Country	Criteria	Regulatory Functions	Scope
***EU countries:** Bulgaria (BDA), Croatia (HALMED), Cyprus (PHS MoH), Czechia (SUKL), Estonia (SAM), Greece (EOF), Hungary (NNGYK), Latvia (ZVA), Liechtenstein (LLV), Lithuania (VVKT), Malta (MMA), Poland (URPL), Romania (NAMMDR), Slovakia (SUKL), Slovenia (JAZMP).	**WLA**	**Approved Function**	**Approved Scope**
Indonesia (BPOM)	**WLA**	1. Registration and marketing authorization 2. Licensing establishments 3. Regulatory inspection 4. Laboratory testing 5. Regulatory Authority (RA) lot release	**Vaccines**

For newly added EU countries, Eudra GMP and CPP from two reference authorities are mandatory to be submitted.

For human medicinal products submitted for registration based on reference approval from the newly added reference countries, during the first six months following the implementation of this decision, the applications shall be referred to the Scientific Evaluation Committees for Medicinal Products to assess the medical need for the product prior to granting approval to proceed with the registration process. Upon the expiry of this six-month period, the matter shall be re-evaluated following submission to the Technical Committee for Drug Control.
The updated list shall come into effect as of 01/01/2027, provided that the list of reference regulatory authorities shall be updated in line with international developments, subject to review and approval by the Technical Committee for Drug Control.

Decisions of the Technical Committee for Drug Control at its session on 21/05/2026

- The decision of the Technical Committee for Drug Control at its session on 21/05/2026 is amended to read as follows:

Approval of the recommendation of the Scientific Committee for Veterinary Medicinal Products and Feed Additives, issued at its meeting held on 04/05/2026, concerning veterinary medicinal products containing Cefotaxime. The Committee recommended prohibiting the veterinary use of Cefotaxime, with the implementation of the prohibition and discontinuation of its use as follows:
-No approval shall be granted for the importation of active pharmaceutical ingredients (APIs)/raw materials intended for the manufacture of locally produced veterinary medicinal products containing Cefotaxime.
-No approval shall be granted for the renewal of registration of veterinary medicinal products containing Cefotaxime.
-No approval shall be granted for the completion of registration procedures for products currently under registration. In addition, all registered veterinary medicinal products containing Cefotaxime shall have their registrations cancelled within one year from the date of the Committee's recommendation.

Marketing Authorization Holders (MAHs) shall be granted a six-month grace period to regularize their status and complete the manufacture of products using raw materials already available in the market. Upon expiry of this period, the manufacture of all veterinary medicinal products containing Cefotaxime shall cease.

The sale, distribution, and marketing of all veterinary medicinal products containing Cefotaxime shall be discontinued, and all such products shall be withdrawn from the market no later than one year from the date of the Committee's decision.

Decisions of the Technical Committee for Drug Control at its session on 04/06/2026

- The decision of the Technical Committee for Drug Control at its session on 04/06/2026 is amended to read as follows:
Approval not to accept any new applications for the registration of medicinal products containing the formulation Dimethicone q.s. 10 mL in the Eye Drops dosage form, and not to proceed with the registration of products currently under registration containing this formulation. Such applications shall be cancelled and removed from the Analogues Boxes and the Egyptian Drug Authority (EDA) database, in compliance with the applicable regulatory requirements. This is based on the recommendation of the Scientific Evaluation Committee for Ophthalmology and Retinal Diseases and Surgery Medicinal Products, issued at its meeting held on 29/04/2026.

-Note:
The product was submitted to the Scientific Evaluation Committee for Ophthalmology and Retinal Diseases and Surgery Medicinal Products at its meeting held on 29/04/2026, which recommended scientific rejection of the product for the following reasons:

The applicant failed to submit a scientific dossier or any supporting studies on the active substance despite being requested to do so on several occasions.
No Dimethicone ophthalmic eye drop products are approved in any of the recognized reference countries.
The product has been withdrawn from the French market.
* Approval not to accept any new applications for the registration of medicinal products containing the combination Montelukast + Ebastine, based on the recommendation of the Scientific Evaluation Committee for Chest Diseases Medicinal Products, issued at its meeting held on 27/04/2026.

