Presentation: Judgment of the Court of Justice in the case C-452/14

Spokeswoman: Avv. Francesca Mastroianni

19 to 20 November 2015

Agenzia Italiana del Farmaco

Agenzia Italiana del Farmaco

Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	X	☐	☐	☐ optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	X	☐	☐	☐ optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

*Francesca Mastroianni, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. < I am not receiving any compensation>

Case C-452/14

Concerning a question referred for a preliminary ruling in the proceedings

Agenzia Italiana del Farmaco (AIFA), Ministero della Salute

v

Doc Generici Srl

Agenzia Italiana del Farmaco
AIFA

The dispute in the main proceedings

- The application has been made in proceedings between the AIFA and Doc Generici concerning the amount of fees payable for variations to several MAs.
- Doc Generici is the holder of 62 MAs. It notified AIFA of the change of address of its registered office (type IA variations) and requested that each of the MAs it held be varied.
- AIFA sought payment from that company of a fee of EUR 600 for each of the 62 MAs for which such a variation was requested (‘the decision of 23 March 2013’).

- Doc Generici brought an action before T.A.R. del Lazio (Regional Administrative Court, Lazio) seeking annulment of the decision of 23 March 2013.

- That action was upheld on the ground that a single fee of EUR 600 is payable for a single variation to be made at the same time to all the MAs in force. The court at first instance relied on the provision which states that '*the fee shall cover all authorised strengths, pharmaceutical forms and presentations*', which appears in both Annex 3 to the Decree of the Minister for Health of 24 May 2004 and in Article 3(2)(a) of Regulation No 297/95.

- The TAR del Lazio took the view that Article 3(2)(a) of Regulation No 297/95 also covered situations in which one and the same variation applies to several MAs. It was of the view that that interpretation was consistent with recital 6 in the preamble to Regulation No 1234/2008, which permits an identical set of variations to marketing authorizations owned by the same holder to be grouped together in a single notification in order to reduce the administrative burden entailed in processing them.

- The AIFA brought an appeal against that decision before the Consiglio di Stato (Council of State), a court of final instance. In the order for reference, that court stated that it is clear from national legislation that, since 1997 the fee scheme applicable to MAs for medicinal products issued by the AIFA has closely followed EU legislation. The amount of the national fee is expressed as a percentage of that charged by the EMA under the centralised procedure.

- The Consiglio di Stato entertained doubts as to the validity of the interpretation of EU law adopted by the court at first instance. It considered that Article 3(2)(a) of Regulation No 297/95 applies to a case that is different from that in the main proceedings.

The question referred for a preliminary ruling

- The Consiglio di Stato referred the following question to the Court for a preliminary ruling: '*Must Article 3(2)(a) of [Regulation No 297/95] be interpreted as meaning that type I marketing authorization variations — and, in particular, in respect of the case in the main proceedings, type IA variations — where an identical variation affecting several authorizations belonging to the same holder are concerned, are subject to a single fee, to the extent specified therein, or to as many fees as there are authorizations affected by the variation?*'

Legal Context

Recital 6 in the preamble to Regulation No 1234/2008: '*Each variation should require a separate submission. Grouping of variations should nevertheless be allowed in certain cases, in order to facilitate the review of the variations and reduce the administrative burden. Grouping of variations to the terms of several marketing authorizations from the same marketing authorization holder should be allowed only insofar as all concerned marketing authorizations are affected by the exact same group of variations*'.

Article 3 (‘Medicinal products for human use covered by the procedures laid down in Regulation (EC) No 726/2004’), 2 (‘Variation’), (a) Type I variation fee, of Regulation No 297/95: ‘*A Type I variation fee shall apply for a minor variation to a marketing authorization, as defined in Article 3(2) of Regulation (EC) No 1085/2003. For Type IA variations, the fee shall be EUR 3 000. […]. In the event of the same variation being introduced, this fee shall cover all authorized strengths, pharmaceutical forms and presentations*’.

The Consiglio di Stato seeks to ascertain, in essence, whether Article 3(2)(a) of Regulation No 297/95 is to be interpreted as permitting a national authority to demand, in respect of the change of address of a MAH, payment of as many fees as there are MAs requiring variation.

The intrerpretation by AIFA

It must be made a distinction between NOTIFICATION and FEES:

1) Regulation No 1234/2008 doesn't contain any provision for the fees due for Type IA minor variations. It only authorizes the grouping in a SINGLE NOTIFICATION of several identical applications for Type IA minor variations submitted at the same time.

2) Regulation No 297/95 concerns only fees payable to the EMA and it's not applicable to the fees payable to the AIFA.

3) The fees due to the AIFA for processing groupings of Type IA minor variations may be determined by Italian law.

