European Business Council (EBC) Medical Devices and IVD Committee

Meeting of Representatives

IVD Subcommittee Report

December 10, 2020

Vice Chairperson in Charge Shinichi Eda
Subcommittee Chairperson Miwa Nishida

2020 IVD Subcommittee Action Plan

- In cooperation with JACRI (Japan Association of Clinical Reagents Industries) and the AMDD IVD Committee, strengthening our approach to the government as 3 IVD industry groups
- Active participation in the activities of 3 industry groups as representatives of the EBC
- EBC-led proposal

Results of Activities in 2020

- **Related to Regulatory WG**

Activities related to Regulatory WG

Summary of results of 2020 WG Activities

- **Regulatory WG**
  - Meetings of the Regulatory Affairs WG were held 7 times (6 were web conferences).

- **Results of Regulatory WG Activities**
  - Sharing of concerns/issues regarding electronic of package inserts
  - Information sharing on clinical performance study guidelines
  - Planning of educational workshops (IVDR, VALID act, etc.)

Activities related to Regulatory WG

Activities as 3 IVD industry groups

- **Regular meetings to exchange opinions on approval reviews and safety measures for medical devices and in-vitro diagnostics (Aug. 28, 2020)**

- **Public-Private Dialogue (Nov. 16, 2020)**

- **Working-Level Council on Plan for Collaboration**
  - FY 2020 1st Meeting of Working-Level Council on Plan for Collaboration
    ⇒ Scheduled to be held in June but **canceled**
  - FY 2020 1st Meeting of Working-Level Council on Plan for Collaboration (Scheduled: Jan. 13, 2021)
    - Confirmation of progress on issues to be tackled by the new plan for collaboration

Regular Meeting for Exchange of Opinions
(Aug. 28, 2020) @ Web

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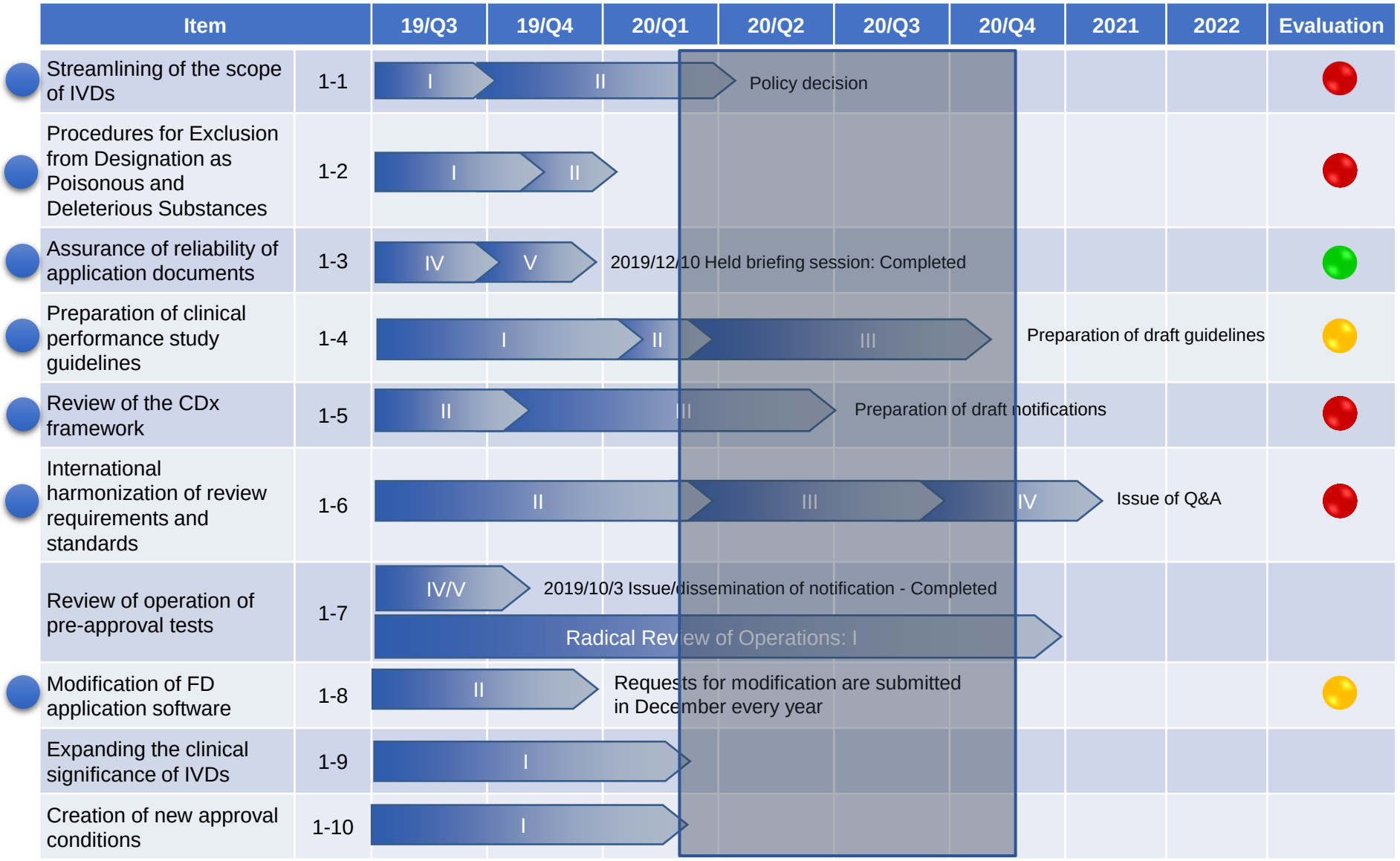
1. **Establishment of a system for handling emerging infectious diseases**
   a. Establishment of Emergency Use Authorization (EUA) System
2. **International harmonization**
   a. Expansion of the definition of in-vitro diagnostics (scope) in light of overseas conditions
   b. Review of classifications
3. **Review of regulations concerning in-vitro diagnostics**
   a. Development of clinical performance study guidelines
   b. Promotion of digitization of PMDA procedures and operations
   c. Procedure for changing operational rules/ over-the-counter (OTC) test drugs
4. **Requests regarding the PMD Act reform**
   a. Electronic codes and UDI codes for information such as precautions: early clarification of operations
   b. Qualification of total responsibility

