

April 20, 2012

## **EFPIA Japan Position on the introduction of Health Technology Assessment (HTA)**

The Central Social Insurance Medical Council (Chuikyo) has created the environment for a discussion on the introduction of HTA in 2014-2016 and wishes to invite expert opinions to this debate.

Our member companies support the position statement on HTA issued on April 18, 2012 by the Japan Pharmaceutical Manufacturers Association (JPMA).

Based on the long and significant experience of various medico-economic assessments accumulated by our association and its member companies in Europe, EFPIA Japan would like to express its position in order to contribute to the current debate on HTA.

As a background, we would like to highlight that the Authorities of Japan have successfully developed a National Health Insurance (NHI) system:

- Allowing universal access to healthcare without restriction based on income or financial resources;
- Providing high quality treatments in appropriate facilities by properly trained medical specialists;
- While controlling healthcare costs increase through various mechanisms, giving Japan one of the best rankings in the world for the ratio of healthcare costs to total budget and the control of its evolution, as well as for longevity and other indicators.

Moreover, the introduction on trial basis in 2010 of a new premium in the NHI Price revision to promote innovation has already generated tangible results towards reducing the 'drug lag':

- Unapproved drugs and indications are quickly being developed as per request of the Regulatory Authorities and Experts Societies;
- More new products are simultaneously developed in Japan and in the rest of the world;
- Japan is more and more perceived as a country recognizing innovation and will therefore attract more investment from the industry, which will ultimately benefit the patients

Demographic perspectives suggest that the current healthcare funding model will need some adjustments:

- Healthcare costs of the elderly are 4 to 5 times higher than the ones of the active population;
- The burden of the rapidly aging population will generate more pressure on the healthcare budget, which current price control mechanisms will not be able to contain.
- Besides aging, the higher focus on prevention will further add to the funding needs.

In this context, the discussion on HTA presents an opportunity for a better evaluation of the merits of certain therapies and for a reflection on the reallocation of healthcare related resources. This debate should not be limited to the drugs component only, as drugs represent only about 20% of the total healthcare costs, but should include medical procedures and devices. HTA used in a selective, judicious way with the right methodology and expectations could add value for the patients and should not only be introduced as a new price control mechanism.

Since its introduction in various countries like Australia, Canada or the UK, HTA became different from its original intent; recent trends point to HTA being used for the purpose of setting prices or restricting access to innovative medicines, e.g. in the UK and recently in Germany, generating patients' concern. Some other European countries are moving to different systems for a better access of their patients to innovation, based on a broader consensus, such as e.g. in Sweden or Switzerland.

HTA should be recognized as one element to be considered for the facilitation of evaluation of innovative drugs, with certain conditions:

- HTA aspects have already been built in the current NHI system through the “comparator pricing method”, various premiums, and mechanisms to contain costs. They provide a basis for a possible evolution of the system;
- HTA cannot be universal: it should apply to certain types of drugs or drug categories;
- HTA should not generate delay in the process of drug approvals and NHI listing;
- HTA itself should not generate an additional burden to society with unnecessary costs and bureaucracy that could be better spent on research and for the quicker access of drugs to patients;
- HTA implementation would require a major effort to build necessary capabilities in the industry and in the administration, and this effort should not be underestimated;
- HTA should reflect real-life conditions: Japan has one of the most comprehensive Post-Marketing Surveillance system, providing a process and source of data that could serve as the basis of an evidence-based HTA review;
- HTA, when used for cost effectiveness considerations, should be used transparently and should not become an unclear area of the pricing system of drugs in Japan.

In any case, a thorough investigation with all stakeholders concerned, including our industry, should be done. We should recognize that the current system has already included some HTA aspects and this should serve as a basis for any evolution for cost-effectiveness. Moreover, any modification to the current system should not be implemented prior to limited, monitored pilots in order to check its relevance and practicality.

Beyond this topic of HTA, EFPIA Japan member companies advocate that it is urgent to move the debate from pricing to funding. We strongly believe that any system should put the patient's needs first, enabling access to the most innovative therapies in the shortest possible time.