Belgian Council of State Clarifies Role of Concerned Member States in Decentralised Marketing Authorisation Procedure

By judgment of 16 January 2020, the Belgian Council of State (*Raad van State/Conseil d'État*), Belgium's highest administrative court, clarified the role of Belgium when acting as concerned Member State (***CMS***) in the context of the decentralised procedure for granting marketing authorisations for medicinal products (***DCP***). In its judgment, the Council of State relied heavily on the rulings of the Court of Justice of the European Union (***CJEU***) in *Synthon* (judgment of 16 October 2008 in Case C-452/06) and *Astellas Pharma* (judgment of 14 March 2018 in Case C-557/16). The Council of State reaffirmed the limited discretionary powers of the CMS to call into question the assessments carried out by the Reference Member State (***RMS***) when evaluating a medicinal product under the DCP.

Background

On 21 February 2017, the Belgian Federal Agency for Medicines and Health Products (the ***FAMHP***) granted a marketing authorisation to ophthalmology pharmaceutical company Horus Pharma SAS (***Horus***) for "*Latanoprost Horus Pharma 50µg/ml*", which is indicated for the treatment of open angle glaucoma and ocular hypertension (the ***Belgian MA***). The product is currently being commercialised as Xalof®.

The FAMHP granted the Belgian MA under the so-called "hybrid DCP" on the basis of Articles 10(3), 28 and 29 of Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (the ***Directive***). The Netherlands acted as the RMS under the DCP.

On 2 June 2017, a competitor of Horus, Théa Pharma NV (***Théa***), filed a petition with the Belgian Council of State seeking the annulment of the Belgian MA. After having been informed of the proceedings by the Council of State, Horus filed a petition for leave to intervene in the proceedings in support of the position of the FAMHP. Horus was assisted and represented by Van Bael & Bellis.

Findings of the Council of State

On 16 January 2020, the Council of State dismissed Théa's action for annulment in its entirety. The Council of State based its decision on the CJEU's *Synthon* and *Astellas Pharma* case law.

The Council of State started its analysis by identifying the "hybrid DCP" and the applicability of Articles 28 and 29 of the Directive. Pursuant to Article 28(5) of the Directive, each EU Member State involved in a DCP is required to adopt a decision in

conformity with the approved assessment report within 30 days after acknowledgement by the RMS of the agreement between the RMS and every CMS.

Next, the Council of State referred to the CJEU's *Synthon* judgment. It held that it follows from *Synthon* that, pursuant to the Directive, EU Member States cannot call into question, on grounds other than those relating to risks to public health, the assessments carried out by another EU Member State in the context of an application for mutual recognition of a marketing authorisation previously granted by that EU Member State. The Council of State added that EU Member States, when invoking such risks to public health, must follow a specific procedure in accordance with Article 29 of the Directive.

In this regard, it is worth noting that the European Commission has published guidelines on what constitutes a risk to public health (*see*, Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC here). These guidelines clarify that the risk to public health must concern a situation where there is a significant probability that a serious hazard resulting from the medicinal product in the context of its proposed use will affect public health. Serious in this context means a hazard that could be life-threatening or result in death, hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, congenital anomaly/birth defects or permanent or prolonged signs in exposed humans.

The Council of State continued its reasoning by invoking the CJEU's judgment in *Astellas Pharma*. In this judgment, the CJEU confirmed the *Synthon* case law and held that, pursuant to the Directive, the CMS participating in the DCP (which concludes with the acknowledgement, by the RMS, of the general agreement of the EU Member States where the application for a marketing authorisation was submitted) are required to adopt a decision in conformity with the assessment report for the medicinal product in question. Therefore, when such general agreement has been acknowledged, the competent authorities of those EU Member States may not call into question the outcome of the DCP when making their decision on the placing on the market of that medicinal product in their territory.

The Council of State noted that the FAMHP did not apply the specific procedure included in Article 29 of the Directive during the DCP for "*Latanoprost Horus Pharma 50µg/ml*". According to the Council of State this demonstrated that the FAMHP considered that no public health risk exists in relation to the aforementioned medicinal product. Théa had failed to demonstrate the existence of any risk to public health and any failure of the FAMHP in this respect, and the FAMHP in any event was better positioned than the Council of State to make that assessment.

The Council of State concluded that, in the absence of any risk to public health, the FAMHP was not entitled (and still is not entitled) to call into question the assessments

carried out by the RMS. Furthermore, the annulment of the Belgian MA only could have resulted in the FAMHP subsequently granting a new Belgian marketing authorisation to Horus for the same medicinal product. As a result, the Council of State found that Théa lacked any standing for its pleas which, therefore, were declared inadmissible.

Importance

With its judgment, the Council of State applied the CJEU's case law in *Synthon* and *Astellas Pharma* holding that the regulatory authorities of the CMS (*in casu*, the FAMHP) cannot deviate from the outcome of the DCP.

In accordance with the above case law, the CMS can only rely on grounds relating to risks to public health during the DCP to contest the RMS' assessment. As soon as the RMS has acknowledged the agreement by the CMS with the RMS' assessment, the CMS can no longer call into question the outcome of the DCP.

In conclusion, parties envisaging to contest an application for a marketing authorisation under the DCP at the level of the CMS should intervene prior to the CMS' agreement to the RMS' assessment report. Any objections that are raised in this context should relate to risks to public health, which, in turn, should fit the narrow definition of a serious risk to public health as described in the European Commission's guidelines.