-Note:
The product was submitted to the Scientific Evaluation Committee for Chest Diseases Medicinal Products at its meeting held on 27/04/2026, which recommended scientific rejection of the combination for the following reasons:

-There is no additional therapeutic benefit from combining Ebastine and Montelukast in the treatment of bronchial allergy or allergic rhinitis.
-Montelukast has no established role in the treatment of allergic rhinitis alone. According to internationally recognized clinical guidelines, it should only be used in patients with allergic rhinitis associated with asthma. Therefore, combining both active substances in a single dosage form may encourage inappropriate use in patients with allergic conditions who do not have asthma.
-Montelukast is associated with serious neuropsychiatric adverse reactions, as highlighted in the U.S. FDA Boxed Warning, including, but not limited to, agitation, aggression, depression, sleep disturbances, suicidal ideation, and suicidal behavior (including completed suicide).
-Accordingly, there is no scientific justification for combining it with another active substance that may increase the potential for adverse effects, particularly when single-ingredient products containing these active substances are already available on the Egyptian market.

* Approval not to proceed with the registration of medicinal products currently under registration for dental anesthesia presented in Vial dosage form. Such applications shall be cancelled and removed from the Analogues Boxes and the Egyptian Drug Authority (EDA) database, in compliance with the applicable regulatory requirements. Furthermore, no new registration applications for medicinal products intended for dental anesthesia shall be accepted, including reference products, unless they are presented in the Cartridge dosage form. This is based on the recommendation of the Scientific Evaluation Committee for Dental Diseases and Surgery Medicinal Products, issued at its meeting held on 20/04/2026.

-Note:
The appeal was submitted to the Scientific Evaluation Committee for Dental Diseases and Surgery Medicinal Products at its meeting held on 20/04/2026, which recommended rejecting the use of local anesthetic products in Vial presentation for dental clinics, despite the reference status of several products currently under registration, for the following reasons:
-The proposed vial presentation is unsuitable for use in dental clinics, as it is likely to be used for more than one patient, thereby increasing the risk of cross-contamination and infection.
-The usual dose of local anesthetic used in dental practice ranges from 1.7 mL to 2.2 mL. The Cartridge presentation is intended for single-patient use, thereby minimizing the risk of infection and facilitating accurate dose administration.

-The use of an insulin syringe with a vial, as proposed in the company's appeal, does not permit safe and reliable aspiration prior to injection, thereby increasing the risk of inadvertent intravascular administration, which may result in serious and potentially life-threatening complications.

* Approval not to proceed with the registration of medicinal products currently under registration for dental anesthesia presented in Ampoule dosage form. Such applications shall be cancelled and removed from the Analogues Boxes and the Egyptian Drug Authority (EDA) database, in compliance with the applicable regulatory requirements. Furthermore, no new registration applications for medicinal products intended for dental anesthesia shall be accepted, including reference products, unless they are presented in the Cartridge dosage form. This is based on the recommendation of the Scientific Evaluation Committee for Dental Diseases and Surgery Medicinal Products, issued at its meeting held on 20/04/2026.

-Note:
The appeal was submitted to the Scientific Evaluation Committee for Dental Diseases and Surgery Medicinal Products at its meeting held on 20/04/2026, which recommended rejecting the use of local anesthetic products in Ampoule presentation for dental clinics, despite the reference status of several products currently under registration, for the following reasons:
-The proposed 5 mL ampoule presentation is unsuitable for use in dental clinics, as it may be used for more than one patient, thereby increasing the risk of cross-contamination and infection. The usual dose of local anesthetic in dental practice ranges from 1.7 mL to 2.2 mL, which is appropriately provided in the Cartridge dosage form intended for single-patient use.
-The use of an insulin syringe with an ampoule, as proposed in the company's appeal, does not permit safe and accurate aspiration prior to injection, thereby increasing the risk of inadvertent intravascular administration, which may result in serious and potentially life-threatening complications.

Decisions of the Technical Committee for Drug Control at its session on 16/07/2026

- The decision of the Technical Committee for Drug Control at its session on 16/07/2026 is amended to read as follows:

First: Levamisole-Containing Human Medicinal Products

* The Committee resolved not to accept new human medicinal products containing Levamisole for registration and to cancel human medicinal products containing Levamisole that are currently under registration, based on the recommendations of the Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases at its meeting held on 18 May 2026, as well as the decision of the Pharmacovigilance Committee at its meeting held on 26 February 2026.

Note:

The appeal was submitted to the Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases at its meeting held on 18 May 2026.

