SNITEM

Medical Devices Evaluation and Reimbursement
IMAPS Workshop
December 4, 2012
SNITEM profile

- SNITEM the leading trade organisation, was set up in 1987
- It draws together more than 315 companies
- SNITEM estimated that its scope (medical device and Healthcare ICT markets) corresponded to a global turnover of 10 billion euros. (60% of the market)
- 25 permanent staff
- a wide variety of skills and profiles: engineers, doctors, pharmacists, health economists, legal specialists, etc
- This diversity allows skills to be pooled for all the fields covered by SNITEM
Activities

In accordance with the applicable rules of law, particularly competition law, SNITEM’s main activities are:

• to inform, to support and to federate, but also
• to organise the nationwide grouping of companies working in the market of products or services
• to examine and defend the economic and industrial interests of its members and to represent them, in dealings with the authorities and with any public or private organisations, Chambers of Commerce ...
• to study any matters of economic, professional and technical nature relating to the Medical Technology, Medical Device and Healthcare ICT industries
• to develop and maintain, among its members, respect for the general interests of the Profession

On becoming members of the organisation, companies pledge commitment by signing SNITEM’s Code of Ethics Charter
SNITEM in context

Patient Associations
Centres of competitiveness
Learned Societies
Representative bodies and associations for health professionals (doctors, specialists, pharmacists, engineers, ...)
User Associations
Representative bodies and professional associations in the field of health, both French and European
University teaching
Healthcare manufacturing associations
HEALTH TECHNOLOGY ASSESSMENT (HTA) ORGANIZATIONS

• **Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM):** The law of 1st July 1998 created the French Health Products Safety Agency within a global context of reinforcing health monitoring and control of all products for human use. Therefore, the ANSM is the competent authority for all safety decisions taken concerning health products from their manufacturing to their marketing.

• **Haute Autorité de Santé (HAS):** The French National Authority for Health was set up by the French government in August 2004 in order to bring together under a single roof a number of activities designed to improve the quality of patient care and to guarantee equity within the healthcare system.

• **Commission Nationale d’Evaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS):** The purpose of the CNEDiMTS as part of HAS body is to provide scientific opinion concerning the usefulness, interest and good use of medical devices and other non-drug healthcare products. Since July 2010, CNEDiMTS took over the mission of assessing medical and surgical procedures that were previously assessed by a separate HAS specialist committee.
ORGANIZATIONS WHO DETERMINE THE REIMBURSEMENT

• **Health Ministry**: The Health Minister determines if a device will be admitted to reimbursement, based on the appraisal by the CNEMiDTS, the price or tariff is fixed by the CEPS

• **CEPS (Comité Economique des Produits de Santé)**: It determines the price or the tariff after negotiation with the manufacturer

• **UNCAM (Union Nationale des Caisses d’Assurance Maladie)** is the decision making body for coding and fixing medical procedures tariffs, on the basis of HAS appraisals and after negotiation with health professionals unions within a specific committee
CE Marking
Classification of MDs as a function of risk

- Class I  Low degree of risk
- Class IIa  Medium degree of risk
- Class IIb  Increased potential for risk
- Class III  Very significant potential for risk
  (includes active implantable MDs)

The First Mandatory Step to French Market Access for all Medical Devices!
Principal procedures for reimbursement

1. General case of MDs integrated in the DRG (Disease Related Group) in health establishments: guidance of COMEDIMS (Committee on medicinal products and sterile medical devices)
   Public Tender Regulation (no health technology assessment at national level)

2. MDs included on LPPR: (a positive reimbursement list) guidance of CNEDiMTS (MD used in the community by patient and those reimbursed in addition by the DRG)

3. MDs reimbursed within framework of the medical procedure: guidance of CNEDiMTS
MDs included on LPPR
(a positive reimbursement list)

- Reimbursement for a medical device used in ambulatory care or too expensive to be funded with DRGs Tariffs is submitted to enlisting on this positive list, including 4 groups (so called “titres” in French”):

I. MDs for treatments and devices for life care, dietetic food and dressing articles
   II. External prostheses and orthoses
       III. Implantable devices
       IV. Physical handicap vehicles

MDs included on LPPR
Listing under the medical device own trade name
MDs included on LPPR

