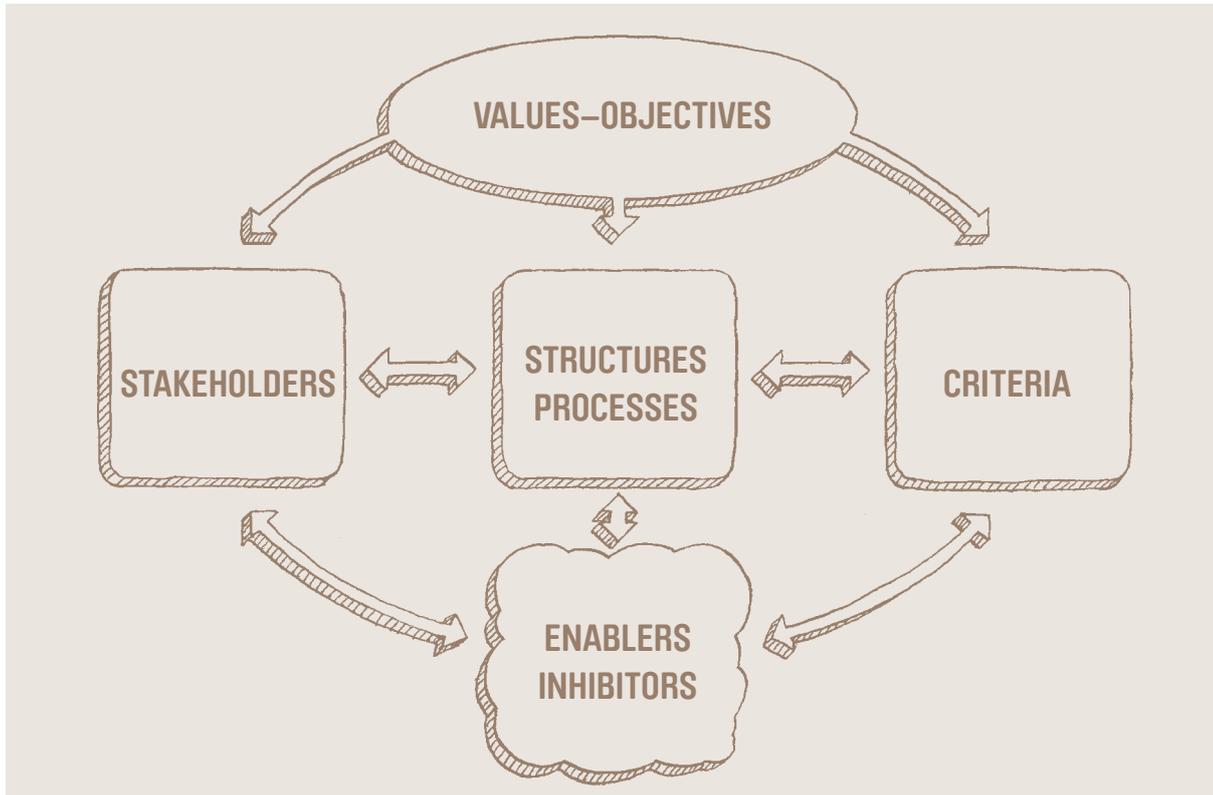


## CONCEPTUAL FRAMEWORK FOR HEALTHCARE REIMBURSEMENT DECISION MAKING



**Values and objectives** are positioned at the top. In the original drawing, values were depicted in a rather implicit way. In this new visualization, values represent the link between the reimbursement decision-making system and the higher levels: the healthcare system, public health and society. They are also influenced by various determinants, which may include our own culture and worldview, our history (for the values) or the political context (for the objectives).

The next two main components are:

- > The **structures and processes**. How are decisions made? Who is involved? Who makes the decisions? What are the steps? What are the conditions for these procedures?
- > The substance. What **criteria** are used in making decisions?

Both dimensions are at the core of the overall conceptual framework that is being proposed. They were also positioned centrally in the original figure since they were considered to represent the substance of the system. The criteria are now positioned on the right, just below the values and objectives that should directly influence them.

The structures and processes are positioned to the left of the criteria and correspond to the procedural pathway. Obviously, the way in which the structures and processes are set out will also depend on our societal values and objectives.

**Stakeholders** are defined as those who have an interest in the system and play a part or should play a part in making decisions. This role can be interpreted in different ways and at different levels, for example at the level of values, their translation into criteria or the definition of and/or participation in the structures and processes.

We have grouped under the heading “**enablers and inhibitors**” all the determinants that directly influence decision-making. Most of these determinants can have a positive (enablers) and/or negative (inhibitors) effect on the system.

An example is the media, forming part of the enablers and inhibitors, but not presented as stakeholders. The role of the media in the system is not the same as that of the actual stakeholders. However, the media does play a role inside the system, which can be considered as either enabling (e.g. by requesting and stimulating transparency) or inhibiting (e.g. by disrupting the process through biased information).

The distinction between the macro, meso and micro levels is implicit in the visualization. Structures and processes will obviously be different at micro and macro levels. However, during the discussions it was argued that the underlying principles can and probably should ultimately be the same. As for the criteria, there was a high level of consensus that they should actually be the same at the different levels even if criteria may be weighted slightly differently.

The stakeholders can also play different roles at different levels, but should probably play a part at all three levels.