After reviewing the reports received from the European Medicines Agency (EMA), as well as the regulatory status of Levamisole in reference countries and the positions of international regulatory authorities, the Committee recommended restricting/withholding the registration of Levamisole for human use for the following reasons:

Serious adverse effects associated with the use of Levamisole, including leukoencephalopathy, as reported by the EMA in its report dated 26 March 2026. Accordingly, the benefit-risk balance is considered unfavorable for medicinal products containing this active substance.

The active substance has been withdrawn from several reference countries and by various international regulatory authorities, including the U.S. Food and Drug Administration (FDA), France, and Canada, for safety-related reasons.

Serious cases associated with the use of Levamisole have been identified worldwide, according to the report submitted by the Pharmacovigilance Administration.

Safer therapeutic alternatives are available in the Egyptian market for the same indications, such as Albendazole.

The recommendation is consistent with and supports the decision of the Pharmacovigilance Committee at its meeting held on 26 February 2026.

The General Administration of Pharmaceutical Pharmacovigilance conducted the relevant research and assessment, and the matter was presented to the Pharmacovigilance Committee on Thursday, 26 February 2026. **The Committee issued the following decision:**
Based on the EMA decision dated 13 February 2026, which stated, inter alia, that leukoencephalopathy had been confirmed as a serious adverse effect of Levamisole, the Committee noted that:

Leukoencephalopathy is a rare but serious adverse effect of Levamisole that damages the white matter of the brain.
The condition may be debilitating and life-threatening, particularly if left untreated, and its diagnosis may be complex.
Available evidence indicates that leukoencephalopathy may occur following a single dose of Levamisole, with symptoms potentially developing several months after treatment.
No measures have been identified that can effectively reduce this risk, nor has any particular population been identified as being at higher or lower risk.
Other medicinal products are authorized in the European Union for the treatment of parasitic worm infections.
Considering that Levamisole-containing medicinal products are used to treat mild parasitic worm infections, while Levamisole-induced leukoencephalopathy is a serious condition with an unpredictable onset, the PRAC concluded that the benefits of Levamisole-containing medicinal products no longer outweigh their risks and recommended the withdrawal of their marketing authorizations in the European Union.
The PRAC recommendation was based on newly evaluated safety data obtained through continuous pharmacovigilance activities, including reports of serious cases of leukoencephalopathy and central nervous system demyelination following the use of Levamisole, as well as a review of the published scientific literature. The PRAC also considered the input of independent experts in infectious diseases and neurology, in addition to input from the World Health Organization (WHO).

The Committee also took into consideration the FDA's withdrawal of the product in 1990, as well as the regulatory positions of several other reference countries.

Accordingly, the Pharmacovigilance Committee recommended the following:

To comply with the EMA decision and withdraw Levamisole from human use.
It is noteworthy that the Pharmacovigilance Committee had previously recommended restricting the registration of the product at its meeting held on 3 September 2023.
To refer the product to the Scientific Committee for Registration of Veterinary Medicinal Products, as Levamisole is excreted in the milk of cattle, according to the information reported from Switzerland.

Second: Dantron-Containing Medicinal Products

* The Technical Committee for Drug Control resolved to cancel all registered medicinal products containing Dantron and remove them from the Egyptian Drug Authority's list of pharmaceutical equivalents and database, in accordance with the applicable regulatory rules, based on the recommendation of the Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases at its meeting held on 18 May 2026.

Note:

The appeal was submitted to the Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases at its meeting held on 18 May 2026.
The Committee recommended rejecting medicinal products containing Dantron in all pharmaceutical dosage forms for the following reasons:
According to the scientific references, studies conducted in experimental animals have demonstrated an association between the use of Dantron and the development of intestinal adenocarcinoma and liver tumors. A similar risk in humans cannot therefore be excluded.
Effective and safer therapeutic alternatives are available in the Egyptian market.
Dantron is used in terminally ill patients, and there is a potential risk of misuse of Dantron-containing medicinal products in patients suffering from constipation in other clinical circumstances.

Third: Fixed-Dose Combination of Vonoprazan, Metronidazole, and Clarithromycin

* The Technical Committee for Drug Control resolved not to complete the registration procedures for medicinal products under registration containing the following fixed-dose combination (FDC): Vonoprazan 20 mg + Metronidazole 500 mg + Clarithromycin 500 mg
Accordingly, such products shall be cancelled and removed from the Egyptian Drug Authority's list of pharmaceutical equivalents and database, in accordance with the applicable regulatory

rules. The Committee further resolved not to accept new medicinal products containing this fixed-dose combination.
This decision was based on the recommendation of the Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases at its meeting held on 15 June 2026.

