



CONGRESS HIGHLIGHTS

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Health is Wealth: Step II Toward to a European Lead Market in Healthcare

Principles of Classification in Healthcare based on Innovation

Summary of the discussion in Salzburg on June 6th 2007

The Goal for Classifying Medical Provisions is to bring all medical practice to the highest possible State of the Art and to find a common European basis for the medical arts. Medical progress is inextricably linked to innovation; and both innovation and medical progress are a source of improved public health outcomes and a dynamic lead market development. Classification should be a guiding framework to systematically (re-) evaluate treatment provisions of modern medicine. This should also support decisions in investment and reimbursement of health care. With constant reevaluation outdated concepts are removed freeing up resource for the financing of new and improved concepts.

The report "Health is Wealth" to the European Parliament recommends in the Cluster Medical Arts a classification of all Medical Provisions. In the meeting with the Health Council on October 10, 2005 the wish was expressed to develop principles for classifying Medical Provisions.

The Academy formed an interdisciplinary group composed of medical experts in their field, representatives from industry, the European Commission and the Council, health administration and insurance providers,



which met on June 6th to formulate a draft on the principles for rational classification of medical provisions.

Any classification of medical practices and technologies should appropriately address the specific characteristics of medical innovation. Innovation in medical processes and technology is the single most important driver of improvement in Health Care. New and better techniques and methods are appearing every day to help practitioners in their efforts both in fighting and preventing diseases. Innovation is a result of a continuous effort which needs to be sustained in order to fully support the improvement of a population's health. Medical progress can occur as radical innovation or as a constant "evolutionary"

improvement in small, but multiple steps, both of which are important to improve our health-care system over time. Such progress improves not only the quality of provision but ultimately the quality of life.



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Medicine and its practice have a broad reach across every cultural endeavour, from prevention to intervention by way of prediction and prognosis, diagnosis, therapy, rehabilitation and long term care. Innovation is incremental knowledge based on experience and scientific investigation which meets a hitherto unmet medical need and thereby creates a new market. The transformation from bench to clinic requires an exact scientific process according to high scientific standards, extensive clinical testing and a huge upfront investment of the innovator. The transformation steps depend on the nature and severity of the disease, the invasiveness of the intervention and the acceptability of risk or possible harm to the patient.

New evolving areas that can be expected to find a new market focus include

- e-Health and e-Medicine
E-Health is a powerful tool to improve the quality of care, ensure free access across borders to information for professionals and patients; similarly mobility of the patients will become easier as a result. E-Health is a tool to



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stimulate a European market in all areas of medicine and gives quick access to information. There is a quick local know-how translated in the European area on a large scale for the benefits of patients. E-Health is complementary to medical information and innovation. The created network is a facilitator for common quality in Health Care in all Europe.

- Other fields in the innovative area are all the new upcoming developments in Nanotechnology for better understanding of diseases and fighting them.

- The Information technology (IT) gives a further stimulus in propelling modern medicine, especially in research and patient care and is a prerequisite for e-Health and e-Medicine.

Molecular medicine and Gene technology are expanding fields in understanding diseases and finding key elements for therapy. Prediction might be influenced by gene technology. Moreover molecular medicine and gene technology open new doors to a better understanding of individual patients' diseases and to engage in personalized medicine.

Truly innovative technologies must be given the market freedom to demonstrate their clinical value by collecting clinical data from real world use to supplement the limited data of clinical studies submitted for initial regulatory approval. Therefore, innovative technology is to be considered in the Classifications as Class I (classification described below) for a period of five years with subsequent reevaluation and re-classification if appropriate.



This is necessary to ensure that new technologies are reimbursed fully thus providing a viable incentive for innovation. As older techniques are shown to be inferior they will be eliminated from the medical offer.

Classification is based on evidence which can be gained by experience, consensus and studies in various forms.

The gold standard of evidence is the randomized clinical trial. Well designed, observational and population-based clinical trials without randomization can also provide valuable data especially when assessing parameters like quality of life, treatment satisfaction, compliance or dramatic effects.

Evidence from respected authorities based on clinical experience, descriptive studies, reports from experts or consensus studies are sources of evidence too.

Similarly, clinical outcomes over periods longer than characteristically observed in RCTs are also an important measure.

The strength of recommendations can be graded:

- strongly recommended with strong evidence of efficacy and substantial clinical benefit,
- generally recommended when there is strong or moderate evidence for efficacy, but limited clinical benefit
- not recommendable owing to moderate evidence against efficacy and adverse outcome, unless benefit outweighs risk in the absence of other treatments
- never recommendable in strong evidence against efficacy or adverse outcome (CDC-Grading).

Classifying medical provisions has been established in the area of medical interventions, mainly the basic classification foresees three classes:

Class I: based on a rich and robust data base comprising randomized studies and clinically-based experience and evidence.

Class IIa: mostly based to consensus studies

Class IIb mostly based to experience

Class III: based to the clinical experience.

Classification linking evidence and long term outcome to disease severity

Class I: highly effective: life threatening and acute situation (e.g. fracture, myocardial infarction)

Class IIa: effective: chronic and long term conditions

Class IIb: less effective: (e.g. homeopathy, natural medicine, but cosmetic surgery too)

Class III: no effect: disturbances in general feeling

Class I and IIa are items to be reimbursed totally.

Class IIb and III are covered by the patient.

For diagnosing a triple classification seems to be feasible, as well for prevention as

Effective
Less effective
Non effective

which can be adapted to Class I, IIa, IIb, III too.

In drug therapy:

Class I: safe and effective

Class IIa: effective

Class IIb: safe

Class III: neither safe nor effective

The classification gives the basis for reimbursement of medical provisions: Class I and Class IIa are items to be reimbursed via the Solidarity in Taxes and insurances,



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Class IIb and Class III are those items, where the costs are covered by the patients.

The final goal in classifying is a constant re-evaluation of the medical provisions to maintain a relevant and state of the art assessment status. This is a contribution for a constant quality control and insurance. This is a tool for adequate reimbursement.

Classification means a constant re-evaluation of medical practice and is the basis for quality management. Furthermore classification provides an indispensable and common basis for a European Market and supports the concept of a European Lead Market.

With a constant quality control a basis for a homogenous Europe-



wide medical care of the highest international standard is given. This is the vision of a European Lead Market in Health.

As next step the Academy should launch a report on: Creating an Innovate Europe: toward the European Lead Market in Health. This

report should design a European concept for a Lead Market and how to implement this Lead Market according the Lisbon and Maastricht Criteria.

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