## Values and objectives

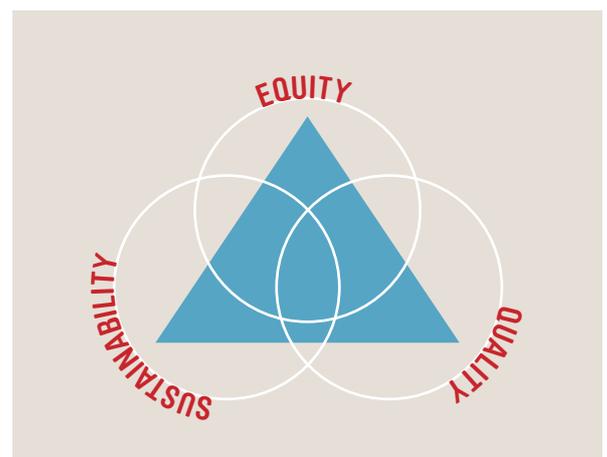
Values and objectives are different concepts, but they are placed side-by-side in the drawing. Values have an ethical claim upon us as human beings. They influence the way we behave and the way we make decisions. Placing objectives and values together in the drawing is also a way of underlining their interconnection.

The values, and the hierarchical order in which they are placed, will help us to choose adequate actions to realize them. The process of translation into objectives is one way of making this more concrete. Values do come from society, and the importance and influence of societal values on the healthcare system is not straightforward.

> **Values** correspond to answering the question “**why?**”

> **Objectives** correspond to answering the question “**Where do we go?**”. They are partially based on societal values and represent a first operational translation.

The objectives of a healthcare system and of a reimbursement policy were defined in a KCE (Belgian Health Care Knowledge Centre) report<sup>1</sup> from 2010 based on a comparative analysis of drug reimbursement systems in five EU countries. They defined three objectives: system sustainability, equity and quality of care. Because these three objectives are interdependent, the authors of the report presented the objectives as a triangle to illustrate the need to find a balance between the three objectives.



These objectives were not challenged or questioned during the workshop.

<sup>1</sup> [https://kce.fgov.be/sites/default/files/page\\_documents/KCE\\_147C\\_Drug\\_reimbursement\\_systems\\_4.pdf](https://kce.fgov.be/sites/default/files/page_documents/KCE_147C_Drug_reimbursement_systems_4.pdf)

The discussions made it clear, however, that there is a significant gap between values (and the value system) and objectives:

- > It has not been made explicit how and which values form the basis for defining decision-making criteria.
- > There is not necessarily a consensus on the value system, i.e. which values are part of it and how they are ordered (hierarchy).

This gap between values, objectives and criteria was identified in the workshop, but it was found that it could not be bridged in the workshop context due to the need for a societal debate.

Nevertheless, this gap is important, not for intellectual reasons or to ensure that the system is designed in an appropriate way, but mainly because society has been and is still changing. Therefore, we should be clear about our values and the extent to which we agree or disagree on them. Due to the nature of these societal changes and developments, they do justify a societal debate around values and their translation into operational terms within the decision-making system.

The way in which our decision-making system is influenced by societal values, as was explained during the workshop, is highly dependent on our worldview in Western societies. The “modern world” view is dominant in our society, especially when we are considering medicine. One participant described it as follows:

“We are actually determined by modernity and by our belief in enlightenment. By the belief in progress. By knowledge and increasing knowledge. By improving technology, we are capable of doing things. We can change things. Certain diseases that have not yet been cured are simply not curable at the moment. In the end, we will be able to find cures for them. This is our belief in the progress of knowledge and

the progress of mankind. This very much determines the way in which we think or feel or decide within our health-care systems.”

This worldview is being challenged today by various trends and evolutions taking place in our society. Budgetary constraints represent one such challenge, but others include the limits of the technology push and of the innovation-based model as we have been experiencing it in the last 60 years. (cf. Vollmann, pages 77).

The right to high-quality healthcare for all is also being challenged. Recent data from the Research Centre of the Flemish Government<sup>2</sup> showed that this value no longer seems to be shared by the whole population. One-in-five respondents from a representative sample of the Flemish population considered that reimbursement of healthcare costs could be made dependent on the behaviour of the person affected.

This point of view potentially undermines the basis of solidarity, as contributors will be less inclined to contribute to a system that they do not perceive as fair. Based on this study, reimbursing the costs of people who are considered to have contributed to their own health problems is one example of what is not considered fair by one-fifth of the population.

One practical way forward to structure the societal discussion to define the values would be to take into account:

- > Societal values relevant to the healthcare system and resource allocation decisions (autonomy, individual freedom, equality, equity etc.);
- > The importance of those values (weighting and hierarchy);

2 Edwin Pelfrene, SVR 2013: <http://www4.vlaanderen.be/dar/svr/afbeeldingennieuwtjes/gezondheid/bijlagen/2013-03-11-webartikel2013-2-gezondheidszorg.pdf>

- > The content and implication of key ethical concepts related to resource allocation (e.g. solidarity, justice and the proper role of responsibility, see chapter 5 above);
- > The content and implication of ethical theories in relation to resource allocation, such as:
  - **Egalitarianism:** looking at the way in which the system is equally accessible to all. Does it help to guarantee fair equality of opportunity by protecting and promoting people's ability to function?
  - **Consequentialism:** focusing on the actual consequences of decisions and actions, possibly followed by correction of earlier choices.
  - **A capabilities approach:** looking at the way in which decisions and actions contribute towards people's broader capabilities in terms of leading a good life (i.e., a holistic approach, looking beyond a merely functionalist interpretation of the goals of medicine and healthcare by taking people's broader quality of life into account).