Note:
The appeal was submitted to the Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases at its meeting held on 15 June 2026.
The Committee recommended not approving the medicinal product from a scientific standpoint for the following reasons:
Insufficient information is available to adequately assess the safety and efficacy of the proposed combination for the treatment of Helicobacter pylori (H. pylori) infection.
Insufficient pharmacokinetic (PK) and pharmacodynamic (PD) studies are available to adequately evaluate the proposed fixed-dose combination.

Decisions of the Technical Committee for Drug Control at its session on 06/08/2026

- The decision of the Technical Committee for Drug Control at its session on 06/08/2026 is amended to read as follows:

* The Technical Committee for Drug Control decided that not to accept new medicinal products and not to approve the completion of registration procedures for medicinal products currently under registration containing both Vitamin B12 and Metformin Hydrochloride in a single formulation, regardless of whether the product contains any additional active ingredients besides these two substances.

Such medicinal products shall be removed from the Egyptian Drug Authority's list of pharmaceutical equivalents and cancelled from its database, in accordance with the applicable regulatory rules.

This decision was made in light of the absence of studies demonstrating the pharmacokinetic (PK) and pharmacodynamic (PD) characteristics of the combination, as well as the absence of studies demonstrating the efficacy of the combination as a fixed-dose combination (FDC), pursuant to the decision of the Scientific Evaluation Committee for Medicinal Products for Endocrinology and Metabolism at its meeting held on 29 June 2026.

* With regard to registered medicinal products containing Duloxetine, the Technical Committee approved extending the deadline previously granted by the Impurities Committee on 5 April 2026, with the extended deadline ending on 30 April 2027.

The Committee further approved the continued manufacture and marketing of these medicinal products during the granted extension period, provided that the level of the impurity N-Nitroso Duloxetine does not exceed the temporarily permitted limit of 670 ng/day.

During the granted extension period, additional samples of these medicinal products shall be collected and retested once every six months, whether from the same batches from which samples had previously been collected or from other batches of the same medicinal product that are currently on the market. This shall be undertaken to monitor the impurity levels and verify the continued compliance of the results with the established limits.

Furthermore, throughout the granted extension period, the concerned companies shall be required to take the necessary measures to minimize the formation of nitrosamine impurities.

Medicinal Products Under Registration Containing Duloxetine
With regard to medicinal products containing Duloxetine that are currently under registration, the concerned companies shall ensure that the level of the impurity N-Nitroso Duloxetine remains within the permitted limit of 100 ng/day, in accordance with the limits approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Decisions of the Technical Committee for Drug Control at its session on 20/08/2026

- The decision of the Technical Committee for Drug Control at its session on 20/08/2026 is amended to read as follows:

* All Marketing Authorization Holders (MAHs) of medicinal products containing **Domperidone 10 mg in tablet form** shall comply with the following requirements:

1. **Indication:** The approved indication shall be restricted to the **symptomatic treatment of nausea and vomiting** only.
2. **Duration of Treatment:** The duration of treatment shall **not exceed one week**.
3. **Dosage:** The maximum recommended daily dose shall **not exceed 30 mg**.
4. **Patient Population:** The use of the medicinal product shall be restricted to **adults and adolescents aged 12 years and older, with a body weight of 35 kg or more**.
5. **Warnings and Contraindications:** All relevant **warnings, precautions, and contraindications** included in the package leaflets of the corresponding medicinal products approved in the **reference countries** shall be incorporated into the approved product information, as applicable.
6. **Pack Size:** The medicinal product shall be marketed in a pack containing **20 tablets only (two blister strips)**.

These requirements are based on the recommendations of the **Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases**, issued during its meeting held on **29 July 2026**.

Note:

-The medicinal product was presented to the **Scientific Evaluation Committee for Medicinal Products for Liver and Gastrointestinal Diseases** during its meeting held on **29 July 2026**. Following its review, the Committee recommended the following:

- Restriction of the indication to the **symptomatic treatment of nausea and vomiting** only.
- Limitation of the **duration of treatment to a maximum of one week**.
- Limitation of the **maximum daily dose to 30 mg**.
- Restriction of use to **adults and adolescents aged 12 years and older, with a body weight of 35 kg or more**.

- Ensuring the inclusion of all relevant **warnings, precautions, and contraindications** stated in the package leaflets of the corresponding medicinal products approved in the **reference countries**, as applicable.
- The Committee further recommended that the medicinal product be supplied in a **pack containing 20 tablets only (two blister strips)**.