

VIPS ASSOCIATION OF SWISS PHARMACEUTICAL COMPANIES

THRESHOLD VALUES IN HEALTHCARE POLICYMAKING

Final report
Zurich, 20 February 2012

Dr Rolf Iten, Judith Trageser, Anna Vettori



iNFRAS

INFRAS

BINZSTRASSE 23
P.O. BOX
CH-8045 ZURICH
t +41 44 205 95 95
f +41 44 205 95 99
ZUERICH@INFRAS.CH

MÜHLEMATTSTRASSE
45
CH-3007 BERNE

WWW.INFRAS.CH

THRESHOLD VALUES IN HEALTHCARE POLICYMAKING

vips Association of Swiss Pharmaceutical Companies

Final report, Zurich, 20 February 2012

Dr Rolf Iten

Judith Trageser

Anna Vettori

Supporting group:

Semya Ayoubi, General Secretariat, Swiss Federal Department for Home Affairs

René Camenisch, vips Association of Swiss Pharmaceutical Companies

Dr Ignazio Cassis, National Assembly FDP

Prof. Stefan Felder, Faculty of Business and Economics Department of Health, Basel University

Walter P. Hölzle, vips Association of Swiss Pharmaceutical Companies

Martin Rubeli, vips Association of Swiss Pharmaceutical Companies

Dr Sven Seitz, vips Association of Swiss Pharmaceutical Companies

Jean-François Steiert, National Assembly SP

Dr Athanasios Zikopoulos, vips Association of Swiss Pharmaceutical Companies

SUMMARY

BACKGROUND

The starting point of the present study is the ruling of the Swiss Federal Supreme Court on the so-called “Myozyme case” of November 2010.¹ The ruling prompted a broad discussion in the media and among specialists about the sense and purpose of threshold values. Healthcare expenditures have risen steadily in Switzerland in recent years. Although this has led to measures intended to contain costs, the rationing of services has so far not been an issue. At most, the question of the extent to which health insurance should assume the costs for the treatment of rare diseases and very expensive drugs has been mooted. Threshold values should be seen as a means for allocating politically and/or naturally limited resources and should therefore be viewed in the context of an overarching debate about rationing and prioritisation.

The aim of the present study is to help make this discussion more objective. To this end, the theoretical and empirical underpinnings and the practical use of threshold values in healthcare policymaking at home and abroad were examined, and preliminary conclusions were drawn to contribute to the public debate about the subject in Switzerland. However, the present study is not restricted solely to a discussion of threshold values. Rather, the issues are examined from a broad point of view that takes into account various approaches for rationing and prioritising within the healthcare system. The extent to which an immediate need for rationing exists in Switzerland is controversial.

POINTS OF VIEW ON RATIONING

Threshold values lie at the core of an economic view of the rationalisation issue. However, there are also other ways of looking at the issue, foremost among them the legal, ethical, medical and public-health points of view. On the one hand, the various points of view share key features:

- › All of them accept in principle that every member of society must be guaranteed a certain level of basic medical care.
- › Economists, ethicists, public-health officials and the majority of doctors advocate explicit rationing and transparent allocation criteria if it must be assumed that resources for medical services are limited.

¹ Swiss Federal Supreme Court, II. Social Law Section, Ruling 9C_334/2010 of 23 November 2010 in *Publisana Health Insurer vs F.* regarding health insurance. Cf. points 7.6, 7.6.3 and 7.8 of the ruling.

- › Other commonalities between the economic and ethical point of view relate to cost-effectiveness, which corresponds to the utilitarianism concept in ethics. Healthcare services should be provided in such a way as to maximise the expected health effect.
- › Finally economic criteria are also reflected in Swiss law, in which efficacy and expediency but also cost serve as criteria for the distribution of funds.

On the other hand, there are also major differences between these various points of view:

- › Rationing that is based on the utilitarian principle and maximises overall benefit in terms of costs for individuals is at odds with the ethical and legal principle of equality and the public-health goal of equitable access to healthcare for all population groups. According to the principle of equality, one person's life is worth that of another, irrespective of whether it is a happy or joyless life or an economically valuable or economically unproductive one.
- › Economics and utilitarianism in ethics do not consider societal preferences with regard to the allocation of resources other than maximisation of health effects. In particular, these approaches do not consider theoretical principles of fairness, as enshrined in the theory of egalitarianism. For example, according to the principle of fairness, the treatment of serious life-threatening illnesses must take precedence over the treatment of minor ailments. However, utilitarianism defines care priorities solely in terms of the logic of cost-efficiency.

