Maintaining original medicinal products in Reimbursement Code

24 July 2019 | Contributed by Preslmayr Attorneys at Law

Healthcare & Life Sciences, Austria

- **Introduction**
- **Facts**
- **Decision**
- **Comment**

Introduction

The Organisation of Austrian Social Security pays for the medicinal products included in the Reimbursement Code. The product manufacturer or authorised distributor (hereafter, the originator) and the Main Association of Social Security Institutions (Main Association) must agree on the price that the Organisation of Austrian Social Security will pay to the originator for the medicinal product.

When a generic is added to the Reimbursement Code, the originator must reduce its price in order for the product to remain therein; if a third generic is added, a further price reduction must be agreed. If the Main Association and the originator cannot agree on a price, the product will be removed from the Reimbursement Code.

Facts

An originator's proprietary medicinal product, Subutex, was listed in the yellow area of the Reimbursement Code. On the entry of a third generic, Buprenorphin, in the yellow area, the Main Association requested Subutex's removal from the code because the new price recommended by the Evaluation Commission of Medicinal Products could not be agreed. The originator claimed that a group of insured persons had considerable interest in retaining Subutex in the code, thus justifying a higher price – namely, substitution patients (ie, persons using the medicinal product because of their drug addiction) who would refuse generics, terminate the substitution treatment or switch to other less suitable and ultimately more expensive active ingredients if they no longer received the original product.

In its appeal to the Federal Administrative Tribunal, the originator submitted extensive data on therapy durations and discontinuation, consumption and mortality rates during and after treatments. However, the originator submitted no data on the proportion of substitution patients who had legitimate reasons for refusing generics which caused them to discontinue their therapy or switch to another active ingredient.

Reviewing the data, the tribunal argued that a 2012 publication demonstrated that the patient rejection argument was not always justified and often stemmed from inadequate information. Further, a 2011 publication offered a descriptive summary of (non-systematic) compiled studies and clinical case reports. Therefore, the originator could not prove that a group of insured persons had considerable interest in retaining Subutex in the code, thus justifying a higher price.

In legal terms, the Federal Administrative Tribunal stated, among other things, that it was necessary to examine whether the originator had offered a reasonable price reduction or whether the Main Association's refusal thereof was technically justified. While the Reimbursement Code generally sets the same price for products with the same active ingredients, certain circumstances relating to characteristics of an original product and the conditions that it treats can justify leaving the original product in the code at a higher price (eg, if it would be difficult to switch patients to a generic). However, the originator provided no evidence to justify a refusal of the price reduction to the level of the third generic. The expert statements submitted by the originator failed to disprove, without further evidence, the therapeutic equivalence of the generics and Subutex.

Although the originator had requested an oral hearing, the tribunal considered it unnecessary. Appeals concerning the Reimbursement Code cannot introduce new evidence. As the facts had been established by the Main Association, the tribunal therefore relied on the evidence taken by the Main Association.

The originator filed a complaint with the Constitutional Court, which was dismissed and referred to the Supreme Administrative Court.**(1)**

Decision

In the Supreme Administrative Court proceedings,**(2)** the originator argued that the main question was whether drug addicts' switch from Subutex to Buprenorphin generics had caused the alleged difficulties already raised in the first-instance procedure (eg, a higher probability of treatment discontinuation and increased mortality). For this purpose, the originator submitted a variety of scientific documents and, in support of these allegations, witness or expert opinions.

The appeal to the Federal Administrative Tribunal mainly concerned questions of fact. Therefore, according to the Supreme Administrative Court, the tribunal would have had to hold an oral hearing. The originator's right to list and distribute Subutex for a certain price was a civil right under Article 6 of the European Convention on Human Rights. Further, there is no Supreme Administrative Court case law on the question of the "evidential value of statements by individual experts within the meaning of sec 24 (3) of the Rules for the Reimbursement Code".

In particular, it appears questionable whether the Federal Administrative Tribunal could deny the evidential value of such evidence. The tribunal had simply overruled these comments without citing scientific evidence for its opinion. According to Article 6(2) of EU Transparency Directive (89/105/EEC), a decision not to include a medicinal product in the list of reimbursable products must be based on objective and verifiable criteria. However, the criteria on which the Main Association, the Federal Administrative Tribunal or the Evaluation Commission based their decisions remain unclear; neither the Main Association nor the Federal Administrative Tribunal complied with the obligation under Article 6(2).

The Supreme Administrative Court cited Section 351(c)(10) of the Social Security Act, which reads:

> *If there is a successor product (generic) for a proprietary medicinal product the following applies to maintain the financial equilibrium of the social security system:*
>
> > *1. The Main Association has to agree with the manufacturer of the original product on a price reduction of 30 %, so that the proprietary medicinal product remains in the code. For the inclusion of the generic in the Reimbursement Code the Main Association agrees with the manufacturer of the generic on a price which is 25,7 % below the reduced price of the original product. All further generics shall be included by the Main Association in the code if there is a sufficient difference in price to the first generic. As soon as a third price reduction is caused by a generic, the Main Association may agree with the manufacturer of the original product on a further price reduction. If no agreement is achieved, the original product is removed from the code.*

In its 14 March 2012 decision,**(3)** the Constitutional Court stated that, notwithstanding the use of the term 'may', the Main Association cannot:

- agree price reductions with some manufacturers while sparing others; or
- refrain from removing original products where no agreement is reached.

