



Eucomed Six Key Principles

for the Efficient and Sustainable Funding & Reimbursement
of Medical Devices

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Six principles for Funding & Reimbursement

This position paper addresses 6 principles for the Funding & Reimbursement (F&R) of medical devices that Eucomed has identified to maximise the effectiveness, value and overall sustainability of Europe's healthcare systems: ↓

1 Transparency of funding & reimbursement policies

2 Predictability & consistency in decision-making processes

3 Stakeholders' involvement in funding & reimbursement processes

4 Enabling patient access to care

5 Supporting & rewarding innovation

6 Creating seamless care

Executive Summary

To guarantee future growth and prosperity there is a critical need for effective and sustainable European healthcare systems.

This position paper provides Eucomed's recommendations on how to ensure that the Funding & Reimbursement (F&R) of medical devices and services becomes a core component of a sustainable, effective and patient-centred healthcare system.

Healthcare systems need to encourage the introduction and development of innovative new devices that provide relevant benefits to patients, physicians, payers, providers and the overall healthcare system.

The need for the continued sustainability of Europe's healthcare systems and value-driven innovation is particularly important due to an ageing population. This, combined with the subsequent increase of chronic diseases, and the need to maintain universal coverage and equal access are only some of

the factors that indicate that European healthcare systems now have a clear challenge - to increase their efficiency, whilst at the same time ensuring a high quality of care.

Eucomed believes that healthcare should always be viewed as an investment for society and identifies 6 principles for the F&R of medical devices: **transparency, predictability & consistency, stakeholder involvement, access to care, rewarding & encouraging innovation, and creating seamless care.** These principles will

- Maximise the effectiveness, value and overall sustainability of Europe's healthcare systems;
- Support innovation-rewarding F&R systems;
- Guarantee value for payers;
- Ensure that patients are able to receive the healthcare they need and deserve.

Introduction

The medical device industry plays a significant role in enhancing efficiency and ensuring the sustainable functioning of healthcare systems. Medical devices and services deliver benefits to patients and innovative solutions to healthcare providers to deal with existing and new healthcare challenges.

In Europe, the F&R of medical devices is provided independently by each Member State. Every Member State has its own system resulting from its own particular political, administrative and constitutional structure (e.g. with different levels of public and private expenditure¹). Inconsistently applying the 6 principles we propose in this paper creates inefficiencies in healthcare systems and also uncertainty for manufacturers. This leads to:

- Unnecessary delays in access to innovative technologies;
- Slow adoption of new and effective technologies;
- Inequalities in guaranteeing that patients receive the most effective and efficient treatment;
- A negative impact on investment in Europe with the latest technologies being made available in other countries first;
- Healthcare system inefficiencies not driven by a value-based approach but more focused on

savings whilst ignoring patient clinical outcomes and quality of life improvements and benefits for society and a sustainable healthcare system.

Acknowledging the presence of independent F&R systems across Europe, sharing best practices and encouraging a focus on funding mechanisms for innovative medical devices, would enable a more timely and effective uptake. While the European Union (EU) does not have the mandate to legislate and install a single reimbursement system, there is enormous value in working at a European level on healthcare. Member States are committed to working together to share experiences and information about approaches and good practice².

To guarantee future growth and prosperity there is a critical need for efficient and sustainable European healthcare systems, particularly in this era of a rapidly ageing European population and the consequential growth of chronic diseases (the cause of 70-80% of European healthcare costs³).

Reviewing and adapting F&R infrastructures will be a necessity. Eucomed highly encourages countries to optimise their F&R systems by focusing on the 6 principles below which are applicable to current and new systems.

This position paper comes at a particularly important time in the ongoing policy debates in Europe. The outcome of these discussions will have an impact on the trajectory of the F&R of medical devices in Europe. These important debates include:



1 See appendix 2

2 Council Conclusions on Common Values & Principles in European Union Health Systems, 2006

3 Improving Health for All European Citizens, European Commission, May 2013

The Cross-Border Healthcare Directive that came into force on 25 October 2013 and has new provisions for cross-border reimbursement;

The European Semester process, in which the European Commission gives advice and recommendations to Member States on their spending and budgetary plans, which includes the healthcare sector and healthcare reforms;

Multiple domestic initiatives within European countries, as well as amongst international organisations, such as the OECD, which have investigated current public and private healthcare financing.

1. Transparency

The way in which national F&R policies are developed should become more transparent. More transparency within a legal and administrative framework provides clarity and makes it easier to approach and interact with the relevant authorities from the beginning.

Current Limitations & Consequences

In some countries and regions, F&R decisions are mainly politically-driven and are often without transparent processes. Some countries for example do not describe F&R methods, criteria to adjust rates, coverage status, etc. In a transparent F&R system any change to processes is announced well in advance.

