Brief Overview of the Draft Amendment of the Standard for Biological Ingredients

1. The Standard for Biological Ingredients

According to Pharmaceutical Affairs Law, the Standard for Biological Ingredients (SBI) has been notified in order to provide guidance for necessary measures to be taken when a biological ingredient is used in manufacturing pharmaceutical, quasi-drug, cosmetic and medical device (hereinafter referred as “pharmaceuticals, etc. ”).

2. Background

The Amendment of Pharmaceutical Affairs Law (PAL) was enacted in Nov. 2013, where a new category of product, Regenerative Medicine Product, was defined. In this situation, a research reports regarding a possible direction of SBI amendment for Regenerative Medicine Product have been released. Based on these reports as well as global discussions of BSE risks on Bovine-derived Biological Ingredient, the draft SBI amendment has been prepared.

3. Main Points of the Draft Amendment

The draft amendment intends;

- To include Regenerative Medicine Product in the scope of SBI.
- To consider pharmaceuticals, etc. approved under PAL as raw materials conforming to the SBI, in the case where they are used in manufacturing other products appropriately.
- To clarify that additive or medium derived from human blood is not considered as blood product but as raw material derived from human in SBI in accordance with the revision of the Act on Securing a Stable Supply of Safe Blood Products. Human blood can be taken not only for manufacturing blood product but also for using as raw material for drugs, medical devices and regenerative medicine products according to the Act on Securing a Stable Supply of Safe Blood Products.
- To clarify that processes to inactivate or remove viruses in a raw material derived from human is not required if rational explanation is provided. For example, the autologous blood plasma is used to culture a regenerative medicine products, the process to inactivate or remove viruses may not be required.
- To clarify that manufacturing processes of raw material derived from human can be recorded and stored in accordance with other standards, not SBI.
- To add the countries recognized as “country with negligible BSE risk” in accordance with the assessment of World Organization for Animal Health (OIE) to the list of countries where bovine raw material can be prepared.

- To clarify that the confirmation of eligibility of the donor animal for a raw material derived from animal cell or tissue well as the storage of the confirmation record are not required when it is used as a submaterial, has been used actually and has been prepared from a well-identified cell-bank.
- To clarify that the confirmation of origin and region of a raw material derived from animal is not required when it has been confirmed that the donor animal is health.
- To clarify that manufacturing processes of raw material derived from animal can be recorded and stored in accordance with other standards, not SBI.