Improving Patient Access to Medical Devices and Technologies:
Common Understanding on Health Care Funding, Reimbursement and Technology Assessment
Executive Summary

Patient Access to Health Care

- All patients have the right to timely access to up-to-date medical care, including medical devices and technologies.

- The CE marking, as well as U.S. FDA approval and Japan's shonin, are reliable standards for ensuring that only safe medical devices and technology, which perform as intended, are made available to patients.

- Health care professionals should play a central role in deciding which medical treatment and technologies that they believe would best improve the quality of patient care, both generally and on an individual patient basis**.**

- Governments should provide adequate funding and reimbursement for existing and new medical devices and technologies over the long term as a way to ensure patient access to quality medical care. Healthcare budgets should take into consideration demographic developments.

- Payment and coverage decisions should be based on market factors, reflecting international experience, clinical benefit and comparisons to alternative therapies when relevant.

- Payment and coverage levels should be routinely and frequently updated to keep pace with market and medical developments in order to reflect benefit and cost of new technologies and procedures.

- Patients should always have the right to contribute personally to the cost of treatment of their choice.

Health Technology Assessment

- Health Technology Assessment is a useful and recognized instrument which yields valuable information to assist health care professionals, providers and payers in the decision making process.

- Health care professionals and industry experts should be at the center of the assessment. While national institutions may evaluate the outcomes, they should not have a monopoly on the assessment process.

- Data requirements should be sensitive to the medical device innovation process. International clinical and research data as well as actual market experience should be accepted as sufficient evidence.

Innovative Technology

- On the introduction of innovative technology governments should adopt a flexible approach, which is decentralized, and based on clinical freedom and patient-focused decision making.

- In order to provide timely patient access to improved treatment, there should be a mechanism for making innovative medical devices and technologies available and funded on an interim basis while they are further evaluated.

- By allowing regional coverage decisions, or by giving private insurers discretion to cover and pay for certain technologies, governments can avoid long bureaucratic queues and realize benefits.

- Clear, transparent and published rules of the decision making process should be provided at the outset to the industry and interested parties. The process should also be rapid, (<90 days) given the very short product life cycle of innovative medical devices (often less than 2 years).

- A formal process of appeal should be in place allowing manufacturers a fair hearing and entitlement to provide additional data if appropriate from medical experts.

HIMA

EUCOMED (Incorporating AdvaMed)

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Introduction

EUCOMED is a scientifically based association representing 43 multi-nationally operating corporate members and 25 national and pan-European associations (totaling around 3000 SME enterprises) involved in research, development, manufacturing, testing, sales and distribution of medical devices, technologies and services in the health care sector. HIMA is a global industry trade association based in Washington, D.C. with offices and/or affiliates in Japan, Europe and Asia. HIMA represents more than 800 international manufacturers of medical devices, diagnostic products, and medical information systems that produce 50 percent of the $147 billion purchased annually around the world.

The purpose of this paper is to establish a common platform within the medical technology community concerning the provision, funding and reimbursement of medical devices and technologies.

HIMA and EUCOMED wish to proactively participate in, and contribute to**,** the societal debate concerning the availability, acceptance, assessment and funding of medical devices and technologies, particularly emerging technologies, as it relates to best patient care. Providing innovation in health care to increase patient well being, improve quality of life and reduce mortality in a cost beneficial way is at the forefront of industry's position.

The medical devices industry is significantly different in nature to the pharmaceutical industry. The product life-cycle of new medical devices and technologies is often as short as 18-24 months with a constant stream of new and revised technologies emerging daily. In order for society to best benefit from such extraordinary advances, new methods for providing access, obtaining economic evaluations and providing coverage must be explored. The medical devices industry is keen to assist all stakeholders, however possible, in achieving these objectives in an open, transparent and shared way. To this end we would like to contribute the following platform for discussion.

I. Right to safe and effective treatment in health care systems

All patients have the right to timely access up-to-date medical care and medical device and technology.

- The CE marking, as well as U.S. FDA approval and Japan's shonin, are reliable standards for ensuring that only safe medical products which perform as intended are made available to patients.

- Health care professionals should play a central role in deciding which medical treatment and technologies would best improve the quality of patient care.

- This choice may be informed by economics of care based on health technology assessment output where such data are available.

- Patients should always have the right to contribute personally to the cost of appropriate treatment of their choice.

II. Patient access to quality medical care must be ensured by an adequate level of funding and reimbursement for existing and new medical devices and technologies

- ***Payment and coverage decisions should be based on market factors, reflecting clinical benefits and cost effectiveness.***

Where governments choose to establish payment and coverage limits for medical products and services or restrict their sales, patient access to quality medical devices and technologies is unnecessarily delayed, price competition is undercut, and incentives for innovation are stifled. Market mechanisms, rather than imposed pricing by government authorities, will ensure patient access to appropriate medical products and services.