Evolution of each title from 2007 to 2010

<table>
<thead>
<tr>
<th>Year</th>
<th>Titre I</th>
<th>Titre II</th>
<th>Titre III</th>
<th>Titre IV</th>
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<tr>
<td>2007</td>
<td>1 335</td>
<td>812</td>
<td>121</td>
<td>137</td>
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<td>2008</td>
<td>1 398</td>
<td>861</td>
<td>137</td>
<td>115</td>
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<tr>
<td>2009</td>
<td>1 477</td>
<td>905</td>
<td>115</td>
<td>118</td>
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<tr>
<td>2010</td>
<td>1 486</td>
<td>956</td>
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</tbody>
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- Titre I: +8.4% from 2007 to 2010
- Titre II: +5.6% from 2007 to 2010
- Titre III: +1.0% from 2007 to 2010
- Titre IV: +0.6% from 2007 to 2010
MDs included on LPPR

How to be listed in the LPPR?

Two pathways exist:

- **Listing under “generic line”** which is the general rule to which a tariff for reimbursement is attached. The manufacturer only needs to label its product with the corresponding LPPR code (existing tariff of reimbursement). Existing generic lines are reviewed every 5 years, to ensure that the description corresponds to the evolution of MDs.

- **Listing under the medical device own trade name**, where they are specifically designated and described. It is necessary when the device is innovative or presumed to impact Health care expenditure or requires a specific follow-up for safety issues.

*In this case, a two steps process is to be followed!*  
*described in the next slide*
MDs included on LPPR
Listing under the medical device own trade name

Technical assessment:
• Innovative characteristics
• Expected service
• Added value for the patient
• Number of patients who might benefit

Tariffs fixing:
• If the CNEDiMTS’ appraisal is positive
• After negotiating with the manufacturer
• Set tariff for reimbursement
MDs included on LPPR
CNEDiMTS: Assessments

Main criteria
Actual Benefit

Dossier submitted requesting reimbursement

Risk/benefit ratio

Public Health benefit

Position of the device in the therapeutic strategy

Insufficient → STOP

Reimbursement

Assessment AB

Sufficient

Assessment of Added Clinical Value

<table>
<thead>
<tr>
<th>I</th>
<th>Major improvement</th>
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<tbody>
<tr>
<td>II</td>
<td>Substantial improvement</td>
</tr>
<tr>
<td>III</td>
<td>Moderate improvement</td>
</tr>
<tr>
<td>IV</td>
<td>Minor improvement</td>
</tr>
<tr>
<td>V</td>
<td>No improvement</td>
</tr>
</tbody>
</table>
3 **Reimbursement of a device through a medical procedure**

When the medical device is delivered to the patient only within a medical procedure that is not already coded for reimbursement, they are enlisted on various lists:

- NGAP: General list of professional procedure (nurse and dentist procedure)
- CCAM: Common classification of medical procedure (in an ambulatory setting or within hospital)
- NABM: Medical biological procedure

Based on HAS appraisal, the Committee of grading of Medical Procedure (CHAP= Commission de Hiérarchisation des Actes Professionnels) managed by the Health Insurance Union (UNCAM= Union Nationale des Caisses d’Assurance Maladie) will fix reimbursement tariffs and rates for medical procedures.
To summarize the French Market Access!

1. Medical device used in hospital setting
   - Yes
     - Included in DRG?
       - Yes
         - Reimbursement via DRG tariffs
       - No
         - Generic line?
           - Yes
             - Use combined with medical procedure?
               - Yes
                 - Reimbursement based on existing code OR
                   - Creation of a new code & new tariff
               - No
                 - P&R process
                   - For new medical device
           - No
             - Reimbursement based on existing tariffs

2. Included in DRG?
   - No
     - Use combined with medical procedure?
       - Yes
         - Reimbursement based on existing code OR
           - Creation of a new code & new tariff
       - No
         - P&R process
           - For new medical device
Conclusion

My advices to access to the French Market!

• It’s not easy to success in the MD French Market without reimbursement!

• Very early, you have to include the assessment tools in your product development strategy!

• You have to demonstrate the benefit for the patient!
Thank you for your attention

Suggested readings
-Medical Device Assessment in France, Guidebook HAS, December 2009

Useful links
-Comité Economique des Produits de Santé: http://www.sante.gouv.fr/ceps

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