EUROPEAN BUSINESS COUNCIL IN JAPAN
THE EUROPEAN (EU) CHAMBER OF COMMERCE IN JAPAN

IVD
(IN VITRO DIAGNOSTICS)
ISSUES AND RECOMMENDATIONS

PERIODICAL MEETING WITH MHLW ON APPROVAL EXAMINATIONS & SAFETY MEASURES

Periodical Meeting with MHLW on Approval Examinations and Safety Measures

YEARLY STATUS REPORT: Progress

- At a meeting in August 2017 with MHLW's Pharmaceutical Safety and Environmental Health Bureau and PMDA, held to discuss approval examination and safety measures, the EBC Medical Equipment & Diagnostics Committee/IVD Sub-committee, jointly with the Japan Association of Clinical Reagents Industries (JACRI) and the IVD Committee of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD), presented the following recommendations:

Periodical Meeting with MHLW on Approval Examinations and Safety Measures

RECOMMENDATIONS

- The PDMA has increased its staff to speed up IVD approval times. In order to accelerate this process, all stakeholders should be given an opportunity to discuss and contribute to the creation of a new framework, and efforts and progress should be monitored.

- The following five items should be implemented quickly: addition to the approval/recognition standards; streamlining of approval examination requirements; revision of the pre-approval test system; releasing of clinical performance test guidelines at an early stage; revision of unique Japanese approval requirements.

- Labels and attached documents should be simplified.

Periodical Meeting with MHLW on Approval Examinations and Safety Measures

RECOMMENDATIONS

- The Government should introduce changes in the product changeover time-frame.
- MHLW together with relevant stakeholders should create an action plan to deal with changes in the environment surrounding clinical diagnostics/IVD. Special care should be taken over how to handle innovative diagnostics using advanced technologies, including next-generation sequencing and mass spectrometers, as well as how to promote genetic testing in genome medicine and diagnostics using AI.
- As a basic agreement has already been reached, discussions should be held on what measures are necessary to implement actual usage of the bio bank.

IN VITRO DIAGNOSTICS (IVD) DRUG MEDICAL REIMBURSEMENT

In Vitro Diagnostics (IVD) Drug Medical Reimbursement

YEARLY STATUS REPORT: Progress

- Since April 2016, the EBC has been given the opportunity to participate in and express its opinion at meetings of the Central Social Insurance Medical Council (*Chuikyo*) on insurance coverage for IVDs (E2 and E3).
- The EBC Medical Equipment & IVD Committee/IVD Sub-committee, together with JACRI and the IVD Committee of AMDD, have set up a "Joint Task Force to Negotiate with Chuikyo" and held discussions on the state of IVD medical reimbursement.
- The Task Force made the following recommendations to MHLW's Health Policy Bureau Economic Affairs Division and Health Insurance Bureau Medical Economic Division at their meeting in July 2017 on medical reimbursement.

In Vitro Diagnostics (IVD) Drug Medical Reimbursement

RECOMMENDATIONS

- "Medical usefulness and "innovativeness" should be taken into consideration when determining HIP. (It is currently not clear how the level of innovation of new products is evaluated.)
- Although the Japanese Government has been promoting home medical care, the cost to patients of conducting home testing is currently high. Home testing as well as management of home specimen examinations should be added to the HIP system.
- The Japanese Government should introduce additional HIP in respect of cases where urgent testing for heart disease or infection is required and so an immediate diagnosis is performed at a primary care doctor's clinic.

In Vitro Diagnostics (IVD) Drug Medical Reimbursement

RECOMMENDATIONS

- Infection prevention measures should only be introduced on condition that usage standards for microbial testing are included.
- The *Chuikyo* should consider the role for diagnostics in pre-emptive medicine where onset pre-intervention is carried out.