THRESHOLD VALUES AS AN APPROACH TO PRIORITISATION

The basic issues in the debate about rationing and prioritising revolve around assigning priority to indications, procedures or patient groups (prioritisation) in cases where essential services are withheld for financial reasons (rationing) or to redress inequalities in access to healthcare services (discrimination). Threshold values are just one of several ways by which healthcare services can be prioritised and/or rationed. As a decision-making criterion, the classical threshold-value concept appears at first glance to be rationally justified and fair: Threshold values are based on the cost-efficiency concept. As such, they prioritise medical services that are particularly effective in relation to their costs. Threshold values are usually expressed as upper limits, often in the form of costs per year of life gained. To determine these upper limits, various economic approaches

can be used. Some approaches are more suitable for controlling the healthcare services budget (threshold values with budgetary limitation), while others are better at taking into account the societal concept of the monetary value of a life (threshold values with value limitation). An interesting characteristic of the threshold-value concept is that all medical services can in principle be compared using the same neutral benchmark. The limitations of the threshold-value concept can be seen in the fact that, although it maximises the health benefit for society as a whole – insofar as this can be measured – corresponding to the utilitarian concept of fairness, individual social groups, such as the elderly, the severely ill, the disabled and people with rare diseases are disadvantaged. This, in turn, is at odds with the concept of fairness, according to which everyone must have equal access to vital medical services (egalitarian ethics). Because of these ethical problems, alternative concepts of explicit rationing have emerged that either link the cost-efficiency criterion with other (social and ethical) criteria to prevent potential discrimination or are based on entirely different criteria.

APPLICATIONS IN PRACTICE

Looking abroad, we see that efforts are underway in many countries to find a rational solution to the problem of scarce resources in the healthcare system in general and the limited possibilities of a healthcare system based on the solidarity principle. Those efforts differ in how far they go and the specific points they emphasise.

However, all the countries share the problem of being faced with a fundamental conflict inherent in collectively financed healthcare. On the one hand, costs are rising due to the growing needs of the population, demographic ageing and medical progress. On the other hand, it is becoming increasingly difficult to provide the budgetary funds for collective financing, whether from taxes or insurance premiums. The basic thrust of the debates about rationing is also similar in every country: ultimately, the aims are, first, to establish collectively financed services in the face of the imminent scarcity of resources and, second, to regulate access to those services fairly and in a way acceptable to all concerned.

Developments abroad can be summarised as follows:

- › Rationing and prioritisation have long been an issue in countries (or member states) with state healthcare services financed through taxes, e.g. Great Britain, New Zealand, Sweden, Norway and Oregon (Medicaid). In those countries healthcare expenditures are subject to more political pressure than in countries with a healthcare

system financed from contributions, e.g. Germany and Switzerland. Accordingly, the debate about rationing and prioritisation is more restrained in the latter.

- › Explicit threshold values are only very occasionally used: The National Institute for Health and Clinical Excellence (NICE) in Great Britain uses a bandwidth model based on the threshold-value approach with value limitation. In Oregon services are prioritised by using a threshold value based on the budgetary limitation approach (funding line). In neither case are the threshold values based on scientific principles – with a willingness-to-pay or human capital approach.
- › Two different approaches can be distinguished in the debate about prioritising and rationing:
 - › The first is prioritisation according to basic principles, as in Sweden and Norway: This results in the definition of prioritisation groups that prioritise services at a superordinate social level. However, these basic principles have proved to be too abstract for specific prioritisation at the micro level (doctor-patient decisions: assignment to a waiting list or denial of therapy).
 - › The second approach is the prioritisation of indications/procedures based on the definition of healthcare services, as in Oregon and Great Britain. In these cases specific allocation rules have been defined in the form of a service catalogue.
- › The example of Oregon makes it clear that cost-efficiency cannot be implemented as the sole criterion for prioritisation, as it leads to socially undesirable results. In order to give due consideration to social preferences and medical, ethical and legal requirements, various prioritisation criteria are applied in all the countries studied (among others the so-called “rule of rescue”). In individual cases there is also room for manoeuvre to allow exceptions or privately funded solutions (out of pocket, private insurance).
- › All the countries studied have, in some form or another, institutionalised their prioritisation processes and made them transparent. Prime examples in this respect are Great Britain and Oregon: Great Britain clearly separates the *assessment* of services from their *appraisal* and the decision to include or exclude services. In addition, both groups are broadly supported: The appraisal group is multidisciplinary in composition. The decision-making group includes representatives drawn from relevant players and patients (scientists, the National Health Service, industry, patient organisations). Oregon, for its part, is an example of a democratic procedure, where the preferences of the population are also taken into account in the prioritisation process.

