Legal alert

Reliance mechanism for the sanitary registration of biological pharmaceutical products

On February 5, 2025, the Institute of Public Health of Chile (ISP) published the **Exempt Resolution No. E679-2025** establishing that the *reliance* mechanism will apply when requested by the applicant.

The resolution aims to implement an accelerated registration procedure, reducing processing costs and improving access to medicines. This mechanism exempts the submission and review of certain documents if they have already been evaluated and approved by high-surveillance regulatory agencies.

I. Key aspects of the procedure:

- Application admissibility: The ISP must review and validate the admissibility of the submission within 10 business days, ensuring compliance with the formal requirements set out in **Exempt Resolution No. 2232/2020.**
- Validation by high-surveillance agencies: The applicant must demonstrate that the product has been approved by at least two of the following agencies:
    1. European Medicines Agency (EMA)
    2. U.S. Food and Drug Administration (FDA)
    3. Medicines & Healthcare products Regulatory Agency (MHRA) - United Kingdom
    4. Therapeutic Goods Administration (TGA) - Australia
    5. Pharmaceutical and Medical Devices Agency (PMDA) – Japan

II. Exclusions from the reliance mechanism:

- The *reliance* mechanism will not apply if the product has been rejected for health reasons by any of these agencies.
- Products authorized under conditional, emergency, or equivalent registrations will not be considered as fully approved unless the agency has conducted a complete assessment of their quality, safety, and efficacy.

III. Documentation requirements:

- Applicants are encouraged to submit an official approval letter or equivalent documentation issued by the referenced agencies.
- If the evaluation report and Q&A document from the registration process of at least one of the two agencies are provided, the ISP will only review the summary module (Module 2), skipping the detailed review of Modules 3, 4, and 5 (quality, non-clinical, and clinical information).

IV. Final registration:

- Once the *reliance* requirements are met, the ISP will register the product under the conditions approved by the high-surveillance agencies, including therapeutic indications, instructions for use, and effectiveness period, among other aspects.

For more information please review the following link: **Exempt Resolution No. E679-2025**

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