Issues to be tackled by the Plan for Collaboration – Roadmap (1) –



Issues to be tackled by the Plan for Collaboration – Roadmap (2) –

Item		19/Q3	19/Q4	20/Q1	20/Q2	20/Q3	20/Q4	2021	2022	2023
Review of classifications	1-11									
Approval system based on IVD characteristics	1-12	I			Indication of whether there are products that correspond to IVDs					
Development of list of infectious disease epidemics overseas	1-13	I								
Labeling of common reagents	2-1	II			Decision on direction					
Achievement of targets for standard overall review period	3-1	Throughout the year								
Improvement and effective use of consultation system	3-2	Throughout the year								
Skill improvement for reviewers and applicants	3-3									
Streamlining and optimization of PMDA operations	3-4	I		II		Decision on response policy				

COVID-19

Public-Private Dialogue (Nov. 16, 2020) @Web

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Opinions and Requests from the In-vitro Diagnostics Industry: Issues Made Visible by the COVID-19

[JACRI, AMDD, EBC]

1. Formulation of contingency plans for emerging infectious diseases

In an emergency (outbreak of an emerging infectious disease), it is necessary to formulate, promote, and support a “strategy that is consistent from R&D through production and supply” in order to promote the smooth and rapid development and supply of in vitro diagnostics without confusion. Please draw up and disseminate concrete and feasible contingency plans involving ministries, related agencies, and industry

2. Proper provision of tests with confirmed quality and accuracy

For when there is an outbreak of an emerging infectious disease, we request that you design the following type of system to ensure that the public is properly provided with tests for which a certain level of quality and performance have been confirmed through a transparent process.

- Creation of the Emergency Use Authorization (EUA) system: review of the quality and accuracy of tests and authorization of their use
- Applicability to government testing and insurance-covered testing: Only for tests authorized for use

3. Development of environment for ensuring a stable supply system

When there is an outbreak of an emerging infectious disease, the following measures should be taken to ensure smooth expansion of the testing system and a stable supply system.