In Switzerland there had been relatively little debate about prioritising and rationing in the healthcare system in recent years until the Federal Supreme Court ruling on the Myozyme case. Although a certain degree of explicit rationing is exercised with regard to the scope of services covered by the basic health insurance, prioritisation approaches are based on the efficacy, expediency and cost-efficiency of healthcare services (EEC criteria). However, in the past those criteria were regarded less as a rationing instrument than as a means to ensure cost-efficiency. As in most of the countries studied, no explicit threshold values exist in Switzerland.

By contrast, differences vis-à-vis countries abroad are evident in the decision-making process: Compared to other countries, the prioritisation criteria are less transparent. Hence, the EEC criteria have not yet been fully operationalised. Also, unlike in Great Britain, there is no separation in the Federal Office of Public Health (FOPH) between the assessing and decision-making instances. Moreover, unlike in Oregon, the population is not directly involved in the process.

CONCLUSIONS

The following lessons can be drawn from the analysis of the threshold-value concept and experience gained in other countries:

- › The ethical difficulties associated with the threshold-value concept show that cost-efficiency is not suitable as the sole criterion for rationing or prioritising. If cost-efficiency is applied as an allocation criterion, it should be embedded in other (socio-ethical) prioritisation criteria. The criterion of urgency, or the “rule of rescue”, appears particularly important in order to better take into account seriously ill patients. The same applies to criteria or systems designed to prevent discrimination of population groups.
- › Any decision regarding what criteria to apply to resource allocation within the obligatory health insurance system (OKP) and in comparison to other social services (education, etc.) must be preceded by a public debate about values (normative discussion). This could also help to assess the willingness of the population to pay for services in the healthcare system.
- › Abstract prioritisation specifications at a superordinate social level are not in themselves sufficient to make decisions at the level of routine medical practice. Against the backdrop of experience gained abroad, it appears more sensible to establish concrete allocation rules for routine medical practice based on

democratically defined normative principles. Comprehensible rules are called for that allocate resources at a superordinate social level and that help medical staff, patients and relatives to make delicate decisions in individual cases as fairly but also as efficiently as possible. This would eliminate uncontrolled rationing at the micro level or replace rationing by socially supported measures.

- › Any allocation rules should be developed on the basis of a fair decision-making process. This could be facilitated by the principles of the model of accountability for reasonableness, which emphasises procedural fairness rather than the criteria themselves. In any case, the involvement of the public or insured persons should be ensured, as the decisions pertain to the use of their contributions.
- › Starting points for the institutionalisation of allocation decisions in the Swiss healthcare system are the catalogue of services (Annex 1 KLV), the positive lists of drugs and clinical guidelines that have increasingly been formulated in recent years against the backdrop of evidence-based medicine. Such guidelines can facilitate decision-making in routine clinical practice based on empirical findings and, for example, provide doctors with rules about when treatment is indicated and when the most expensive of various drugs should be prescribed. Embedding rationing rules in such guidelines has the advantage that they can be formulated by expert groups specifically for individual medical disciplines and patient groups and are transparent. The guidelines must be based on or substantiate rules at a superordinate level and must not contain any arbitrary separate assessment criteria. Medical staff can base their decisions on the recommendations of the guidelines. At the same time, the guidelines allow room for manoeuvre in the decision-making process, which medical staff can take advantage of in individual cases. However, any such individual case decisions must be well justified by the guidelines. In principle, threshold values can also be embedded in guidelines. In this context they serve more as an orientation aid than as an exclusion criterion.

APPROACHES FOR FURTHER CLARIFICATION

Experience abroad suggests that a possible approach for dealing with the rationing issue lies in a combination of democratically legitimate criteria and practical guidelines derived from them, allowing sufficient room for manoeuvre to take into account individual cases. Optimisation between these conflicting aspects is a delicate balancing act. In this context a number of questions need to be clarified in the social debate, for example:

- › What resources can we/do we want to make available to the collectively financed healthcare system? To what extent do limits exist with regard to society's willingness to pay for services within the healthcare system (basic primary care)?
- › Is it actually necessary to ration services in the collectively financed Swiss healthcare system?
- › What is the legitimate need for services of the healthcare system and what are the "essential services" of basic medical care?
- › What form of funding distribution can maximise the benefit for society?
- › To what extent should health inequalities be taken into account?
- › What rules can be derived from this for the allocation of limited resources in the healthcare system?
- › What effects do various allocation rules have on society and the economy?

In this context demands are placed on society as a whole, politicians, the scientific community and players in practice:

- › Society is called upon to conduct the necessary debate openly and transparently and to define the appropriate preferences.
- › Politicians must define the preferences of society in the form of a suitable framework for the healthcare system.
- › The scientific community must provide the necessary foundation for rational decision-making and implementation of decisions.
- › Finally, the practical players in the healthcare system are responsible for ensuring that the social and political will is appropriately implemented.