

Regulation on Approval and Review of Biological Products

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Chapter 1: General Rules

Article 1 (Purpose)

The purpose of this Regulation is to ensure the propriety of product approval and review by specifying detailed procedures for the review of safety and efficacy, specifications and analytical

potency and safety cannot be evaluated by only physical and chemical tests.

12. A recombinant DNA product (hereinafter referred to as the recombinant product) refers to a pharmaceutical that contains peptides or proteins as active ingredient produced through genetic manipulation technology.
13. A cell culture-derived product refers to a pharmaceutical that contains peptides or proteins as active ingredient produced through cell culture technology.
14. A cell therapy product refers to a pharmaceutical manufactured through physical, chemical, and/or biological manipulation, such as culture, proliferation, or selection of autologous, allogeneic, or xenogeneic cells in vitro. However, it is excluded the case where a medical doctor conducts minimum manipulation which does not cause safety problems of autologous or allogeneic cells in the course of the surgical operation or treatment at a medical institution (simple separation, washing, freezing, thawing, etc. to the extent of maintaining the biological properties).
15. A gene therapy product refers to genetic materials or a pharmaceutical that contains genetic materials that are administered into a human body for the purpose of disease treatment, etc.
16. An orphan drug refers to a pharmaceutical that is required urgent introduction since it is used for rare diseases and appropriate alternative pharmaceuticals are not available and it is designated by the Minister of MFDS.
17. An accompanied material refers to the product which is pharmaceuticals, quasi-drugs under the 'Pharmaceutical Affairs Act,' and medical devices under the 'Medical Devices Act.' as an item that is required for use the product and materials other than the product that intended to approve in the same packing for the product.