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CHILEAN PUBLIC HEALTH INSTITUTE ESTABLISHES PROCEDURE BASED ON RELIANCE FOR THE SANITARY REGISTRATIONS OF BIOLOGICAL PHARMACEUTICAL PRODUCTS

On February 5, 2025, the Exempt Resolution No. E679/25 of the Chilean Public Health Institute (ISP) was published in the Official Gazette. This resolution establishes an internal procedure to apply a reliance mechanism in the granting of sanitary registrations for biological pharmaceutical products.

The resolution indicates that, to improve regulatory operations efficiency and avoid duplication in the review of backgrounds evaluated by other agencies, the ISP must consider the evaluations of other regulatory authorities when reviewing and granting sanitary registrations for biological products.

Additionally, the ISP, committed to generating a new procedure for the faster approval of biological medicines, has seen the need to implement new instructions to expedite the processing of these products' applications.

Thus, the resolution establishes the following reliance procedure for the registration of biological products:

1. Stage of admissibility of the application: must be completed within 10 business days from the receipt of the file (currently in effect for sanitary registration applications).

2. Evaluation stage, which begins after the admissibility review is concluded: In this stage, the evaluator will verify that the applicant has demonstrated that the product is the same as approved by at least two of the following high-surveillance agencies:

• European Medicines Agency (EMA);
• U.S. Food and Drug Administration (FDA);
• Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom;

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• Therapeutic Goods Administration (TGA), Australia; and
• Pharmaceutical and Medical Devices Agency (PMDA), Japan.

If the product has been rejected for health reasons by any agency, the reliance mechanism will not be applicable.

3. Include the presentation of an official approval letter issued by the agencies (or an equivalent document) confirming that the same product submitted for registration in Chile was approved by those authorities. This will allow the submitted dossier to be **considered accredited without further procedures, speeding up the evaluation process for the sanitary registration** .

4. Registrations granted as conditional, emergency registrations, or other equivalents, will not be considered approved for reliance purposes , as they correspond to authorized products that have not demonstrated a complete and favorable evaluation of the product's quality, safety, and efficacy by the reference agency.

5. The evaluation report and the question-and-answer information from at least one of the two agencies, if additionally submitted, will allow the evaluation to be conducted in an abbreviated manner, and only the summary module (module 2) will be reviewed without the need to review modules 3, 4, and 5 of the background presentation format, based on the Common Technical Document (CTD).

6. If the requirements for regulatory reliance are met, the ISP will register the product according to the conditions approved by the high-surveillance agencies, including therapeutic indications, presentation, potency, instructions for use, and period of efficacy, among others.

Finally, the resolution establishes that the ISP will maintain its control over the approved sanitary registration and may modify, require modifications, suspend, or cancel the registration if there are justified reasons to do so.

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