First Fundamental Decision of the Federal Supreme Court of Switzerland on Cost-Effectiveness in the Area of Human Healthcare

*Felix Kesselring**

Case BGE 136 V 395 et sqq. Publisana Krankenversicherung v. F.[1]

In rendering this decision, the Federal Supreme Court of Switzerland entered for the first time into a detailed analysis of questions relating to the cost-effectiveness of human healthcare. The decision, concerned with the availability of a drug for a rare genetic disease, makes it clear that the maximum amount available from a public health insurance provider for the medical treatment in a particular case has been reached once the amount requested by the individual patient cannot also be provided to all other persons in a comparable situation. It remains unclear, however, how cost-effectiveness is to be assessed below this maximum amount (author's headnote).

I. Facts

In mid-2007, F., from Switzerland, was diagnosed with Morbus Pompe, a very rare genetic metabolic disease (a so-called *orphan disease*). Morbus Pompe causes progressive muscle weakness. Myozyme (a so-called *orphan drug*) is currently the only drug available for the treatment of Morbus Pompe. The effect of Myozyme is moderate. The drug can only alleviate the symptoms of the disease but it cannot postpone, let alone prevent, its fatal outcome. The strongest effect of the drug manifests itself within the first 26 weeks of the treatment, while it hardly changes thereafter. F. was compulsorily insured with Publisana, one of many public health insurance providers in Switzerland. In October 2007, Hospital X requested a costs authorisation for treatment with the drug Myozyme. Publisana preliminarily authorised the costs for a sixth-month treatment. As a result of the treatment, F.'s condition stabilised and the patient's quality of life improved significantly. In June 2008, Hospital X requested a continued costs authorisation. Publisana refused to bear the costs. After the subsequent termination of the treatment, F.'s condition deteriorated considerably.

F. lodged a complaint against the decision of Publisana with the Insurance Tribunal of the Canton of Aargau (one of the 26 cantons in Switzerland). In February 2010, the Insurance Tribunal of the Canton of Aargau approved F.'s complaint and ordered Publisana to bear the costs of the treatment for a preliminary period of two years (the costs for the additional one and a half years amounted to between CHF 750,000 and CHF 900,000). Publisana appealed against the decision of the Insurance Tribunal to the Federal Supreme Court of Switzerland (hereinafter "the Court"). The question at issue before the Court was only the continuation of the treatment beyond the first six months, i.e. a period of treatment of one and a half years (CHF 750,000 to CHF 900,000).[2]

* Lic. iur. Felix Kesselring, attorney at law, VISCHER Ltd., Zurich, Switzerland, <fkesselring@vischer.com>.

1 Judgment of the Federal Supreme Court of Switzerland of 23 November 2010 (BGE 136 V 395 et sqq.; 9C_334/2010). The judgment is available in German only. It can be downloaded from the website of the Federal Supreme Court of Switzerland (<http://www.bger.ch>). The judgment deals mainly with Art. 5, para. 2 and Art. 8, para. 1 of the Federal Constitution of the Swiss Confederation (SR 101) and with Art. 24, Art. 25, paras. 1 and 2, litera b, Art. 34, para. 1 and Art. 52, para. 1, litera b of the Federal Act on Health Insurance (SR 832.10), Arts. 34 and 64 et sqq. of the Federal Ordinance on Health Insurance (SR 832.102) and Arts. 30 et sqq. of the Federal Ordinance on the Reimbursement in the Compulsory Health Insurance (SR 832.112.31).

2 Case 136 V 395 et sqq., consideration 1.

II. Judgment

The Court rejects the obligation of Publisana to bear the costs of the continued treatment for two reasons. Firstly, the treatment with the orphan drug Myozyme does not have a substantial therapeutic benefit. Secondly, even if the treatment did have a substantial therapeutic benefit, Publisana could not be obliged to bear the costs for reasons of economic efficiency.