In trying to provide an answer to these issues, we have to be able to answer the question: "Why?".

Once the answer has been better defined, it can serve as a basis to answer the questions on the way forward and, "Where should we go?" This is a political question and process that leads to defining the objectives to be pursued by the system.

Based on the discussions during the workshop and the theoretical background set out in chapter 5, we can relate the

three objectives of accessibility, quality and sustainability provided by the KCE report to the following arguments:

- > **Equity:** is strongly related to the values of solidarity and justice, namely the willingness of people to publicly organize a healthcare system that protects and promotes fair equality of opportunity for all by providing accessible healthcare, based on the common interest shared by all people in the group.
- > **Quality:** in meeting the basic healthcare needs of people. It is a moral obligation of every just society to guarantee equal access to decent-quality care. As such, just healthcare is not about the endless provision of resources and services to increase personal happiness. Its moral importance is derived from the way it protects people's functioning and opportunity in a qualitative way.
- > **Sustainability:** qualifications must be introduced to avoid unreasonable demands on social resources to implement the right to healthcare. As discussed in chapter 5, we must take into account both the internal and external dynamics of scarcity into account. Consequently, as a society, we have to decide how much of the country's Gross National Product will be spent on healthcare. This should be followed by a discussion on what kinds and types of healthcare should be included in this public package. This debate needs to take place in a transparent and democratic way. (See also the sections in this chapter, "Criteria" and "Structures and processes", which address the question, "How?").

## Criteria

Values (why?) and objectives (where to go?) are further translated into criteria to be used when making decisions. Criteria are the response to the question “how?” which comes after both “why” and “where to go”. In the box below, the right column sets out the criteria for healthcare reimbursement decisions, as they appeared during the workshop. In the left column we have listed the criteria as they are defined today in the Belgian decision-making system for reimbursement of health interventions.

The criteria in the right column are arranged in sequence to take into account their potential weight depending on the level (micro, meso or macro) at which decisions are made. The top of the list is more relevant to macro-level decisions, while criteria further down the list are more relevant at the micro level. This is open to debate and interpretation, and there was a consensus among workshop participants that criteria should be quite similar for decisions taken at different levels.

It is also clear that at the macro level, for example, a committee that advises on reimbursement and the conditions in which a treatment is to be reimbursed, needs to strike a balance between the following: a set of rather vague reimbursement conditions where prescribing physicians are allowed to decide when and how the treatment is appropriate, and setting rather strict conditions, often leaving limited room for the judgement of prescribers themselves.

The difference between the two columns expresses a gap between an ideal situation and the current situation.

Not all criteria were discussed in detail during the workshop, and we will further develop in this section two specific criteria mentioned in the right column that were discussed in greater depth: medical needs and effectiveness and cost effectiveness.

CRITERIA TODAY IN BELGIUM	CRITERIA FROM WORKSHOP AND DISCUSSIONS
<ul style="list-style-type: none"> <li>- Budget impact</li> <li>- Efficacy</li> <li>- Effectiveness</li> <li>- Social and therapeutic need</li> <li>- Cost-effectiveness</li> </ul>	<ul style="list-style-type: none"> <li>- Social need</li> <li>- Medical need</li> <li>- Fair innings<sup>3</sup></li> <li>- Budget impact</li> <li>- Efficacy</li> <li>- Effectiveness</li> <li>- Cost-effectiveness</li> <li>- Therapeutic need</li> <li>- Organizational impact</li> <li>- Individual responsibility</li> </ul>

<sup>3</sup> Resources should be deployed so as to achieve the most equal distribution of healthy years across a population (Alan Williams 1997).

## MEDICAL NEEDS

As mentioned in chapter 5, concerning the issue technology push, the research agenda is very much dominated by the market and therefore by the potential for profit. There is little guarantee that this market-based approach will lead to the most important medical needs being met.

The discussions in the workshop clearly advocated a change of paradigm in this respect, with a need to identify and prioritise unmet medical needs and develop mechanisms to channel research resources towards the most pressing needs. It should be noted that there is a distinction between medical need and therapeutic need. Medical need refers to the severity of a patient's health condition and the degree of suffering or risk of dying. Therapeutic need refers to the current availability of treatment options for a patient.

When there are no therapeutic options for an existing medical need, this is often referred to as an "unmet medical need".

## EFFECTIVENESS AND COST-EFFECTIVENESS

During the workshop, considerable dissatisfaction was expressed with the lack of evidence on effectiveness and the need for more and better discussions on comparative effectiveness research. Decisions are often made on the basis of efficacy because data on effectiveness is not yet available. Perhaps sufficient incentives do not yet exist for industry to design studies to collect objective information on effectiveness once they have obtained marketing authorization.

Yet, reimbursement decisions should be based on data on effectiveness. As a result, better estimates of potential or observed effectiveness are needed.

The following descriptions of the "three steps of evidence" are typically referred to in the European setting:

### Efficacy, effectiveness and efficiency or cost effectiveness

**Efficacy:** the performance of a drug in strictly controlled situations such as the randomized clinical trial, with stringent inclusion and exclusion criteria.

**Effectiveness:** the performance of a drug in everyday practice, where patients take other drugs, are not always compliant and suffer from several diseases.

**Efficiency or cost-effectiveness:** what does it cost in relation to its effectiveness?

Part of the solution would be a more systematic use of registries and observational studies after a product has received marketing approval. Results would be made accessible to stakeholders. However, good registries are expensive.