- Emergency response: Preparing environment such as purchase guarantees and allocation of measuring equipment
- Efforts to be made at all times, before an epidemic starts: “maintenance of measuring equipment at medical institutions, etc.”, "securing and developing human resources"

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Results of Activities in 2020

- **Reimbursement WG related**

Summary of results of 2020 WG Activities

- **Reimbursement WG**
  - Meetings of the WG were held 6 times (5 were web conferences)

- **Results of Reimbursement WG's activities**
  - Review of 2020 Medical fee revisions
  - Strategy for the 2022 revision of medical fees
    - ➢ Value appeals for POCT testing, where home care and community medical care are Key Words
  - Preparation for regular meetings with authorities

Activities related to Reimbursement WG

Activities as 3 IVD industry groups

- **3-Group Joint Committee (JACRI, AMDD and EBC) on the Medical Insurance System**
  - Participated in the 6 committee meetings held
  - 2020 Medical fees revision
    - Consultations on comprehensive molecular testing for cancer
    - Review
  - Compilation of IVD Industry Groups' Requests for Revision of Medical Fees in 2022
  - 3 IVD industry groups' response to administrative requirements

- **Exchange of opinions with the MHLW (Economic Affairs Division and Medical Economics Division) on regular meetings**
  - Meetings to exchange opinions were held 3 times (including a laboratory tour)
  - Exchanges of opinions on molecular testing for cancer were held 3 times (including a visit to the NGS laboratory)

Review of 2020 Medical fee revisions

1. Clarification of evaluation of medical usefulness and innovativeness of in-vitro diagnostics — Ongoing
2. Implementation of an action plan for antimicrobial resistance (AMR) countermeasures – Enhancement of an implementation system for microbial testing that contributes to AMR countermeasures – — Ongoing
3. Handling of medical fees for tests using in-vitro diagnostics and test items for which there is a coexisting LDT — Adddressed
4. Contribution of POCT to "ensuring high-quality home medical care" — Ongoing
5. Introduce Response to market expansion after insurance listing
6. Introduce Comprehensive molecular testing for cancer — Request reconsideration

Review of 2020 Medical fee revisions

1. Clarification of evaluation of medical usefulness and innovativeness of in-vitro diagnostics

Ongoing

<<Issues>>

- At present, applications are submitted in a cumulative manner, but in actual practice, they are reviewed by comparing them with existing items that are similar in principle of measurement, seriousness of target disease, etc. Transparency is not ensured because the review is conducted without a clear evaluation mechanism.
- If this situation continues, both foreign and domestic companies will have to avoid launching products in the Japanese market owing to lack of proper evaluation. This means that it will be difficult to introduce cutting-edge diagnostics into Japan, and there is a risk that we will not be able to contribute to patients and medical practice.
- Japanese companies lead the world in the field of in-vitro diagnostics, and the unpredictability of the handling of IVD in the insurance system is also an issue from the standpoint of their continued competitiveness.

<<Proposal>> Clarification of design of system for evaluating usefulness and innovativeness; clarification of content of evaluation

- We would like you to establish a system to evaluate medical usefulness and innovativeness when insurance is applied.
- When an evaluation system is established, from the viewpoint of ensuring transparency, the details of the evaluation should be presented in the proposed classification notified to MAHs at the time of insurance listing and in the "insurance category for in-vitro diagnostics and number of insurance points (draft)" at Chuikyo.

Review of 2020 Medical fee revisions

2. Implementation of an action plan for antimicrobial resistance (AMR) countermeasures – Enhancement of an implementation system for microbial testing that contributes to AMR countermeasures –

Ongoing

<<Issues>>

- There is no requirement concerning the system for carrying out microbial testing in the facility criteria for “infection prevention measure premium 1” Therefore, even if “infection prevention measure premium 1” is included in the fee calculation, the system for microbial testing may vary from one facility to another, and the medical treatment provided may also differ. For this reason, there also is concern as to whether antimicrobial resistance (AMR) countermeasures are being promptly implemented.
- There are many companies that want to contribute to AMR countermeasures, and they are devoting efforts to promoting the spread of microbial testing while developing and selling the products that are necessary for conducting this testing. While we welcome requests and recommendations from academic societies to establish systems of microbial testing that contribute to AMR countermeasures, the memberships of academic societies include diverse stakeholders, so they have not presented a unified opinion on systems for conducting microbial testing.

<<Proposal>>

Please add the following requirements to the facility criteria for “infection prevention measure premium 1”.

- Microbial testing should be performed in-house (At least the blood cultures should be performed within the facility)
- Microbial testing should be performed on Saturdays, Sundays, and holidays as well (at least for blood cultures)

Review of 2020 Medical fee revisions

3. Handling of medical fees for tests using in-vitro diagnostics (IVD) and test items for which there is a coexisting LDT

Addressed

<<Status>>

- Laboratory Developed Tests (LDTs) developed by individual laboratories play an important role in medical care, including tests for the diagnosis of rare diseases, etc.
- In some cases, an IVD is developed and insured for a test item that is reimbursed as an LDT test
- Since IVDs are subject to review and evaluation under the PMD Act, the quality and accuracy of testing using the IVD is guaranteed to be of a certain level.