Regarding the first reason (no evidence of a substantial therapeutic benefit).[3] Referring to the relevant legislation[4], the Court explains that, as a rule of public health insurance law, a public health insurance provider has to cover the costs of a drug which has been prescribed by a physician, which is being employed in accordance with the approved indications/uses specified in the instructions, and which is included on the list of reimbursable pharmaceutical products. To be included on the list of reimbursable pharmaceutical products, a drug has to be effective, appropriate and economical. Referring to its previous case-law[5] the Court states that a drug not included on the list of reimbursable pharmaceutical products must be reimbursed by a public health insurance provider in two exceptional circumstances. Firstly, where there is a so-called therapeutic complex, and, secondly, where the disease is life-threatening or associated with serious and chronic health risks and no other effective treatment method is available. In the second case, however, there would need to be a substantial therapeutic (curative or palliative) benefit (i.e. a substantial therapeutic effect). Applying this case-law, the Court holds that Myozyme lacks a substantial therapeutic benefit, both generally and in respect of F. in particular.

Regarding the second – and more pertinent – reason (economic inefficiency of the treatment). The Court considers that the principles of economic efficiency and proportionality[6] necessitate an assessment of the cost-effectiveness of the relevant pharmaceutical product. The larger the therapeutic benefit, the higher the justifiable costs.[7] It cannot be argued that costs considerations are ethically or legally impermissible when human health is at issue. The financial resources available to address social needs are not infinite. In the view of the Court, the purpose of public health insurance is to provide an up-to-date and comprehensive basic coverage which is at the same time cost-efficient and, therefore, cannot cover all methods of treatment which are medically available. In addition, both the public and the Court are aware that costs considerations play an important role in everyday medical practice.[8]

The Court draws attention to the lack of generally recognised criteria (also from a political perspective) in order to assess cost-effectiveness. This results in considerable uncertainty and legal inequality amongst patients.[9] Based on the relevant case-law, the Court considers costs of approximately CHF 100,000 for an additional year in a human life to be proportional, while costs of between CHF 1.85 million and CHF 3.85 million for a saved human life are not. This view corresponds to the considerations given to cost-effectiveness in other countries, to different approaches in health economics and the maximum costs normally employed in Switzerland for therapies. The amounts are further commensurate to those in other areas in which a certain expenditure is required in order to save human life (e.g. in the areas of accident and illness prevention). The Court, however, does not consider the individual theoretical proposals and threshold values in any greater detail.[10]

An assessment of the cost-effectiveness of a particular medical treatment on the basis of generally applicable criteria is particularly important with a view to achieving legal equality.[11] In a situation in which goods and services provided by the Government are limited, the principle of legal equality would be violated if services were provided to certain insured individuals but not to others who are in the same position. In this respect, the Court refers, on the one hand, to the criterion of social compatibility in order to distinguish between social use and exces-

3 Case 136 V 395 et sqq., considerations 4–6.

4 Art. 24, Art. 25, paras. 1 and 2, litera b, Art. 34, para. 1 and Art. 52, section 1, litera b of the Federal Act on Health Insurance; Arts. 34 and 64 et sqq. of the Federal Ordinance on Health Insurance; Arts. 30 et sqq. of the Federal Ordinance on the Reimbursement in the Compulsory Health Insurance.

5 BGE 131 V 349 et sqq. and BGE 130 V 532 et sqq., both concerning a so-called *off-label-use* (i.e. the practice of prescribing drugs for an unapproved indication or in an unapproved age group or unapproved dose).

6 Art. 32, para. 1 of the Federal Act on Health Insurance and Art. 5, para. 2 of the Federal Constitution of the Swiss Confederation respectively.

7 Case 136 V 395 et sqq., consideration 7.4.

8 Case 136 V 395 et sqq., consideration 7.5.

9 Case 136 V 395 et sqq., consideration 7.5.

10 Case 136 V 395 et sqq., consideration 7.6.

11 Art. 8, para. 1 of the Federal Constitution of the Swiss Confederation.

sive social use of public property[12] and, on the other hand, to commentary regarding distributive justice. The Court, however, refrains from an in-depth analysis. In the reverse, this means that, in order to ensure an equal application of the principle of proportionality, services can only be provided to an insured individual if they could be provided to all other insured persons in a similar situation.[13]

In the light of these principles, the Court in the present case does not recognise the economic proportionality of the treatment with Myozyme. The Court bases its decision on the disproportionate relationship between the costs at issue (between CHF 750,000 and CHF 900,000 for one and a half years) and the benefit of the treatment. To award the costs to F. would also violate the principle of legal equality, as a generalisation of the costs is not possible. In Switzerland, there are statistically at least 180,000 people with an equally limited quality of life as that of F. In order to improve the quality of life of these people to a comparable extent as proposed for F., the necessary costs of treatment would be an estimated CHF 500,000 per person per year and thus a total of approximately CHF 90 billion per year. This would be about 1.6 times the amount of the total costs of the public health service or slightly more than 17 % of the total gross domestic product. The public health service is therefore obviously not able to provide these services to F. on a generalised basis. The relevant costs thus cannot be borne in the present case either.[14]