The traditional approach of pushing the cost of such studies towards the industry has potentially adverse effects on the reliability of the data. The solution probably lies in "smart approaches" and in greater cooperation at the EU level, with public-private partnerships to reduce the cost of such approaches to build evidence along the way.

The above discussion also shows that the availability of an adequate health information system would make it possible to obtain much more information on effectiveness and cost-effectiveness.

## LESSONS LEARNED – REFOCUSING ON THE DEMAND SIDE

Some lessons can be learned from the various discussions on the need to shift the focus of the healthcare system as a whole, as well as the system of decision-making on reimbursement. The focus should be shifted from a supply-side to a demand-side orientation.

Our decision-making system for the reimbursement of drugs should contribute to the process of matching the supply of therapies with the need. The decision-making system should also select for reimbursement those therapies, products and services that correspond to real needs.

Different cases and discussions in the workshop showed that the healthcare sector is characterized by failures in the way the market mechanisms operate. Discussions also revealed that supply and demand are not as well matched as they could be.

The decision-making system itself is very much dominated by the supply side, mainly because of the de facto monopoly of initiative that exists on the supply side. For example, the industry takes the initiative to request the reimbursement of a new drug. Theoretically there is an opening for any stakeholder to take initiative and ask for reimbursement, but in practice it will be the pharmaceutical or medical device company that takes the lead. If the company's policy is to concentrate its marketing on specific countries, it will do so.

This supply-side orientation is an illustration of the influence of the "modern world view", i.e. our belief that progress will solve all problems, as explained above.

Our decision-making system is also based on the belief in a functioning market. For example, when a new drug obtains marketing authorization (a decision often taken at EU level), it means that in many cases the new drug will be offered in competition with other drugs that are already on the market.

Whether or not this new drug is better than existing drugs is not a criterion for decision-making at the EU level, because

comparative effectiveness data, and certainly comparative cost-effectiveness data, are not required for market authorisation.

Apparently it is believed that the market will function properly and if the drug is indeed better, it will take over market share from the drugs already on the market. If not, it will never gain a significant market share. However, this belief in a functioning market is too optimistic. Many examples were provided of market mechanisms failing to ensure the correct balance between demand, i.e. needs and supply.

This is partly compensated by the fact that reimbursement authorities increasingly request comparative effectiveness data, or at least predictions of effectiveness, on the basis of models. However, even though therapeutic added value is investigated, the decision to reimburse the new drug has no consequences for drugs already on the market, which continue to be reimbursed.

Two main routes were identified to compensate for this situation:

> Should such market failures lead to a greater role for the State or more governance? What was advocated as a solution is more governance rather than more State. In this case, governance could mean mechanisms to compensate for failures or intervene in the markets. These should be defined and implemented with involvement of the relevant stakeholders.

In Belgium, some of the conditions are in place to adopt such a process. The law makes provision for revising classes of drugs used in to manage specific diseases. An individual revision one-to-three years after a reimbursement decision is also possible and sometimes takes place.

> More transparency can contribute to improved market functioning. This is mainly through the availability of information on the effectiveness of treatments. If and when prescribers and patients have access to objective information on "effectiveness" and "efficiency", better treatments will be used more. Less effective treatments will disappear faster.

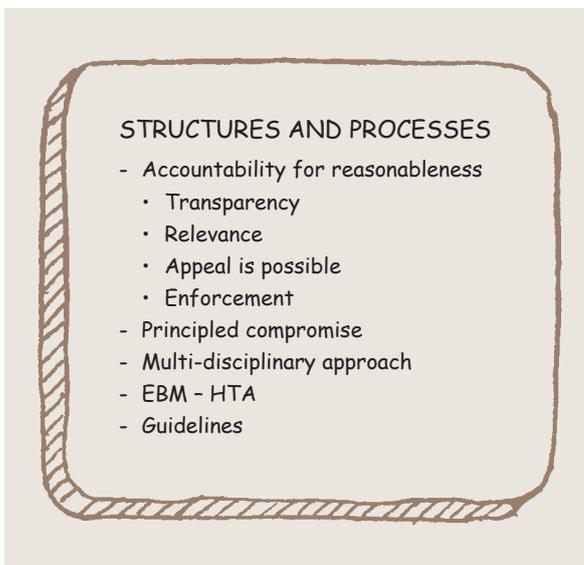
## Structures and processes

In terms of the criteria, structures and processes represent a response to the question “how?” This question follows “why” and “where to go”.

In the case of “structures and processes” as a component of the decision-making system, a strong consensus emerged among workshop participants. There are probably three reasons for this:

- > The perception that the existing structures and processes are not meeting expectations and should be overhauled.
- > The possibility of compensating for the lack of a clear translation of values into objectives and criteria by ensuring fairness in the decision-making process itself.
- > The possibility that good structures and processes may protect against possible inhibitors, i.e. factors that hinder decision-making based on valid criteria and in line with societal values and objectives.

The table below outlines the main concepts that were integrated into the mind-map.



The Accountability for Reasonableness concept (A4R – see box below) was generally considered as a model on which to base an improved decision-making system.

### Accountability for reasonableness (A4R)

A4R comprises four criteria by which the strength of decisions can be measured:

- > **Publicity:** decisions should be made available to the public, which means more transparency.
- > **Relevance:** decisions should be influenced by evidence that fair-minded people would consider relevant.
- > **Appeal:** there must be mechanisms for challenge and review of decisions reached.
- > **Enforcement:** there should be effective mechanisms to ensure the other three conditions are implemented and regulated.