<<Issues>>

Even after the IVD is covered by insurance, the spread of the approved IVD does not make progress because the LDT coexists with the test using the IVD for the same test item, so equalization of testing does not occur. As a result, patients may miss opportunities to undergo a certain level of testing .

<<Proposal>>

From the viewpoint of ensuring the quality and accuracy of laboratory tests, we would like the following to be reflected in insurance coverage of in vitro diagnostics for test items for which LDT are used:

- Separation of LDTs from the tests using in-vitro diagnostics
- Subsequent establishment of a transitional period and arrangement of the corresponding LDT test items

Review of 2020 Medical fee revisions

4. Contribution of POCT to "ensuring high-quality home medical care"

Ongoing

<<Status>>

- In recent years, POCT-compatible testing equipment and reagents that can be used at home have been sold, and medical care based on clinical tests has become possible. Spreading POCT tests in the field of home medical care has enabled us to provide "high-quality medical care".
- Performing POCT testing in the home care setting may reduce the severity of the patient's prognosis owing to early assessment of the disease state and intervention in the acute care setting, and it is currently attracting attention in the field of cardiovascular diseases and infectious diseases.

<<Issues>>

- Since rapid testing at home is not widespread and the patient's condition cannot be judged objectively, coordination with medical specialists, etc. is delayed, and the opportunity for early intervention is missed, or unnecessary emergency transport is performed.
- There is concern as to whether accuracy control for home care testing is being properly performed

<<Proposal>>

We would like you to consider a system for POCT tests that differs from that for existing tests in the cardiovascular and infectious disease areas, where demand is particularly high, in order to deliver POCT tests that have ensured quality and accuracy and can enable early assessment of disease state in home care patients.

⇒ e.g., additional medical fee for POCT performed at home, etc.

Activities for regular meetings on 2022 revision

Requests for regular meetings with the authority (draft)

1. Evaluation of in-vitro diagnostics
   - (1) Evaluation and clarification of medical usefulness and innovativeness
   - (1) Regarding consistent handling of medical fees for tests using in-vitro diagnostics and test items for which there is a coexisting LDT
   - (2) Fair Evaluation (E3 Challenge Application)
2. Enhancement of an system for performing microbial testing to contribute to countermeasures against emerging and re-emerging infectious diseases and countermeasures against AMR
3. Contributing to medical outcomes through rapid testing and emergency assessment
4. Contribution of POCT to "ensuring high-quality community medical care"
5. Review of establishment of test items in molecular testing for cancer
6. Handling of testing in the discussion of insurance coverage for infertility treatment

EBC is in charge

Results of Activities in 2020

- **Position Paper**

Outline of IVD Position Paper

I. Development of relevant laws and regulations to optimize the safety and efficacy of in-vitro clinical testing (IVD, LDT)

1. Development of new legislation to realize the review and approval process and safety measures according to the risk level of in-vitro clinical testing
2. Systematization of EUA for clinical tests required for emerging infectious diseases, etc.

II. Appropriate evaluation of technological innovation in testing fees and reform of testing technology evaluation methods

1. Transparency in evaluation of technological innovation
2. Optimization of technical fees for existing tests and review of the allocation of testing fees, assessment fees, additional fee, etc.

2021 Basic Action Plan

Basic Action Plan of IVD Subcommittee

- In cooperation with JACRI (Japan Association of Clinical Reagents Industries) and the AMDD IVD Committee, strengthening our approach to the government as 3 IVD industry groups
- Active participation in the activities of 3 industry groups as representatives of the EBC
- EBC-led proposal

Action Plan of Regulatory WG

- **Promotion of appropriate response to revision of the PMD Act**
  - Response to electronic of package inserts
  - Response to use of UDI system

- **Promotion of 2nd Collaboration Plan**
  - International harmonization of applications (consideration for acceptance of foreign regulations)
  - Making approval system more rational by reviewing definition of IVD (scope)

- **Deepening understanding of overseas regulations and promoting international harmonization**
  - Understanding of IVDR and VALID act, etc.

Action Plan of Reimbursement WG

- **Strategic Activities toward 2022 Revision of Medical Fees**
  - Proper evaluation and value appeal of POCT tests
  - Collaboration with JACRI /AMDD/EBC Joint Committee on the Medical Insurance System

- **Consideration of expansion of market to preventive medicine and medical examinations**
  - Identifying issues
  - Formulation of Action Plan