III. Comment

Up to the present case, neither the Swiss Government nor legislature nor the courts have dealt adequately with the question of cost-effectiveness in human healthcare. There has been so far no answer to the question of to what financial extent a public health insurance provider has to cover the costs of a medical treatment with an orphan drug. In the present decision, the Court enters for the first time into an extensive analysis of questions relating to the cost-effectiveness in human healthcare.

It should be noted at the outset that there was no need for the Court to enter into this discussion. The Court had already determined that Publisana was not required to cover the costs of Myozyme on the basis that there was no substantial therapeutic benefit. However, the discussion of efficiency helped the Court to reach a more broadly-based decision and is to be considered as an instance of judicial law-making in an area which clearly lacks legislative regulation.

At the very beginning of its considerations of cost-effectiveness, the Court states that: "[t]he question of costs cannot be pushed aside by the simple assertion that it was ethically ... impermissible to enter into costs considerations when concerned with human health".[15] The Court bases this statement on the consideration that, both in the law in force (e.g. in respect of the list of reimbursable pharmaceutical products) and in general medical practice, the view is taken that not every medically available treatment is paid for or provided.[16] While the formulation used by the Court still allows ethical considerations in the analysis of cost-efficiency, the Court refrains from such considerations in the present case.

As far as considerations of cost-effectiveness of the Court are concerned, one should note the following.

Regarding the effectiveness. The Court requires a substantial therapeutic benefit as a prerequisite for the public health service to bear the costs on an exceptional basis.[17] The precise extent of such benefit is, however, not discussed by the Court. First of all, it remains unclear whether the Court considers the subjective (self-perceived) benefit in addition to the objective benefit. Secondly, it is unclear whether, for the purposes of the cost-effectiveness analysis, only the effect to the insured is relevant (direct benefit) or whether the potential benefit to a third party is equally relevant. A third-party benefit is a benefit which arises to a third party on the basis that the treatment enables the insured to perform again (or to continue to perform or to perform for the first time) certain tasks (for example, the making of child-support payments). This third party can also be the State and the third-party benefit can, for example, be seen in the avoidance of unemployment and of the resulting state benefits. In the present decision, however, the Court seems to consider that, for the purposes of the cost-effectiveness analysis, only the objective direct benefit is relevant. Nevertheless, the Court's decision does not expressly exclude the con-

12 For example BGE 132 I 97 et sqq. and BGE 121 I 279 et sqq.

13 Case 136 V 395 et sqq., consideration 7.7.

14 Case 136 V 395 et sqq., consideration 7.8.

15 Case 136 V 395 et sqq., consideration 7.5.

16 Case 136 V 395 et sqq., consideration 7.5.

17 *Cf.* considerations of the Court above section II.

sideration of either a subjective or third-party benefit. The line of reasoning taken by the Court in this decision appears to conform to the assessment of the right to life in criminal law. Criminal law considers the life of one human being to be equal to the life of any other human being, irrespective of whether such life constitutes a happy or an unhappy life or an economically valuable or less valuable life.[18] This objective approach apparently taken by the Court allows for the difficult qualitative assessment of an individual human life to be largely disregarded.

Regarding the costs. In this respect, the Court held that, on the basis of the principle of legal equality, it is in any case not possible for treatment costs to be covered by the public health service once the costs at issue in the particular case could not be covered in respect of all other persons in a similar situation. This line of reasoning is generally convincing. It is noteworthy, however, that the Court presumes the financial resources of the public health service to be actually limited. Yet, the financial strength of the public health service is, at least theoretically, not limited, as opposed to public property (to which the Court makes reference in its decision) or donor organs. It is not clear from the present decision whether the Court considers that such an "artificial" limit should be equally applied in other areas concerned with the public administration of goods and services.

