Regular opinion exchange meeting regarding approval reviews and safety measures for medical devices and in vitro diagnostic drugs

A regular opinion exchange meeting was held on September 14, 2023.
From the Ministry of Health, Labor and Welfare, the heads of related departments, including Director Jo and Deputy Director Yoshida, and from PMDA, including Chairman Fujiwara and the heads of related departments, attended.
From the medical device industry, JFMDA, AMDD, and JACRI participated, and from the EBC, Chairman Mori, Vice Chairman Eda, Sub-committee chairman Nishimuta, and Committee Member Makishima participated.

This meeting aims to optimize the regulation and review of medical devices, summarizes the discussions that are regularly held with the Medical Device Review Management Division and PMDA, and shares new issues.

Together with AMDD, the EBC made recommendations on the following points:

- Establishment of an examination system according to the characteristics of programmed medical devices
- Cyber security
- Regarding PMDA's consultation system and examination period
- Utilization of real-world data for regulatory filings
- Handling of clinical trial data
- Review of tracking system
- International harmonization of various regulations and standards
  MDSRP
  ISO,QMS,GCP

Regarding programmed medical devices, efforts are expected to be realized, such as the issuance of DASH for SaMD2 and efforts to establish a two-stage approval system.
However, there is still room for further improvement, and we look forward to continued efforts.

Regarding the application of Article 12, Paragraph 3 of the Basic Requirements

Standards for Medical Devices, sufficient consideration should be given to international considerations for manufacturing and sales of items that will continue to be sold beyond the April 2024 enforcement date.

I understand that the consultation system at PMDA has improved significantly over the past few years.
Rather than consider further shortening the number of standards review bodies, the industry believes that it should aim for higher quality reviews.
We would like to request that you continue to share issues regarding submitted materials and inquiries, and we would also like to ask you to dig deeper into new medical devices and improvements (including clinical use).

The handling and utilization of real-world data, clinical trial data, etc. is an issue that we have great expectations for in the future, so we would like to continue to discuss how this can be handled.

Although data on patients implanted in specific medical devices is personal information that requires special consideration, we believe that there are a number of issues with how to handle it. New "identification codes" have been introduced, and it is becoming possible to consider new countermeasures in the future. We would like to ask you to start considering this.

Medical devices are required to comply with various regulations and standards, and as product sales become globalized, their international harmonization is essential. Mutual recognition agreement between Japan and the US and Japan and Europe should also be considered.

【IVD】
EBC, along with JACRI and AMDD, submitted their opinions as representatives of the IVD industry. The contents are as stated below.

1. Requests regarding amendments to the Pharmaceutical and Medical Device Act
2. Problems related to pre-approval testing and suggestions for improvement
3. Establishment of examination requirements and standards
    3-1. Towards a review of the notification of matters to be noted for approval

applications

3-2. Review of review categories for pathogen gene items

Current regulations regarding IVDs are classified as "pharmaceutical". On the other hand, there are also regulations related to “medical devices.''
Overseas, it is regulated as a "medical device" category.
Furthermore, since it is classified as a "pharmaceutical," the requirement for a manager in terms of business type, etc. is to be a pharmacist.
There is a need for laws and regulations tailored to the characteristics of in vitro diagnostic drugs, and consideration should be given to making them independent from the "pharmaceutical" classification.

Specifically, we believe that the following items should be considered.
Matters that should be considered in connection with the revision of the Pharmaceutical and Medical Devices Act regarding the regulation of in vitro diagnostic drugs, etc.

1. Review of the scope and approval system (category) of in vitro diagnostic drugs
2. Review of classification categories for in vitro diagnostic drugs
3. Implementation standards for clinical performance testing
4. Building a defect/adverse event reporting system
5. Establishment of examination requirements and standards
6. Others

There is an increasing number of cases in which new items that have not been previously required are required when applying for approval.
In vitro diagnostic drugs take years to decades to develop. Since it takes time to prepare new application materials, etc., advance notice and a certain period of transitional measures are required when changing the requested materials.
These matters necessary for approval review and points for improvement would be expected to jointly discussed.

Pathogen gene items are classified as items that do not meet the approval standards, but genetic testing and measurement methods have little difference in measurement technology from methods that apply immune reactions.
Therefore, we believe that it can be sufficiently examined as an approval standard item.

Regarding items related to pathogen genetic testing and measurement methods, we propose the following review classifications according to the characteristics.

- New pathogen genetic test items ⇒ New items
- For items other than new items, review categories are set according to the characteristics of the item.
- However, even if the testing items are known, items that do not correlate with approved items or items that have clearly different measurement principles are considered non-conforming to the approval standards.

EBC, AMDD and JACRI made many recommendations, and future responses to each were discussed and agreed upon. Many future concrete studies and tasks will be discussed and will be proceeded in the "Collaborative Plan for Optimization of Medical Device Regulation and Review" and "Collaborative Plan for Optimization of In-Vitro Diagnostic Drug Regulation and Review."