The interpretation by the Court of Justice

It is apparent from the title itself that Regulation No 297/95 concerns only fees payable to the EMA. With regard to the fees applicable for services provided by the EMA in the case of a change of address of the MAH, it is apparent that, in the case of the grouping of the same variation to the terms of several MAs owned by the same holder, the EMA considers that the fee applicable, as fixed by Regulation No 297/95, is payable in respect of each individual variation and each individual MA within the grouping. It is therefore clear that, for a variation of that kind, relating to several MAs owned by the same holder, the EMA's practice is to demand payment of as many fees as there are MAs requiring variation.

Regulation No 1234/2008 authorises the grouping in a single notification of several identical applications for Type IA minor variations submitted at the same time.

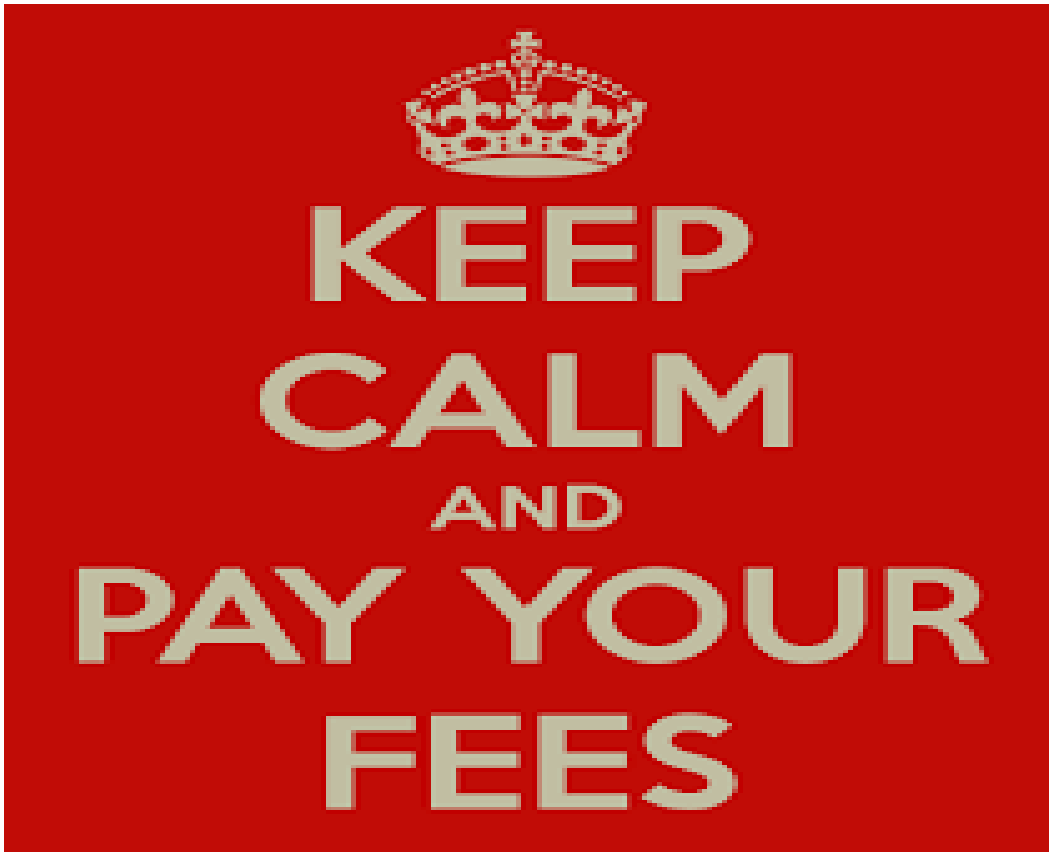
According to recital 6 in the preamble to that regulation, such grouping is intended '*to facilitate the review of the variations and reduce the administrative burden*', but only '*insofar as all concerned marketing authorisations are affected by the exact same group of variations*'.

Regulation No 1234/2008 does not contain any provision governing the amount of fees that may be charged by competent national authorities for processing such groupings of Type IA minor variations.

The question whether those national authorities may demand payment of as many fees as there are MAs requiring variation, notwithstanding the fact that the applications for variation are grouped together, has to be determined, in the absence of any legislative provisions adopted by the European Union, by national law.

The decision

Neither Regulation No 297/95 nor Regulation No 1234/2008 requires a competent national authority to demand, in respect of the change of address of a MAH, payment of as many charges as there are MAs requiring variation, and nor do those regulations prohibit such an authority from demanding such payment.


KEEP
CALM
AND
PAY YOUR
FEES

THANK YOU FOR YOUR ATTENTION!

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