EBC Medical equipment and IVD committee

Representative meeting

IVD subcommittee report

2021/12/09

Executive summary

- In 2021, we continued the activities carried out since 2020 despite COVID-19, and we have requested the "system of emergency approval" and the "revision of medical fees planned in 2022".
- In 2022, we will work toward better IVD regulation in anticipation of the next PMD act revision.
- In addition, we intend to continuously promote evaluation of innovation for examinations toward the revision of medical fees in 2024.

1. 2021 activity results

- Regulatory WG

Regulatory WG: 2021 activity results summary

●Regulatory WG

- Held WG meetings 8 times （web conference）

●Activity results of regulatory WG

- Shared concerns / issues regarding the digitization of IFU (*tempu-bunsho*)
- Exchanged views on revising IFU (*tempu-bunsho*)
- Exchanged views regarding cross-reagent CDx
- Exchanged views regarding SaMD

Initiatives as 3 organizations in the IVD industry

Regular opinion exchange meeting on approval review and safety measures for medical devices and in-vitro diagnostic reagents (27 Aug. 2021)

Collaboration Plan Working-level Meeting (13 Jan. 2022)

- Confirm progress of initiatives in the new collaboration plan

Exchange of views on cross-reagent CDx

- Consider operation
- Exchange views on the draft notification

Regular meetings with the Pharmaceutical Safety Measures Div. of MHLW and the Quality Control and Safety Measures Div. of PMDA for medical devices

- Examine change from side effect report to adverse event report
- Concerns regarding IFU (*tempu-bunsho*) for in-vitro diagnostics reagent
  - Standardize the display method of revised parts
  - Examine “revision consultation” of IFU (*tempu-bunsho*)

Regular Opinion Exchange Meeting (27 Aug. 2021) @Web

Construction of a system when emerging infectious diseases occur

- Introduce a new license system in the event of an emergency

International harmonization

- Promote international harmonization
- International harmonization from an export perspective

Review of regulations on in-vitro diagnostic reagents

- Accelerate the digitization of administrative procedures and operations

Matters concerning law revision

- Qualification requirements of person responsible for business license

2. 2021 activity results

- Reimbursement WG

Reimbursement WG: 2021 activity result summary

●Reimbursement WG

- Held WG 9 times（web conference）
- Held a study session on examination in home medical care by inviting an outside lecturer

●Reimbursement WG activity results

- Theme and strategies for medical fees revision in Reiwa 4 (2021)
  - ➢ Promoted value of POCT in home medical care / community medical care as the key words
  - ➢ Promoted value of emergency examination that contributes to medical outcome
  - ➢ Reviewed evaluation of malignant tumor-related generic examination
- Preparation for the ~~a~~ regular meeting
- Preparation for statement of opinion on the industry by subcommittee

Initiatives as 3 organizations in the IVD industry

- **Joint medical insurance system committee with JACRI, AMDD and EBC**
  - Participated in the 12 committee meetings that were held
  - Summarized requests as an IVD industry organization regarding the revision of Reiwa 4 (2001) medical fees
  - Responded to the government as 3 organizations in the IVD industry
- **Exchange of opinions with MHLW (Economics / Medical Div.) for regular meeting and subcommittee statement**
  - Held opinion exchange meeting 7 times
  - Held opinion exchange meeting for malignant tumor-related generic examination 2 times
- **Regular meeting with MHLW and medical device industry**
  - 41st regular meeting（8 Feb. 2021）
  - 42nd regular meeting（30 Jul. 2021）
- **Industry statements by insurance of medical materials expert subcommittee**
  - 1st industry statement（25 Aug. 2021）
  - 2nd industry statement（26 Nov. 2021）

Industry demands for revision of Reiwa 4 (2001) medical fees

1. Evaluation of in-vitro diagnostics testing
   - ① Evaluation based on usage results（E1,E2,E3 challenge application）
   - ② Evaluation and specification of medical usefulness/innovation
   - ③ Handling of medical fees for examinations in which IVD reagent and LDT coexist
2. Review of malignant tumor-related generic examination items
3. Construction of an efficient medical system by popularizing POCT tests in home medical care
4. Evaluation of emergency examinations that contribute to medical outcome

Contribution to realization: “Countermeasures against emerging and re-emerging infectious diseases” and “Countermeasures for Antimicrobial Resistance (AMR)”

- ① Enhancement of implementation system for microbiological tests
- ② Promotion of nosocomial infection prevention measures through active inspections

3. 2022 activity basic plan

Activity basic plan as IVD subcommittee

- **Collaborate with JACRI and AMDD, strengthen efforts to the government as 3 organizations in the IVD industry**
- **Actively participate in the activities of the 3 organizations in the industry as EBC representative**
- **Make proposals led by EBC**

JACRI: Japan Association of Clinical Reagents Industries
AMDD: American Medical Devices and Diagnostics Manufacture's Association

Regulatory WG activity plan

- **Promote initiatives for the second collaboration plan**
  - International harmonization of review requirements and standards
- **Extract and consider issues for next revision of PMD act**
  - Handling classification of in-vitro diagnostic reagent
  - Scope/definition of in-vitro diagnostic reagent
  - “How it should be” - pre-approval exam
  - Review of IVD classification
- **Deepen understanding of overseas regulations and promote international harmonization**
  - Understanding of IVDR and VALID act.
  - Understanding of SaMD regulations

Reimbursement WG activity plan

- **Strategic activities for the revision of medical fees in Reiwa 6 (2024)**
  - Appropriately evaluate and promote value of POCT tests
  - Promote value of IVD in home medical care

- **Consideration of preventive medicine and health examination for market development**
  - Extract issues
  - Formulate activity policy