Daniels and Sabin (1997)

The workshops discussions went further than the concept of A4R and explored:

- > Solutions to make A4R work in practice;
- > Some of the principles of A4R, such as publicity, which was considered to be a partial answer to the need for greater transparency;
- > Additional concepts or principles that should be integrated in an ideal decision-making system.

In terms of operationalization, the concept of **principled compromise** was presented during the workshop. This concept was considered to be a potential to complement A4R in that its application would make it easier to develop a decision-making system along the principles of A4R.

#### Principled compromise:

During the decision-making process and the related debates, statements and communications should be:

- > **Reliable:** there should be no over claiming.
- > **Reflective:** critically robust positions should be aired and debated.
- > **Respectful:** negotiations should take place in a democratic spirit.

Huxtable (2012); see also page 72

Principled compromise is proposed to assist in those negotiations that take place in situations of scarcity, complexity and uncertainty, which are three characteristics of the situation in which reimbursement decisions are made.

The three “R”s (reliable, reflective and respectful) complement, or can be considered as necessary conditions to fulfil the four principles of A4R.

Workshop participants agreed that work remains to be done to transform both A4R and principled compromise into an operational decision-making system, but that the basis for developing it is in place. Lessons learned from the discussion that could contribute to develop a new decision-making system are discussed below.

## LESSONS LEARNED

### TRANSPARENCY

Transparency, of which publicity is a part, is a condition for a functioning system based on A4R. It received much more attention during the discussions than some of the other underlying principles, probably for two reasons:

- > The low level of transparency in the current reimbursement decision-making system. This is true in Europe in general and also in the Belgian system. Making the system and its decisions more transparent was considered by participants to be a separate key objective.
- > The need for greater transparency to compensate for market failure. Transparency can lead to better functioning markets because market players will be better informed when they make their decisions. The need to create more reliable information on effectiveness, as discussed above, is part of this need for greater transparency.

### REVIEWABLE DECISIONS

Clearly, the key meaning of appeal within the A4R principle is that decisions should become final only after a process in which the preliminary decision is shared with all stakeholders. The decision can thus be reviewed. This concept of reviewable decisions does, in fact, go beyond the concept of appeal in the A4R framework, and it also serves other purposes.

As a participant in one of the panel discussions pointed out: “If we are to have a just decision, it has to be conditional in the sense that we must be aware of new evidence coming along all the time, and we have to reassess it.”

Original decisions on reimbursement are made in conditions of uncertainty and based on incomplete evidence. Not making a decision for this reason is not the right approach, because it would prevent innovations reaching the patients who need them. Making decisions systematically

and permanently reviewable after they have received initial approval for reimbursement is considered to be one solution. We refer here to the above discussion on effectiveness and the need for registries.

There is also a need to make decisions more quickly than is commonly the case today. The principle of reviewing decisions facilitates improvements in speed, as uncertainty is accepted as inherent to the system and it is understood that no decision is definitive.

#### **A MULTIDISCIPLINARY APPROACH**

The value of bringing new disciplines or types of expertise to the decision-making or even the negotiating table was regularly mentioned as a way to improve decisions. The main reason for this is linked to the complexity of the decisions. It is also linked to the fact that additional disciplines bring in different viewpoints that make it possible to fully understand the complex situation, thereby leading to better decisions. Examples include:

- > The presence of patients, which makes it possible to contribute expertise gained through experience, complementing the other experts (on economics, therapeutic aspects, etc.);
- > The involvement of ethicists in the decision-making process at times when data is unavailable and a decision still needs to be made.

This multidisciplinary approach can also be one element of a solution to adapt the decision-making system to handle uncertainty. Decisions must be made in situations that are not only complex, but also feature a high level of uncertainty. Bringing in other disciplines such as ethics or sociology can help to clarify the different issues at stake and make a more appropriate decision even in such a context of uncertainty.

The discipline of risk assessment was also mentioned as something that could add value to the process. In risk assessment, concepts such as complexity, uncertainty and ambiguity are analysed to estimate risks, such as the risk of making a wrong decision. A number of health economists also have expertise in this field of risk assessment.

One final argument supporting the multidisciplinary approach is the need for a holistic approach to decision-making. Reimbursement decisions are not made in a closed environment, but within complex healthcare and public health systems. These decisions must be embedded at every level and weighed against alternatives.

For instance, prevention and financial incentives for changes in behaviour were frequently mentioned as important aspects of better health policies, together with other policies in the context of public health. A multidisciplinary approach is expected to broaden the debate and allows bridges to be built between healthcare reimbursement decisions and other health policy decisions.

#### **STRUCTURE – TWO-TIER HEALTH INSURANCE**

There was a general consensus that not everything can be reimbursed, given the financial resources available. A two-tier approach was suggested, differentiating between a “basic package” that would be available to everybody and would maintain the principle of “full solidarity” (tier 1) and an “additional package” that could be more flexible in terms of what the insured person wishes to contribute in return for receiving certain insurance benefits (tier 2). This could be implemented as follows:

- > Cost-effective treatments for diseases caused by societal and genetic determinants should be available to all.

