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NEW REGULATION FOR THE SANITARY REGISTRATION OF HEMODERIVATIVE PHARMACEUTICAL PRODUCTS

On February 28, 2025, the Ministry of Health (MINSAL) published in the Official Gazette Exempt Decree No. 13, approving Technical Norm No. 240 ("T.N. 240") for the Sanitary Registration of Hemoderivative Pharmaceutical Products.

T.N. 240, developed by the Division of Healthy Public Policies and Promotion of the Undersecretariat of Public Health of MINSAL, in collaboration with the National Agency for Medicines (ANAMED) of the Public Health Institute (ISP),**establishes the requirements and necessary documentation to apply for the sanitary registration of hemoderivative pharmaceutical products** (derived from human blood or plasma),**ensuring their quality, safety, and efficacy.**

Key Aspects of T.N. 240:

•Control of Raw Material:

• Plasma must come from donations at authorized sites and contain sufficient information to contact the donor if necessary.
• Laboratory tests are required for viruses and other conditions, including HIV, Hepatitis B and C, Syphilis, HTLV I/II, and Human Parvovirus B19.
• If plasma donations originate in Chile, General Technical Norm No. 212/2021 or any relevant MINSAL regulation will apply.

•Fractionation:

• Only plasma from donors meeting all health requirements will be processed.
• The type of plasma must be specified according to collection, storage, and transport conditions.

•Storage and Transport:

• Must be conducted under validated and recorded conditions to ensure plasma traceability.

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•Plasma Master File:

• If the product has been previously registered with another regulatory agency, a "Plasma Master File" (for EMA) or equivalent document must be submitted.

•Quality Requirements:

• Compliance with S.D. No. 3/10 of MINSAL and ISP requirements, including description and controls of active ingredients, contaminant removal validations, packaging, and stability studies.

•Safety and Efficacy:

• Preclinical and clinical studies must be submitted according to Article 36 of S.D. No. 3/10.

•Pharmacovigilance:

• The ISP will determine the need for a Risk Management Plan and/or Periodic Safety Reports.

•Batch Control:

• Quality Control Certificates of the plasma used must be presented to ensure the absence of transmissible viruses.

T.N. 240 will come into effect on September 1, 2025.

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