Brief Overview of the Draft Amendment of Pharmaceutical Affairs Law (PAL)

1. **Strengthening of the safety measures for drugs, medical devices and others.**
   (1) Provision of the latest knowledge in package inserts
       - Marketing authorization holders (MAHs) shall prepare and update a package insert based on the latest knowledge.
   (2) Notification system of package inserts
       - Package inserts of drugs or medical devices shall be notified to the regulatory authority by MAHs before placing products on the market and when revisions are made.

2. **Fitted approval system and post-marketing safety measures for medical devices**
   (1) Separation of clauses applicable to medical devices from those of drugs in the PAL.
       - Construction of the new “chapter” on medical devices in the PAL.
       - Change the name of “Pharmaceutical Affairs Law” in order to specify “Medical Devices”
   (2) Simplification of the regulatory systems toward a speedy launching of medical devices.
       - Expanding the third-party accreditation system to specially controlled medical devices designated by standards to be established.
       - Changing the manufacture’s licensing system to the registration system.
       - Placing stand-alone medical software as medical devices in the PAL.

3. **Establishment of well-suited regulation for regenerative medicine**
   (1) Establishment of specific definition of regenerative medicine.
       - Introduction of the separate definition of a regenerative medicine from pharmaceuticals and medical devices in the PAL.
   (2) Marketing Authorisation system for early commercialization of regenerative medicine.
       - Introduction of “Tentative Marketing Authorisation” with conditions and expiration date.
       - Efficacy and safety will be further confirmed after acquiring the Tentative Marketing Authorisation.
   (3) Ensuring safety and ethics in post-marketing phase.
       - Providing adequate explanation to patients by physicians with prior informed consent.
       - Implementing post-marketing safety measures (periodic reports of infectious diseases, record retention and others).