Further, in its 11 March 2014 decision,**(4)** the Constitutional Court emphasised that insureds may have a significant interest in the presence of an original product in the Reimbursement Code for social health insurance reasons, due to certain characteristics of the original product and the conditions that it treats (eg, it may be difficult to switch patients to a generic). For consistency, product prices generally reflect those set out in the Reimbursement Code; however, the Main Association must consider the insureds' interests when negotiating with originators and evaluate the economic interest of social security. In this context, the Main Association's scope of consideration is sufficiently defined by the Constitution and originators are legally protected by the fact that Main Association decisions are subject to appeal.

The Supreme Administrative Court followed this opinion in respect of the relevance of conversion difficulties from original products to generics.

In complaints or complaint responses, the originator and the Main Association may refer only to facts and evidence at the time of the Main Association's decision. The submission of new facts or evidence in the appeal proceedings is permitted only to support or rebut the facts and evidence already put forward at first instance. Such new facts and evidence must be considered only if they are already filed in the appeal or in the response to the appeal.

The objective of the first-instance (ie, medical-therapeutic) evaluation by the Evaluation Commission is to quantify the benefit of the treatment of a certain group of patients with a specific medicinal product compared with therapeutic alternatives. For products with the same active ingredient, it can be assumed that there is no additional therapeutic benefit; as such, the health-economic evaluation must be made according to Section 25(2) of the Rules for the Reimbursement Code. Only in exceptional cases can medicinal-therapeutic reasons (eg, the described difficulties in converting patients to generics) justify a product remaining in the Reimbursement Code. The Evaluation Commission must assess the validity of evidence according to the catalogue of criteria in Section 24(3) of the Rules for the Reimbursement Code (from prospective studies to expert statements). Further, its evaluations must comply with the criteria of scientific, transparent and health-economic evaluations. Conclusive evaluations have the weight of expert opinions. The Main Association (and, on appeal, the Federal Administrative Tribunal) may overrule such evaluations only if they are inconclusive or contradicted by valid expert opinions.**(5)**

Whether the alleged conversion difficulties were to be expected in the present case is a technical question to be answered by an expert. If the parties submit opinions from other experts, they must be reviewed and verified by official or non-official experts as a subsidiary body of the Federal Administrative Tribunal, where appropriate. According to the quality criteria of Section 24(3) of the Rules for the Reimbursement Code, the validity of evidence (ie, the informative value of the documents) does not mean that 'subordinate' documents lack any decisive value of evidence.

The Federal Administrative Tribunal may reject an oral hearing request only if the files indicate that such a discussion cannot help to clarify the dispute. In the present case, the originator requested an oral hearing on the grounds that the Federal Administrative Tribunal needed to verify whether drug addicted patients (potentially suffering from psychiatric disease) may experience conversion difficulties despite proper medical education and treatment.

It could not be assumed that an oral hearing would fail to clarify the originator's claim, particularly since it was not only "a question of technical nature", but also involved taking and discussing expert evidence against a controversial backdrop. The Federal Administrative Tribunal had a duty to:

- consider the principle of immediacy according to Section 24 of the Administrative Tribunal Procedure Act (in order to get a personal impression of the credibility of witnesses, parties and expert opinions); and
- base its assessment of evidence on this impression.

If an oral hearing must be held according to Article 6 of the European Convention on Human Rights or Article 47 of the Charter of Fundamental Rights of the European Union, an assessment of the relevance of this violation of procedural rules is unnecessary. Therefore, the decision had to be set aside.

Comment

The Supreme Administrative Court's decision stresses not only the importance of an oral hearing if it is requested by parties and appropriate to clarify case facts, but also the importance of considering conversion difficulties between original medicinal products and generics for maintaining the former's entry in the Reimbursement Code at a higher

price.

For further information on this topic please contact Rainer Herzig at Preslmayr Attorneys at Law by telephone (+43 1 533 16 95) or email (herzig@preslmayr.at). The Preslmayr Attorneys at Law website can be accessed at www.preslmayr.at.

Endnotes

(1) Constitutional Court, 24 September 2018, E 4056/2017-18.

(2) Administrative Court, 29 January 2019, Ra 2018/08/0238 (ECLI: AT: VwGH: 2019: Ra 2018080238.L00).

(3) B970/09, VfSlg 19631.

(4) B1451/2011, VfSlg 19857.

(5) Supreme Administrative Court, 6 July 2016, RO 2016/08/0012, VwSlg 19415A.

Rainer Herzig