- ***Payment and coverage levels should be routinely updated to keep pace with market developments in order to reflect benefit and cost of new technologies and procedures.***

In the case of fixed prices, transparent procedures should exist in order to update them quickly and regularly. Delaying pricing decisions or limiting price levels restricts the availability of medical products and services to treat patients, discourages competition, innovations and product improvements.

- ***In order to provide the timely patient access to improved treatment, there should be a mechanism for making innovative medical devices and technologies available on an interim basis while the device or technology is being further evaluated.***

For certain technologies, insurance systems can consider restricting access to the technology to a particular site (or sites) where patient outcomes and potential costs can be explored before the technology can be disseminated further.

- ***Over the long-term, governments should consider the need for additional spending on health care as a percentage of GDP to reflect growing aging populations.***

While investments should be made to develop more effective health care treatments, more efficient delivery systems, and constant gains in quality and productivity, rapidly aging populations will require additional funding for health care over the long term. Patients over the age of 65 consume 4 to 5 times as much health care as their younger counterparts.

III. <u>Health technology assessment (HTA)</u>

- ***HTA is a useful and recognized instrument which yields valuable information to assist health care professionals, providers and payers in the decision making process.***

- ***Industry and any qualified party can conduct and present the results of this assessment. While national institutions may evaluate the outcomes, they should not have a monopoly on the assessment process.***

Demands for formal assessment information by health care professionals, providers and payers should be commensurate with the risks, uncertainties and scale of use of the technology. Parties such as health care professionals and industry experts who understand the technology must be involved in its assessment and consideration must be given to the practical impediments (time, cost, patient impact) of performing these assessments. Government's preferred role should be to make available to health care professionals, providers and payers the information that is gathered to assist them in making important medical treatment decisions.

Documented and validated market experience (*e.g.* Register) with the device in other countries, as well as available clinical and research data, is sufficient to efficiently and expeditiously validate new medical devices.

- ***Decentralized decision making for the introduction of innovative technology***

Although each government has the option of issuing national decisions or standards to determine whether a certain medical device or technology should be made available and paid for throughout its health care system, it is important to allow a flexible approach of regional introduction and patient-focused decision making.

By allowing regional coverage decisions, or by giving private insurers discretion to cover and pay for certain technologies, governments can avoid long bureaucratic queues and realize benefits. In addition, health care decision-makers can promote marketplace competition based on demonstrated product value, and also ensure sensitivity to product innovation for medical devices and technology.

IV. Key Criteria for appropriate Technology Assessment for all qualified parties.

Given the reality that governments have or plan to establish health technology assessment processes to determine coverage and payment for new medical devices and technologies, the following standards should characterize these processes:

- ***There should be clear and transparent rules for decision making.***

Manufacturers need to participate in the process and must know from the outset how decisions will be made, the steps in the review process. The process should be predictable, clear and transparent.

All requirements with regards to products and technology assessment must be published and communicated to the industry and all interested parties.

Manufacturers need to be able to access appropriate research resources at reasonable cost and in reasonable time scales.

- ***There should be reasonable time frames for decision making.***

Decisions on coverage and payment should be in less than 90 days given the relatively short product life cycle of many medical devices (i.e. less than two years), with reliance on systems that facilitate the exchange and transmission of clinical and economic information.

- ***Data requirements should be sensitive to the medical device innovation process.***

Types of evidence required should include the judgement or consensus of medical practitioners. Evidence should take into consideration variations in costs based on the location of care, such as in-hospital versus outpatient or home care. Finally, international clinical trial data and actual market experience should be accepted as sufficient data; local trials should not be necessary if significant documented and validated International experience, data or publications are available.

- ***There should be serious consideration of how a device improves patient quality of life.***

Technology assessment decisions should not neglect how a device improves the life of a patient. Decisions that are based solely on costs will ultimately fail patients who depend on access to lifesaving and life-enhancing innovative technologies.

- ***There should be a balanced opportunity for participation in decision making.***

Manufacturers must participate in any discussions and meetings about the data submitted to clarify concerns and present additional arguments to support the reimbursement of their product.

- ***There should be a meaningful appeals process.***

Industry should have access to a formal process to appeal negative decisions and to have a fair hearing and consideration of evidence to refute a negative decision. Specifically, manufacturers should be entitled to request a hearing to present their reasons for appealing the decision and to provide additional support if necessary by medical experts of their own choosing.