Eucomed statement

Patient Access to Medical Devices – A Comparison of U.S. and European Review Processes

New England Journal of Medicine, 2 August 2012

KEY ELEMENTS OF THE EUROPEAN FUNDING SYSTEM NOT CONSIDERED

1. In Europe patient access is not intrinsically linked with reimbursement

Eucomed agrees with the authors, both FDA officials, that it is important to ensure fast patient access to innovative technologies. However, the researchers assume that in Europe patient access is only realized after a new specific reimbursement is set up, which is not the case.

Early patient access is ensured in most European countries through special payment mechanisms and / or leveraging available reimbursement for innovative technologies. Special payment mechanisms speed access and bridge the period between product approval and new specific reimbursement for innovative technology.

Examples of special payment mechanisms, which were not considered by the researchers, include payments via hospital budgets for innovation and special funds that finance innovative technologies during the reimbursement procedure. These examples are common practice in many European countries.

A recent study of the European Health Technology Institute conducted by the London School of Economics (LSE) reported that approximately 70% of countries surveyed use special payment mechanisms for innovative technologies and these are considered to be effective in integrating new technologies into the health system (for more information please download this presentation).

New specific reimbursement for technology in Europe should be viewed as the moment that the public healthcare system has assessed and acknowledged the complete value of the new technology and not as the starting point of patient access.

In reality the FDA officials do not provide a perspective on the timelines for patient access but on the timelines for a new specific reimbursement. In Europe patient access and reimbursement are not intrinsically linked as is assumed by the FDA officials.

QUESTIONABLE METHODOLOGY CONSIDERATIONS

2. Questionable starting point to compare EU and US patient access timelines

The submission of the dossier to the regulators is used as the starting point in the study, which is an intermediate point in reality. A more appropriate and equivalent starting point would be the point in time when the technology is ready to be used – e.g. implanting technology in humans during clinical investigations.
If the submission of the dossier is considered to be the starting point then the time to regulatory approval (and not reimbursement) would be the real hard endpoint.

3. Questionable selection of data sources

- Only **anecdotal** data is used to determine the speed of private insurance reimbursement in the US (66% of the U.S. population is covered by private insurance).

- The FDA officials claim that innovative technologies not covered under an existing diagnosis related group (DRG) require review under the health technology assessment process. However, all examples used in the study already have a DRG. It would have been more appropriate if the researchers would have used 1st generation technologies, which would have shown a different outcome in favour of Europe.

- It is unclear what exact data is used to define the timelines for reimbursement in the different European countries. Eucomed has requested the data.

INCORRECT ASSUMPTIONS

4. HTA does not precede initial patient access

- A big difference between the US and EU model is that in Europe patient access is more progressive and different mechanisms of control apply. In Europe the data on benefits and affordability are collected while having technology (with proven safety and clinical performance) already accessible for patients.

  After receiving the CE mark in Europe, and while the product is available to patients, continuous clinical investigation and observational studies are performed to determine the (long term) effectiveness in terms of benefit and the value of the technologies for patients and society.

  Health Technology Assessments can be set up as an input to grant and define the level of reimbursement and which patient groups benefit most, while also taking cost-effectiveness and budget impact implications into consideration.

5. The FDA officials incorrectly define Notified Bodies as for-profit organisations.

- Notified Bodies are third party Conformity Assessment Bodies, nominated and monitored by Member States' Competent Authorities. As independent bodies with the required technical expertise, Notified Bodies carry out pre- and post-market conformity assessment and certification.

  Notified Bodies may be government bodies (such is the case for Italy, Spain and Portugal) or for-profit organisations (e.g. the TÜVs in Germany and the British Standards Institute, BSI, and Lloyd's Register in the UK).

  The decentralised approach to Notified Bodies has been highly successful not only in terms of ensuring safety, where evidence shows it to be equivalent to the US system, but also in terms of allowing for rapid access for patients and healthcare professionals to the latest innovations for healthcare.