Japan: infrastructure for implementing companion diagnostics needed

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Personalised medicine holds the promise of improved, more targeted treatment for patients and companion diagnostics play a key role in this new healthcare paradigm. Dr Isao Ikeda, chairman of the AMMD's IVD Committee, provides an outline of the key issues Japan needs to address in reforming its regulatory and reimbursement system to take into account this important technology

Companion diagnostics (CDx) involve tests that help in the selection of the appropriate regimens and therapeutic agents for patients by examining their biomarkers (such as genes and proteins) before drug administration. These tests play an essential role in the move towards personalised medicine, which is expected to become more widespread in the future as it not only allows improved quality of medical practices, it also enables more effective use of financial resources.

The FDA in the US has already carried out simultaneous approvals for drugs and diagnostics for malignant melanomas as well as for non-small-cell lung cancer, and has also published draft guidelines for the development of CDx.

However, in Japan, a structure linking the development of CDx to pharmaceutical products is still absent. A prime issue when promoting pharmaceutical products that require CDx in clinical settings is the lack of an infrastructure for the regulatory approval and reimbursement of these tests.

On 21 October 2011, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD), the Japan Association of Clinical Reagents Industries (JACRI), and the European Business Council in Japan (EBC) jointly submitted the "Proposal on Infrastructure Building for Companion Diagnostics for the Promotion of Personalized Medicine" to the Japanese government's Office of Medical Innovation, the Ministry of Health, Labour and Welfare, and the Pharmaceuticals and Medical Devices Agency.

Below is an outline of the issues and the proposals contained in the document:

1. Regarding the requirements for regulatory applications and the developmental and approval processes for CDx

Issue: CDx is closely related to the efficacy and safety of pharmaceutical products. Therefore, as a precondition, these diagnostic tools should be used together with the drugs.

Solution: Hence, we recommend the establishment of the following developmental and approval criteria and in vitro diagnostic (IVD) product processes, which are all linked to the regulatory review of pharmaceutical products.

- Construction of a framework for the implementation of collaborative trials (clinical studies) of pharmaceutical products and CDx
- Review of in vitro diagnostic products in conjunction with pharmaceutical products, and their simultaneous approval
- Development of pharmaceutical requirements, including equivalence tests

2. Regarding insurance reimbursements for in vitro diagnostic products used for CDx

Issue: In order to facilitate the development of CDx and its appropriate implementation in clinical settings, it is essential to optimise the insurance reimbursements for CDx. In addition, a system must be developed in which pharmaceutical products and CDx are covered by insurance simultaneously. The application of insurance coverage currently differs between pharmaceutical products and specimen tests, and this can cause a lag in insurance coverage. In addition to this, technological innovations and developmental efforts made by diagnostics companies are not being duly acknowledged in the current medical fee payment system for laboratory tests.

Solution: To overcome these challenges, we propose the following.

- Construction of an insurance coverage review process for CDx that is synchronised with pharmaceutical product reviews
- Establishment of an insurance point allocation system (approved by the pharmaceutical affairs bodies) to encourage the development and spread of CDx

AMDD is working diligently with JACRI and EBC to establish meetings between the government and industry in order to facilitate both the development of CDx and its approval. We expect that these proposals will help spread effective and safe medical practices, which will benefit the health of every patient and improve their quality of life.

Headquartered in Tokyo, the AMDD represents companies that provide medical devices, IVDs and other advanced medical technology in Japan.

