



When deciding about medicines, the impartiality of the institutions of the EU is out of discussion

Judgement of the Court of Justice of the European Union (CJEU) of 27 March 2019, Dr. August Wolf v the European Commission, Case C-680/16 P

Principle of impartiality

According to the Charter of Fundamental Rights of the EU, every person has the right to have his or her own affairs handled impartially by the institutions and bodies of the EU. This implies that members of the institutions of the EU shall not show bias or personal prejudice (subjective impartiality); and that such institutions shall offer sufficient guarantees to exclude any legitimate doubt as to possible bias on their part (objective impartiality).

Position of the CJEU

Recently, the CJEU has evaluated the objective impartiality of the Committee for Medicinal Products for Human Use (CHMP) in connection with an assessment report regarding a matter referred by German authorities to the CHMP in 2012. Such report, dated on 25 April 2014, analyzes the risk-benefit balance of medicinal products containing high concentrations of estradiol. Three main ideas can be learned from the judgement of the CJEU:

First. To prove the lack of impartiality of an institution or body of the EU, it is not necessary to prove the existence of such lack of impartiality. It shall be sufficient, in the words of the CJEU “for a legitimate doubt to arise which cannot be dispelled”.

Second. When the CHMP draws up assessment reports, special attention should be paid to the role of the rapporteur in view of his or her own responsibilities. Therefore, the CHMP must be particularly vigilant in

attributing such role in order to avoid giving rise to any legitimate doubt as to possible bias. In the present case, the CJEU finds that the appointed rapporteur was not in compliance with her obligation of impartiality because she was an employee of the German national authority that (apart from being the one that referred the matter to the CHMP) had previously positioned itself about the object of the assessment report. The CJEU also considers that, at the time the German authority referred the matter to the CHMP, the decision of such national authority regarding the controversial matter was awaiting an appeal before the national courts; and that the appointed rapporteur was defending the position of German authorities (where she was employed) in the corresponding judicial proceedings.

Third. The fact that EU regulations provide that Member States are to refrain from giving CHMP members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the EMA, it is not sufficient to dispel the doubts about the rapporteur’s lack of impartiality.

Conclusion

CHMP reports, and the Commission decisions based on them, can be questioned using a variety of arguments. The lack of impartiality of the CHMP, as discussed, may be one of such arguments.

The CJEU, in view of its last judgement, seems to be ready to be very strict when it comes to the impartiality of the institutions of the EU.