Poor transparency means that patients are often unable to gain access to the particular medical device that they need. For the hospital, it means being unable to prescribe and use the appropriate treatment and for industry, it creates uncertainties and directly impacts on investment and innovation decisions.

What We Recommend

More transparency is needed in setting new tariffs in hospital and community care settings. Moreover, existing tariffs should be reviewed and updated based on well-defined criteria and timelines. Lastly, greater transparency on the availability of budgets, procurement processes and on the decision-making process would benefit all healthcare partners.

New F&R policies should be communicated well in advance of their implementation and in sufficient detail to permit review by all stakeholders.

DO'S: ↓



Create well-defined and publicly available F&R criteria, processes and timelines



Regularly publish budget allocation decisions

2. Predictability & Consistency

F&R systems for medical devices should have well-defined pathways and timelines governed by clear principles so that outcomes are more predictable. There should be an established link between the reimbursement decision and allocation of funds to ensure timely and equal access of patients to therapies.

Current Limitations & Consequences

Medical device manufacturers are often confronted with irregular and unpredictable data requirements and pathways towards the F&R of innovative devices. This can stifle further innovative efforts and potentially slow down patient access to the medical treatment they require. A lack of predictability causes uncertainty and undermines the F&R system, which can impact the ability of healthcare systems to provide the services and care which are expected of them.

The medical device industry makes substantial investments in research and development. Therefore it is essential to have established and predictable pathways for the F&R of medical devices. This avoids duplication of efforts and delaying the development of required data. Clear criteria keep the momentum of constant innovation going. Manufacturers should know what data is required to guarantee F&R when they start investing into the research & development of a new product.

What We Recommend

Processes should include clear timelines with regards to updates allowing for better/easier inclusion of novel therapies and medical devices.

The data requirements and pathways used to obtain F&R of medical devices should be consistent within the same country and predictable over time. Such pathways need to recognise that medical devices, whilst being a highly diversified group of technologies, tend to exhibit similar characteristics with regards to the speed of innovation and (short) product life cycles.

Reimbursement tariffs should be consistent with costs and/or healthcare providers should obtain sufficient additional funds to enable the use of medical devices to provide access and achieve the desired patient outcomes. There should be a balance between cost and funding across therapies to avoid inequality in access to healthcare.

Once a decision has been made for a particular medical device, and/or a positive appraisal has been communicated from a national, regional or local assessment body, it is essential that appropriate funding becomes available timely. Only then can healthcare providers ensure that the medical device is open to all eligible patients in a fair and consistent manner.

DO'S: ↓

- Define minimum requirements to be considered for F&R

- Adhere to published F&R timelines

3. Stakeholder Involvement

F&R systems for medical devices should encourage and facilitate the participation of all stakeholders to ensure effective and informed decision-making.

Current Limitations & Consequences

The medical device sector includes a broad variety of unique and valuable expertise that should be consulted. Those parties are not always engaged with consistency and sometimes they are taken out of the process entirely.

The use of a medical device is usually part of an overall sequence of care for the patient. The successful adoption of a medical device is therefore the result of a systematic approach requiring different stakeholders to work together.

What We Recommend

F&R authorities should engage in a constructive dialogue and efficient collaboration with all parties involved. Stakeholders have unique and valuable insights that can help them. Closer stakeholder collaboration will ultimately lead to better patient outcomes thanks to a more informed decision-making process. There should be clearly defined platform for all parties to work together.

DO'S: ↓



Create broadly inclusive forums to engage with different stakeholders



Consult stakeholders before the final decision-making

4. Access to Care

Healthcare systems need to ensure that F&R systems for medical devices are drivers for equity, access to care and the rights of patients.

The overarching values of universal and equal access to good quality care have been widely accepted in Europe. This means that no-one is barred access to healthcare; with equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay.

Current Limitations & Consequences

All European healthcare systems aspire to reduce the gap in health inequalities. Current F&R systems however can create barriers for the adoption of, and access to medical devices due to variations in decision making at the regional and national level.

What We Recommend

F&R should facilitate adoption of and access to valuable medical devices. F&R decisions/processes should not be used to limit patient access to treatments or ration healthcare. When a reimbursement decision is made, appropriate funding should be put in place and measures taken to avoid that geographic or other factors impose restrictions on access to optimal healthcare.

DO'S: ↓



Ensure that F&R systems do not create barriers to adoption of, and access to medical devices



Follow-up on reimbursement decisions with appropriate funding

5. Supporting & Rewarding Innovation

Healthcare systems need to encourage the introduction and development of innovative technologies that provide relevant benefits to patients, physicians, payers, providers and the overall healthcare system.