- > Treatments that are not cost-effective or less cost-effective and/or treatments for conditions that are less severe could come under tier 2. The distinctions, however, between cost-effective and less cost-effective and between severe and less severe, are not easy to make.
- > When discussing a two-tier-insurance system, conditions in which the person's lifestyle plays a role create a specific problem. There is a controversy about whether diseases which are related to lifestyle should be covered in tier 1 or tier 2. Chronic diseases such as diabetes, obesity and cardiovascular disease include a lifestyle component. For most people, treatments for these conditions belong in tier 1. Indeed, penalizing less well-educated people with poor lifestyles, for instance, might be considered unethical. Positive incentives that influence behaviour and lifestyle (e.g. healthy nutrition and physical activity programmes) could be considered in tier 2.

## Stakeholders

STAKEHOLDERS INVOLVED IN THE BELGIAN SYSTEM	STAKEHOLDERS THAT WHO SHOULD BE INVOLVED
<ul style="list-style-type: none"> <li>- Those financing the system:               <ul style="list-style-type: none"> <li>• Employers</li> <li>• Employees</li> </ul> </li> <li>- Government and the National Institute for Health and Disability Insurance</li> <li>- Sickness funds</li> <li>- Healthcare service providers</li> <li>- Health Industry</li> <li>- Healthcare professionals</li> </ul>	<ul style="list-style-type: none"> <li>- Citizens</li> <li>- Politicians</li> <li>- Sickness funds/Health insurance providers</li> <li>- Health industry</li> <li>- Healthcare service providers</li> <li>- Healthcare professionals</li> <li>- Patient organizations</li> <li>- Informal caregivers</li> <li>- Patients and their families</li> </ul>

The table above presents the stakeholders who play a role in reimbursement decision-making.

The column on the right is based on the stakeholders who were identified during the mind-mapping exercise. There was some consensus on including these stakeholders. The left column is a presentation of the stakeholders in the Belgian decision-making system today, which includes both those involved at a strategic level, i.e. employers and employees, and those involved at the operational level.

The differences between the two are small. The first difference is the specific role of employer and employee organizations (trade unions) in Belgium, where they act as those financing the system through social security contributions paid by both employers and employees. These did not emerge during the mapping process in the workshop. This is probably due to the fact that citizens contribute to the system via taxes and social contributions, so that those financing the system also appear in the right column.

The second, and related, main difference is linked to the citizen-patient. Patients have a rather informal presence in the Belgian system, which can be partly explained by the special status of the sickness funds (*mutualités*), which are

considered to represent patients, i.e. their own members requiring medical service. In general, citizens are presumably represented by politicians.

### THE ROLE OF THE CITIZEN-PATIENT

In the box below, the citizen-patient is further subdivided into three distinct categories. This distinction is important because the interests of the same individual can differ significantly depending on the category to which she or he belongs.

#### The different roles of the citizen-patient

**Citizen and taxpayer:** a party interested in a system designed to serve society as a whole, as a financier and as a potential beneficiary.

**Service user:** a customer receiving services within by the healthcare system.

**Patient:** a person with an illness who relies on the system both to provide services and to cover part of the cost of treatment, i.e. a main beneficiary of the system.

During the workshop there was no specific or systematic discussion of the role of citizen-patients. Nevertheless, they were often mentioned in discussions. The following lessons can be learned from the two directions taken by participants:

- > Barriers exist to involving citizens and patients. Many people involved in decision-making processes have concerns mainly due to the risk of subjectivity, but also because of the asymmetry of information. However, solutions exist to overcoming these barriers.
- > Citizen-patient involvement in decision-making has real value, but the right type of citizen-patient must be selected: citizens for certain types of decisions, such as ethical choices; customers for other types of decisions, for example at the level of institutions; and patients for their specific expertise based on their experience.

## THE ROLE OF THE PRESCRIBER

The role of the prescriber was also discussed, more systematically and probably in greater depth than the role of the citizen-patient. The consensus is that the prescriber plays a key role in the system. The system expects a lot from prescribers, whether in primary, secondary or tertiary care. Based on the discussions, these expectations are expected to grow.

### SERVING TWO CLIENTS – BOTH THE PATIENT AND SOCIETY

From the health insurance perspective, the prescriber is implicitly expected to play a role of gatekeeper for society. If a treatment is not appropriate, it should not be offered to a patient. However, we have seen that the reality is not that simple, particularly because the prescriber will decide in situations where there is room to discuss with a patient whether a treatment is justified. This often requires balancing rational and emotional arguments.

Moreover, the term “appropriate” can be interpreted in different ways. A prescriber may find a treatment to be appropriate if the benefits outweigh the risk. However, from a societal point of view, a treatment may only be appropriate if it is also cost-effective and affordable.

For decision-makers at the macro level, the patient is a more abstract concept because of the distance and the fact that patients are seen as cases or cohorts rather than as individuals. This aids decision-makers to be “objective” and not influenced by emotions when making decisions. However, the prescriber is faced with an individual when making decisions or recommendations. (See also the fundamental difference between “statistical lives” and “identifiable lives” discussed in chapter V.)

Medical advisers working for sickness funds provide the first line of “support” for the prescriber acting in the gatekeeper role. The colleges for orphan drugs are another example of a decision-making process for individual patients in which a group of experts gives advice to the organization’s medical officer (*médecin-conseil*) who then takes the decision. This is limited to treatments for rare diseases that are often expensive, and is generally considered to represent good practice.