The calculation applied by the Court of the maximum amount available in the case of F. is not convincing. The Court compares the case of F. to that of all persons living in Switzerland whose ability to walk is limited to less than 200 metres. There are apparently 180,000 people in this situation. It is unclear why the Court chose to compare the individual case of F. with that of 180,000 people whose ability to walk is limited to less than 200 metres, rather than (only) with that of the other patients suffering from Morbus Pompe. This latter basis of comparison would, in the opinion of the author, have been factually more appropriate in light of article 8, paragraph 1 of the Federal Constitution of the Swiss Confederation as it concerns the same illness which can be treated with the same kind of medication.[19] The calculation performed by the Court also remains vague in other respects. According to the Court, the 180,000 people apparently only constitute part of the group to be compared. In addition, the financial costs of CHF 500,000 per patient only amount to a vague estimate which apparently would not apply in respect of each patient in the comparison.

Regarding cost-effectiveness. The present decision makes it clear that the maximum available amount has been reached once the amount at issue in the individual case cannot also be provided to all other persons in a comparable situation. It remains unclear, however, how cost-effectiveness is to be assessed below this maximum amount. While the Court considers the relevant case-law and commentary in this respect, it does not show explicitly whether each case is concerned with a curative or palliative benefit and whether the benefit was purely qualitative or also life-prolonging. In the opinion of the author, these differentiations, however, have an important impact on proportionality and thus on the refundable costs.[20] In light of this and in view of the fact that the treatment in question has a purely qualitative benefit, the preliminary conclusion of the Court that approximately CHF 100,000 for an additional year in a human life are still proportional while costs of between CHF 1.85 billion and CHF 3.85 billion for a saved human life are not, lacks differentiation. It is noteworthy that the Court spends surprisingly little time on examining the jurisprudential discussion on distributive justice generally,[21] nor does it apply the debate about distributive justice in the context of organ transplants to the present case.[22] The Court does not explicitly rely on a scientific discussed concept (such as a concept based on *quality adjusted life years [QALY]).* Moreover, the Court does not consider the question of alternative allocation in the sense that the costs requested by F. should be denied on the basis that they were rather to be invested, for instance, in further research into the disease so that the quality of life of more people could be improved. It further remains unclear to what extent the Court maintains

18 *Cf.* Andreas Donatsch, *Strafrecht III*, 9th ed. (Zurich 2008), pp. 3 *et sqq.*; Günter Stratenwerth, Guido Jenny, Felix Bommer, *Schweizerisches Strafrecht Besonderer Teil I: Straftaten gegen Individualinteressen,* 7th ed. (Berne 2010), § 1 margin number 6.

19 *Cf.* similarly Tomas Poledna, Marianne Tschopp, „Der Myozyme-Entscheid des Bundesgerichts", in *Jusletter,* 7 February 2011, margin number 30.

20 *Cf.* Felix Kesselring, „Kosten-/Nutzen-Beziehung im Bereich der menschlichen Gesundheit", in 4 *Aktuelle Juristische Praxis* (2011), p. 576.

21 *Cf.* for instance Jörg Paul Müller, Markus Schefer, *Grundrechte in der Schweiz,* 4th ed. (Berne 2008), pp. 666 *et sqq.* including further references; Markus Schott, *Patientenauswahl und Organallokation* (Diss. Basel, Basel/Geneva/Munich 2001), pp. 55 *et sqq.*; *cf.* references of the Court itself in consideration 7.5.

22 *Cf.* for instance Markus Schott, *supra* note 21, pp. 193 *et sqq.*, or Paolo Becchi, Alberto Bondolfi, Ulrike Kostka, Kurt Seelmann (eds), *Organallokation Ethische und rechtliche Fragen* (Basel 2004).

the limit of CHF 100,000. This question could be left open by the Court as the costs at issue exceeded the maximum amount. It would, however, have been desirable if the Court's considerations of cost-effectiveness had been more concrete and differentiated.

The Court appeals on several occasions to the legislature to deal with the question of cost-effectiveness. This is indeed desirable. For an assessment of cost-effectiveness it is, for example, necessary to answer the question of how one year of a human life is to be assessed financially and of how much the community of the insured and the State are prepared to contribute in order to preserve an individual's state of health. It is the task of the legislature to answer such fundamental questions.[23] It is to be hoped that, following the present decision, the legislature will approach this task. It would be possible for the legislature to calculate a concrete amount which would constitute a maximum amount to be covered by the public health insurance. On the basis of the present decision, the legislature would need to calculate all financial resources available to the public health service and compare these to the direct benefit (and potentially the third-party benefit) which statistically can be expected and be determined in the abstract. This would result in a maximum amount in Swiss franks which could be accorded to each insured individual.