Following the European Commission's 'Green Paper on Innovation', innovation may be broadly defined as "the successful production, assimilation and exploitation of novelty in the economic and social spheres"⁴. In healthcare, improved devices, techniques, procedures and organisational approaches play an important role in improving patient health and/or the quality of service provision. They can fundamentally change the way patients are treated, offer hope to patients who would previously not receive treatment or offer incremental benefits over existing therapies.

The European Commission considers innovation as one of the major instruments for improving patient outcomes and guaranteeing value for money in healthcare. There is empirical evidence that political support and availability of dedicated funding and resources may increase the likelihood of implementing innovations in healthcare⁵.

Current Limitations & Consequences

Dedicated funding schemes to reward innovation have only been implemented in a few countries, often in the form of supplementary payments, innovation payments or coverage with evidence development programs. These schemes are typically inconsistent, non-transparent, unpredictable and limited in scope and time. There is also no link to permanent F&R decisions causing uncertainty for payers, healthcare providers and industry alike.

What We Recommend

Specific budgets should be allocated to support and reward value-based innovation as a bridge to a permanent F&R decision. This will ensure prompt access to treatments without undue waiting time.

DO'S: ↓

- Link funding to the demonstrated value of innovative technologies

- Set aside specific budgets for innovation and maintain them until evidence is complete

- Define pathways to permanent F&R

⁴ 'Green Paper on Innovation', European Commission, 2005

⁵ Mylotte et al; Journal of the American College of Cardiology, 2013

6. Seamless Care

Overall, hospital budgets across Europe are funded separately from and at a higher level than budgets for community and other healthcare settings. This so called “silo” budgeting leads to silo treatment, disruption of the continuity of care, and diminished access to medical technologies that patients need regardless of where they receive care. Silo budgeting has a detrimental impact on the F&R process for medical devices and diminishes incentives for manufacturers to develop innovative technologies for both community and hospital settings.

Current Limitations & Consequences

Currently, F&R is focused primarily on the hospital setting without taking into account the impact this has on the continuity of care across settings (Hospital/Community/Home) or sectors (Healthcare/Social care). Patients often receive high quality treatment in a hospital but then are placed back into the community. Once back into the community, their treatment does not lead to the desired outcome due to the lack of provision for ongoing medical devices and services. This often leads to delayed recovery, higher risk of medical complications, and, potentially, readmission to hospital and reduced quality of life.

The lack of community F&R also provides a perverse incentive for manufacturers to develop innovative medical technologies for the hospital – the highest cost of care setting – rather than the community – the lowest cost of care setting.

Silo budgeting and inadequate community F&R results in barriers to achieving the best outcomes and the lowest total cost of care.

What We Recommend

The funding stream should follow the patient through the healthcare system to ensure access to innovative medical technologies, and appropriate treatment and care in every healthcare setting and across sectors. Healthcare systems need to remove silo treatment and budgeting to help ensure that patients – particularly those with chronic medical conditions – achieve optimal outcomes at the lowest total cost of care.

DO'S: ↓

- Consider introducing flexible, outcomes-based reimbursement

- Create reimbursement structures that provide incentives for innovation across all care

Eucomed Recommendations for Funding & Reimbursement Principles in Europe

Funding and Reimbursement (F&R) in Europe need to change to safeguard effective and sustainable healthcare systems. The medical device industry is committed to play its part in reaching these objectives and welcomes discussions with all stakeholders on proposed principles for F&R of medical devices.

● **Transparency, Predictability and Consistency**

Eucomed recommends that country authorities ensure their F&R processes are transparent, predictable and consistent. We suggest to:

- Create well-defined and publicly available F&R criteria, processes and timelines;
- Define minimum requirements to be considered for F&R;
- Adhere to published F&R timelines;
- Regularly publish budget allocation decisions.

● **Stakeholder Involvement: Effective and timely collaboration**

Eucomed recommends that all relevant stakeholders collaborate in an effective and timely manner to ensure that F&R processes are as efficient as possible. Only then can innovative medical devices/procedures be efficiently adopted into clinical practices which in turn guarantee equal patient access. We suggest to:

- Create broadly inclusive forums to engage with different stakeholders;
- Consult stakeholders before the final decisions-making.

● **Support and reward value-based innovation**

Eucomed recommends that F&R systems should support and reward value-based innovation within the medical devices sector as a means to provide better patient outcomes and overall long-term societal benefits. We suggest to:

- Ensure that F&R systems do not create barriers to adoption of and access to medical devices;
- Follow-up on reimbursement decisions with appropriate funding.