### HANDLING REASON AND EMOTION

Reason and emotion are very closely linked to objectivity and subjectivity. This was very well illustrated by a question put before the participants by Yvonne Denier in her role as philosopher:

“The sky cannot be the limit and we cannot do everything we can even if we wanted to. However, if one of my daughters gets seriously ill tomorrow, all this vanishes. I want physicians to do everything they can to save her. Even though I know that this is completely irrational. What should I do as a philosopher and as an ethicist?”

Potential solutions to help prescribers play this balancing role between reason and emotion are covered in the section, “Enablers and inhibitors”.

Another issue that relates to the role of the physician is time management. Our system strives to achieve efficiency, which means keeping consultations short. Physicians can only play the various roles that society or the health insurance system expect of them if they take the necessary time to enter into a dialogue with the patient and help them to make informed decisions.

If we wish to move beyond medicine, take a holistic approach and integrate reimbursement decisions into the wider context beyond medicine and public health, we need to invest in more time, both for general practitioners (primary care) and specialists (secondary care).

## LESSONS LEARNED

### FILLING THE KNOWLEDGE GAP ON EFFECTIVENESS – THE ROLE OF PATIENTS AND PHYSICIANS

The need for initiatives to fill the knowledge gap described above in relation to effectiveness is also addressed in other sections. Many stakeholders can play a role in this process. Certainly, medical professionals and patients could also play a role. They are a potential source of reliable information on effectiveness and both have a direct interest in accessing reliable and up-to-date information on the effectiveness of treatments.

Initiatives such as [www.curetogether.com](http://www.curetogether.com), [www.pratenovergezondheid.nl](http://www.pratenovergezondheid.nl) and [www.healthtalkonline.org](http://www.healthtalkonline.org) are examples of how this potential is harnessed through initiatives that fall within the broad category of social innovation.

### CHANGING THE BALANCE OF POWER

Much has been said about the role of citizens and patients in the decision-making process. Giving these two stakeholders a more prominent place in the decision-making process will contribute to the objective of “more governance”, to greater transparency and to an improved focus on the demand side.

However, there are risks and difficulties associated with this shift of power. Considerable barriers and risks exist, but none are impossible to manage. This should be done in order to harness the value and improvements that can be achieved with a better power balance.

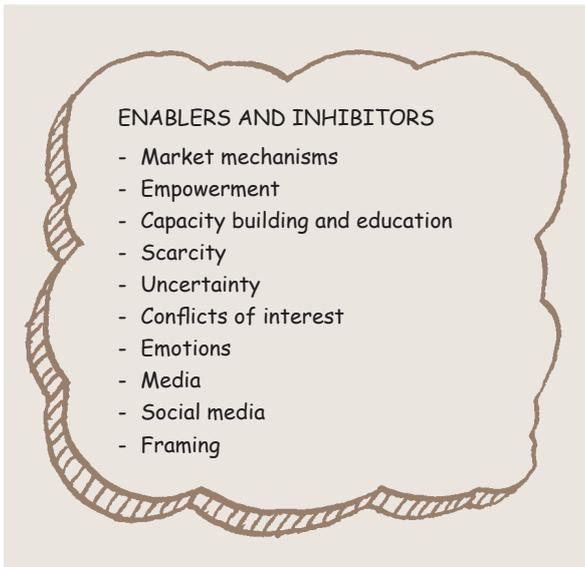
### THE INFLUENCE OF REIMBURSEMENT RULES

The way in which medical interventions are reimbursed has some adverse effects on the behaviour of medical service providers. For instance, it has recently been shown that in Belgium, computed tomography (CT) scans are currently overused at a rate of about 30%.

The use of antibiotics in Belgium is still one-third higher than the EU average and there are 15% more hospital admissions. Forecasting and testing of the potential behaviour of service providers should probably be done systematically before defining payment or reimbursement rules. This could be one way of minimizing such adverse effects.

## Enablers and inhibitors

The enablers and inhibitors from the mind-map include:



Just five of these enablers and inhibitors are developed in this section; most are covered in chapter 5. This section covers empowerment, conflicts of interest, handling uncertainty, handling emotions and framing.

Uncertainty, emotions and framing were important issues in the discussions and are directly linked to several of the points raised above. Empowerment complements the issues raised earlier concerning the prescriber serving two clients.

### EMPOWERMENT

Empowerment (of the patient) is a concept that is not understood in the same way by different actors, as analysed well by one of the participants.

“Doctors seem to associate empowerment with compliance; they think it depends on how well they are able to explain the benefits of the treatment and to ensure that the patient can understand it properly. In hospitals the same word is used when they want to ‘educate’ the patient to become autonomous when leaving the institution. In health

policies, it means that the patient should be given a greater share of responsibility and be heard in the decision-making process. And when patients talk about empowerment, they mean all the above but they also add the opportunity to say no. They want to be actors in process of co-decision or they even want to make their own decisions about their own lives.”

The term “empowerment” was challenged by another participant, who commented that it is overly influenced by the neo-classical, paternalistic approach, and suggested using the term “building capability”.

The concept of building capability is necessary for the patient and for caregivers. For the patient, the main barrier is the asymmetry of information between caregiver and patient, compared with the expectation in terms of shared decision-making and the patient’s individual responsibility.

Resolving this asymmetry of information creates tasks for the public sector, patient organizations and caregivers. This involves an educational task on the part of caregivers. Caregivers must explain to patients the benefits and risks of treatments, as well as preventive and diagnostic measures. However, this must be “fruitful” information that goes beyond fundamental and factual information. It must be information that makes sense to every individual to help inform wise choices. This can be considered as part of care. It is information-related care, which is an essential element of empowerment.