It should be noted that the Court in the present decision fails to discuss the right to life and personal freedom and the right to assistance when in need enshrined in the Federal Constitution of the Swiss Confederation and the Convention for the Protection of Human Rights and Fundamental Freedoms.[24] The reason for this is probably that such a violation of fundamental rights was not argued before the Court. However, an allegation of the violation of a constitutional or fundamental right is a prerequisite for the Court to hear a case in this aspect in the first place.[25] Such an allegation before the Court is also necessary for bringing a case in front of the European Court of Human Rights.[26] It is recognised in both case-law and commentary that positive obligations of protection can result from constitutional and fundamental rights. It is, however, unclear to what extent such obligations exist in individual circumstances.[27] In the present case, the question would have to have been answered if and to what extent Switzerland has an obligation, based on article 10, paragraphs 1 and 2 and article 12 of the Federal Constitution of the Swiss Confederation and article 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms, to pay for medical treatment which would prolong and/or improve the life of patients suffering from genetic diseases.

Since the decision of the Court, small steps have been taken towards the legislative implementation of the cost-effectiveness analysis. On 1 March 2011, the Federal Ordinance on Health Insurance proclaimed that the costs to be covered by the public health insurance providers need to be proportionate to the therapeutic benefit of the particular product.[28] However, a regulatory instrument in the form of an ordinance does not meet the demand of the Court for a formal legislative basis for the assessment of cost-effectiveness. Moreover, the Federal Constitution of the Swiss Confederation requires all significant provisions to be enacted in the form of an act of parliament.[29] In addition, several political proposals in relation to the analysis of cost-effectiveness are currently under discussion.

23 Art. 164, para. 1 of the Federal Constitution of the Swiss Confederation.

24 Art. 10, paras. 1 and 2 and Art. 12 of the Federal Constitution of the Swiss Confederation; Art. 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms (SR 0.101).

25 Art. 106, para. 2 of the Federal Act on the Federal Supreme Court (SR 173.110).

26 Art. 35, para. 1 of the Convention for the Protection of Human Rights and Fundamental Freedoms; Mark E. Villiger, *Handbuch der Europäischen Menschenrechtskonvention (EMRK)*, 2nd ed. (Zurich 1999), margin notes 134 et sqq. with further references; Cases of the European Court of Human Rights, for instance, *Carlson v. Switzerland* of 6 November 2008, Case No. 49492/06, margin numbers 97 et sqq., *G.B. v. Switzerland* of 3 February 2000, Case No. 27426/95 (Decision as to the Admissibility of the Case), margin number 3.

27 *Cf.* Jörg Paul Müller, Markus Schefer, *supra* note 21, pp. 53 *et sqq.*, 74 *et sqq.* and 763 *et sqq.* including further references; René Rhinow, Markus Schefer, *Schweizerisches Verfassungsrecht*, 2nd ed. (Basel 2009), margin numbers 1177, 1252 et sqq. and 3447 et sqq.; Patricia Egli, *Drittwirkung von Grundrechten* (Diss. Zurich, Zurich 2002), pp. 155 *et sqq.*, 235 *et sqq.* and 283 *et sqq.*; Walter Kälin, Jörg Künzli, *Universeller Menschenrechtsschutz*, 2nd ed. (Basel 2008), pp. 325 *et sqq.* and 353 *et sqq.*; Ulrich Häfelin, Walter Haller, Helen Keller, *Schweizerisches Bundesstaatsrecht*, 7th ed. (Zurich 2008), margin numbers 368 and 918; BGE 126 II 300 et sqq., BGE 119 Ia 28 et sqq.; Cases of the European Court of Human Rights, for instance, *D. v. the United Kingdom* of 21 April 1997, Case No. 30240/96, *N. v. the United Kingdom* of 27 May 2008, Case No. 26565/05.

28 Arts. 71a and 71b of the Federal Ordinance on Health Insurance (AS 2011 654).

29 *Cf.* Art. 164, para. 1 of the Federal Constitution of the Swiss Confederation.