● **Appropriate and flexible F&R**

Eucomed recommends that when reimbursement decisions are made, appropriate funding is put in place as well as mechanisms across settings and sectors to provide a continuum of care. We suggest to:

- Link funding to the demonstrated value of innovative technologies;
- Set aside specific budgets for innovation and maintain them until evidence is complete;
- Define pathways to permanent F&R;
- Consider introducing flexible, outcomes-based reimbursement;
- Create reimbursement structures that provide incentives for innovation across all care settings.

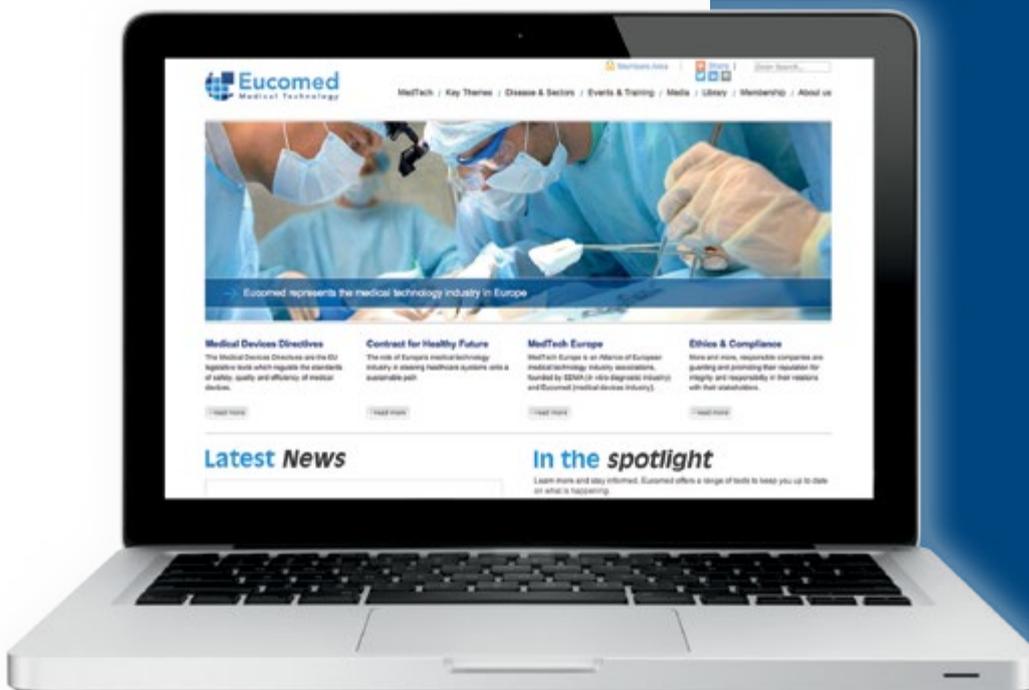
About Eucomed

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people. Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We indirectly represent 25,000 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

Small and medium sized companies make up more than 95% of this sector. The European medical technology industry generates annual sales of €100 billion, has the most patent applications of all industries and employs around 575,000 highly skilled workers. Eucomed is a member of MedTech Europe, an alliance of European medical technology industry associations.

*For more information
visit www.eucomed.org*



Appendix 1

The current state of F&R for medical devices in Europe

In Europe, F&R of medical devices is provided by each Member State, each with their own system resulting from their own particular political, administrative and constitutional structure. Depending on the type of medical device and/or the setting in which it is used (ambulatory, hospital/inpatient, homecare/outpatient etc.), reimbursement systems may also vary within a country.

In **hospital care**, most Member States employ a variation of 'Diagnosis Related Group' (DRG) coding systems that cover the cost of an entire procedure including the medical devices used. In these countries hospitals typically procure medical devices directly from the manufacturer or a licensed distributor.

In those countries where a global budget approach is used to reimburse or fund devices that are part of the mandatory services, procurement also plays an important role.

In some countries a positive list for medical devices with a reference tariff, resulting from direct negotiations between industry and national payers, is also accessible.

In **ambulatory care** the fee-for-service approach is the most commonly used payment scheme. Few countries use this scheme in the inpatient hospital setting too. However, the use of DRGs is becoming more frequent in an ambulatory setting.

Reimbursement of products in **community care** is usually via a prescription system with a positive list of approved medical devices with an associated reference tariff. In some countries, procurement via public tenders is the established practice. The supply is typically handled by pharmacies and appliance contractors. The use of DRGs is also present in a community care setting.

Supplementary, add-on payments, pay-for-performance, risk sharing agreements, disease management schemes and coverage with evidence development schemes have also emerged in different countries within the last 10 years. Most of these new funding schemes however are still at an experimental stage and used on an ad-hoc basis.

Appendix 2

In Europe public funds are the main source of financing, source being taxes or social security contributions (Source: OECD Health Statistics 2013, <http://dx.doi.org/10.1787/health-data-en>).

