Request for a preliminary ruling from the Consiglio di Stato (Italy) lodged on 19 January 2017 — Novartis Farma SpA v Agenzia Italiana del Farmaco (AIFA)

(Case C-29/17)

(2017/C 195/13)

Language of the case: Italian

Referring court

Consiglio di Stato

Parties to the main proceedings

Appellant: Novartis Farma SpA

Respondent: Agenzia Italiana del Farmaco (AIFA)

Questions referred

1. Do the provisions of Directive 2001/83/EC, ([1]) as subsequently amended, and in particular Articles 5 and 6 thereof, with reference in particular to the second recital of the directive, preclude the application of a national law (the provision several times cited being Article 1(4)bis of the Decree-Law), which, in order to pursue the objective of containing expenditure, encourages, by inclusion in the list of medicinal products reimbursable by the national health service, the use of a drug beyond the therapeutic indication authorised for patients in general, regardless of any consideration of the therapeutic needs of the individual patient and notwithstanding the existence and market availability of medicinal products authorised for the specific therapeutic indication?

2. Can Article 3(1) of Directive 2001/83/EC (magistral formula) be applicable when the preparation of the pharmaceutical product is done in a pharmacy on the strength of a medical prescription for an individual patient, but is nonetheless done in batches, in equal quantities and repeatedly, without taking account of the specific needs of the individual patient, and when the product is dispensed to the hospital and not to the patient (given that the pharmaceutical product is listed in class H-OSP) and is used in a facility other than that in which the product was prepared?

3. Do the provisions of Regulation (EC) No 726/2004 ([2]) as amended, and in particular Articles 3, 25 and 26 thereof together with the Annex, which confer on the European Medicines Agency (EMA) exclusive responsibility for evaluating the quality, safety and efficacy of medicinal products for which the therapeutic indication is the treatment of oncological pathologies, both in the context of the procedure for granting authorisation procedure for medicinal products to be placed on the market (compulsory centralised procedure) and for the purposes of the monitoring and coordination of pharmacovigilance activities after the product has been placed on the market, preclude the application of a national law that reserves to the national regulatory authority (AIFA) the power to judge the safety of medicines as regards their use 'off-label', the authorisation of which falls within the exclusive competence of the European Commission on the basis of the technical and scientific evaluations carried out by the European Medicines Agency (EMA)?

4. Do the provisions of Directive 89/105/EEC, ([3]) as subsequently amended, and in particular Article 1(3) thereof, preclude the application of a national law that permits the Member State, in its decisions on the reimbursability of health expenses borne by the patient, to provide for the reimbursability of a medicinal product used beyond the ambit of the therapeutic indications stated in the marketing authorisation issued by the European Commission, or by a specialised European agency, following a centralised evaluation procedure, when the conditions set out in Articles 3 and 5 of Directive 2001/83/EC are not satisfied?

([1]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

([2]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) (OJ 2004 L 136, p. 1).

([3]) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).