Partial amendments to the Order for Enforcement of the Pharmaceutical Affairs Act and other related orders, ordinances and public notices, as well as establishment of new ordinances and public notices related amendment od Pharmaceutical Affairs Act

The amendments and establishments of orders, ordinances and public notices related to enforcement of amendment for the Pharmaceutical Affairs Act will include following;

I. Amendments of the Order for Enforcement of the Pharmaceutical Affairs Act
II. Amendments of the Ministerial Ordinance for Enforcement of the Pharmaceutical Affairs Act
III. Amendments of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics
IV. Establishments of orders, ordinances and public notices related to Regenerative and Cellular Therapy Products and Gene Therapy Products

Major Points on the amendments and establishments are as follows;

I. Amendments of the Order for Enforcement of the Pharmaceutical Affairs Act

1. New clauses on medical devices will be established separate from pharmaceuticals.
2. New category on Software as a Medical Device will be added;
   - Diagnostic Software
   - Therapeutic Software
   - Preventive Software
3. Software as a Medical Device with low risk (defined as General Medical Device) will be exempted from the application of the amended Pharmaceutical Affairs Act.
4. New category for Regenerative and Cellular Therapy Products and Gene Therapy Products will be added;
   - Human Cell -Processed Products
   - Animal Cell -Processed Products
   - Gene Therapy Products

II. Amendments of the Ministerial Ordinance for Enforcement of the Pharmaceutical Affairs Law

1. New clauses on medical devices will be established separate from pharmaceuticals.
2. Procedures on the registration of medical device manufacturer will be defined.

3. Procedures on QMS inspection to a marketing authorization holder of medical devices will be defined.
4. Procedures on license to a marketing authorization holder, a manufacturer for Regenerative and Cellular Therapy Products and Gene Therapy Products will be defined.
5. The Conditions where a marketing authorization holder could omit a package insert of medical device will be defined following.
   ① A package insert indicates obtaining way on its information through the internet.
   ② A marketing authorization holder provides a paper package insert promptly when medical professionals request it.
   ③ A marketing authorization holder provides information to the users promptly when package are changed.
   ④ Information of a package insert can be obtained from the webpage of PMDA.

III. Amendments of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics

1. To harmonize 2nd chapter completely with ISO13485: 2003.
2. To add ISO13485: 2003 such as confirmation by a marketing authorization holder for a manufacturing site to comply the standards, storage period of documents and records, and to establish of reporting system for malfunction or adverse event in 3rd chapter.

IV. Establishments of ordinances and public notices related to Regenerative and Cellular Therapy Products and Gene Therapy Products

1. Since Regenerative and Cellular Therapy Products and Gene Therapy Products has been newly defined in the partial amendment of Pharmaceutical Affairs Act, new ordinances and public notices are established like as those for medical devices as well as pharmaceuticals. These will include the following;
   - Ordinance on Good Clinical Practice for Regenerative and Cellular Therapy Products and Gene Therapy Products
   - Ordinance on Good Laboratory Practice for Regenerative and Cellular Therapy Products and Gene Therapy Products
   - Ordinance on Good Postmarketing Surveillance Practice for Regenerative and Cellular Therapy Products and Gene Therapy Products and
   - Public Notice on designated Regenerative and Cellular Therapy Products and Gene Therapy Products.