Netherlands - Raad van State (Council of State) - 201801209/1/A3 – 10 October 2018 - ECLI:NL:RVS:2018:3298

Article 10(3) Directive 2001/83/EC on the Community code relating to medicinal products for human use – Article 47 Charter of Fundamental Rights of the EU - Articles 26 and 114 TFEU

(Teva Pharmaceuticals Ltd against the Medicines Evaluation Board)

The Medicines Evaluation Board (the MEB) issued, in respect of decisions on 19 May 2016, marketing authorisations to Synthon B.V. and Mylan B.V. for the medicine 'Brabio 20 mg/ml, solution for injection in a pre-filled syringe, RVG 115980', 'Sclerthon 20 mg/ml, solution for injection in a pre-filled syringe, RVG 115987' and 'glatiramer acetate Mylan 20mg/ml, solution for injection in a pre-filled syringe, RVG 115993' (referred to hereafter as: the authorised medicines).

Teva raised an objection to this, an objection that the MEB declared unfounded. Teva subsequently lodged an appeal. The court declared this appeal unfounded. In response, Teva lodged an appeal with the Administrative Jurisdiction Division of the Council of State of the Netherlands (Division).

Conclusion of the Division Judgement of 10 October 2018:
[…]
50. It follows from recitals 42 through 49 that, in the opinion of the Division, Teva's arguments cannot detract from the conclusion reached by the Division in recital 40 on the basis of the wording, objective and historical development of Article 10 (3) of Directive 2001/83/EC.

This means the Division draws the final conclusion that in the question of whether Article 10 (3) of Directive 2001/83/EC can be applied, it is not important whether Copaxone and the authorised medicines contain the same active substance, at least the same therapeutic moiety, but whether the relevant differences between the reference medicine Copaxone and the authorised medicines have been bridged. It is therefore a matter of demonstrating therapeutic equivalence between Copaxone and the authorised medicines.

The Division therefore does not agree with Teva's argument that, from the point of view of safety and efficacy, it is only justified to refer to research data from the reference medicine file if the active substance, at least the therapeutic moiety, is the same. In particular, the Division does not agree with Teva's view that changes to the active substance are only permitted if the changes concern salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives and not the therapeutic moiety.

This condition only applies, in accordance with the wording of Article 10 of Directive 2001/83/EC, to the generic procedure and not the hybrid procedure. In this context it is important that in a change to the active substance, the aforementioned safety and efficacy are ensured by the fact that in the hybrid procedure with preclinical and clinical studies, the difference with the reference medicinal product must be bridged.
[…]

52. Teva has submitted four questions for a preliminary ruling. The Division sees no reason for this in view of the Cilfit judgment (see points 10 and 16).
[…]

NB: An English translation of relevant parts of the judgement is uploaded on Jurifast together with the original complete Judgement in Dutch.