It should be noted that building capability is also relevant to other stakeholders. For instance, a committee that needs to advise on reimbursement and whose members have no training in health economics, is not well equipped to provide well-informed advice.

## CONFLICTS OF INTEREST

Conflicts of interest, which were considered inhibitors, can arise at various levels and at different times. Examples include:

- > It is important that those people or organizations establishing guidelines are free of potential conflicts interests. This is important to the quality of the guidelines.
- > Prescriber decisions can be influenced by advertising, incentives and even by the effect of the decision on their personal earnings.
- > Patients' susceptibility to influence from industry, for example through advertising or funding of associations is a barrier to greater patient involvement in decision-making.

Interests are inherent and cannot be avoided, but it is necessary to ensure that these interests do not lead to conflicts of interests. The solution lies in greater transparency and improved governance. Both are essential elements of a good decision-making system, while both require actions the described above. In this case, transparency means that all of those involved in decisions must provide the information that allows the organization to judge whether there is the potential for a conflict of interest.

Governance corresponds to the need to intervene in market mechanisms whenever conflicts of interest could disrupt the functioning of the market.

## HANDLING UNCERTAINTY

As discussed earlier in this chapter, reimbursement decisions are made in a context of uncertainty. However, the system is not inherently designed to address this uncertainty. This creates tensions. The degree of uncertainty is also expected to grow, if we give patients the benefit of faster

access. In this section, we explore some ways of handling this higher degree of uncertainty.

When considering the four criteria applied to reimbursement decisions, there is uncertainty in relation to each.

## EFFECTIVENESS

To prove that their therapy is better than what already exists, industry must carry out trials. The trials show that the new drug is better but the trial is conducted over one year. However decision-makers want to know what the situation will be five years from now. The trial is always too short in comparison with what decision-makers would like to know.

## MEDICAL OR THERAPEUTIC NEED

This is also an important area of uncertainty. Is it a severe disease? How severe compared to other diseases? A relevant issue raised in discussions is that we look at needs through filters. As one participant commented, decision-makers are "proxying demand" by imagining that needs exist at all. This underlines the supply-side approach in the current system. As a result, it creates the intrinsic weakness of the system to integrate the demand side in decision-making.

## COST-EFFECTIVENESS

Often considerable uncertainty surrounds cost-effectiveness. Our methods are not optimal as both costs and effectiveness are difficult to define precisely. Moreover, one can claim that something is cost-effective, but if we look at the calculations in detail, many mistakes and unjustified assumption can sometimes be found.

## BUDGET IMPACT

The same shortcomings apply to assessing budget impact, where calculations are based on too many unknown variables.

An example of how uncertainty is managed today concerns “performance-based agreements” (Coulton et al. 2012). These agreements involve entering into contracts with industry whereby the price paid depends on the future effectiveness of the therapy. As one participant commented: “If your drug is not as good as you promised you will have to refund us this much money.”

Another approach is to take conditional decisions. This was also explained by a participant: “We will give you the benefit of the doubt and two years from now we will discuss this again and see whether we have more certainty about all of these aspects. Only then will we make a final decision.”

Another participant commented that a decision must always be conditional if it is to be a just decision. It must be a conditional decision because:

- > At the time when we make the decision, we know that the evidence on which we base that decision is incomplete.
- > We know that the future will bring new evidence. When this additional evidence becomes available, we will need to reassess.

## HANDLING EMOTIONS

Clearly emotions play a part in decision-making. Stakeholders face the challenge of balancing the interests of society against their individual interests and emotions. Emotions should not always be viewed as “inhibitors”. They are inhibitors only when based on incorrect or biased information or on incorrect framing, which is discussed below.

During the workshop, various solutions were proposed to meet the challenge of adequately handling emotions:

- > At the macro level, changing decision-making processes to take the situation of individuals more into account (see also above). The systematic and representative use of patient experiences as an expert input into the process would definitely expose decision-makers to parts of the reality that they currently take less into account.
- > At the micro level, training healthcare professionals to act as gatekeepers and to better manage the tensions resulting from the rational and emotional dimensions of their relationship with the patient.
- > Empowering patients will improve the patient-physician dialogue and shared decision-making processes at both the micro and macro levels (see above).
- > Promoting guidelines for use by prescribers could be a solution. The advantage of guidelines is that they document the state of the art and the consensus on what to do in given situations.
- > Another solution is setting out more explicitly our willingness as a society to pay for health benefits, and the factors that affect that willingness to pay. For instance, it may be that we are willing as a society to pay more for health benefits for patients with rare diseases. This view is not necessarily irrational if it has been established according to the principles of accountability for reasonableness and principled compromise.
- > Better framing the information that informs the decision-making process is another way forward.

## FRAMING

Building upon the issues discussed so far, a final factor that can act as an enabler or inhibitor is “framing”. This means that people react in different ways to information they receive, depending on the way in which this information has been presented. For instance, it makes a difference whether the information is presented in absolute numbers or as a percentage, or whether the information is presented in a positive or negative way.

Framing may become an inhibitor if those who are supposed to make decisions are only confronted with one way of framing the information. Or it may cause distortions if different types of framing are used in relation to different dossiers.

Framing can become an enabler if the information is systematically presented in the same formats, so that it is framed in each of the various possible ways. Rather than presenting the information in just one way, this means that it is framed both as a probability and in terms of absolute numbers, both positively and negatively.

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