

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 2 December 2008

on the application of Article 8 of Directive 98/79/EC of the European Parliament and of the Council

(notified under document number C(2008) 7378)

(Only the Portuguese text is authentic)

(2008/932/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

report is identical to the NCAR report DE-2005-07-27-30.

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in-vitro* diagnostic medical devices ⁽¹⁾, and in particular Article 8 thereof,

Whereas:

- (1) The Portuguese medical device authority Infarmed has, by letter of 29 July 2005 ⁽²⁾ addressed to the Italian company Medical Biological Service SRL (hereafter MBS), forbidden the marketing of their HIV *in-vitro* diagnostic test kit 'HIV 1 & 2 Ab' (hereafter the HIV test). Infarmed also obliged the Portuguese distributor Prestifarma Lda to recall the product on behalf of MBS.
- (2) By letter of 1 September 2005 ⁽³⁾ Infarmed notified these measures under Article 13 of Directive 98/79/EC. As justification for their measure Portugal referred to the German Paul-Ehrlich-Institut's health surveillance report 'NCAR DE-2005-07-30' (PEI Case No PEI0026/05). A subsequent exchange of letters clarified that the NCAR reference was misquoted and that the correct NCAR report number was DE-2005-07-07-30 and that this

- (3) The NCAR report DE-2005-07-07-30 states that, shortly after an HIV infection, the HIV test needs 10 to 18 days more than comparable tests to detect the infection (low early sero-conversion sensitivity). For the same reason, the Slovak Medical University had, in its test report of 28 October 2004 ⁽⁴⁾, recommended the Slovak notified body EVPÚ not to certify the HIV test. The test did thus not fulfil the requirement of being conform to the 'state of the art' in the meaning of Annex I (Essential requirements) section A.2 of Directive 98/79/EC and section 3.1.8, third sentence, of the Common technical specifications for *in-vitro* diagnostic medical devices annexed to Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for *in-vitro* diagnostic medical devices ⁽⁵⁾.
- (4) Moreover, as stated by the Paul-Ehrlich-Institut in its letter to the German Ministry of Health of 12 December 2005 ⁽⁶⁾, the documentation made available by the manufacturer shows that the HIV test did not detect all true positive samples, as required by 3.1.8, first sentence, of the Common technical specifications. This failure has never been explained by the manufacturer or his notified body as required by paragraph 3.1.5 of the Common technical specifications. Thus the HIV test does not fulfil sections 3.1.8, first sentence, and 3.1.5 of the Common technical specifications.

⁽¹⁾ OJ L 331, 7.12.1998, p. 1.

⁽²⁾ DGREE/VPS/086/05 — Case No 9.5.1 — 329/2005.

⁽³⁾ DGREE/VPS/094/05.

⁽⁴⁾ Test report No E-650/04 208600.

⁽⁵⁾ OJ L 131, 16.5.2002, p. 17.

⁽⁶⁾ Reference No A2.

- (5) MBS modified the HIV test after taking note of the NCAR report DE-2005-07-07-30. However, the modification did not improve the early sero-conversion sensitivity of the HIV test, as stated by the Paul-Ehrlich-Institut later in a report of 23 August 2007 ⁽¹⁾. As stated on page 10 of this report, the modified test also fails to detect samples already confirmed as true positive by Western blot or immunoblot assays.
- (6) The Commission consulted the Member States by letter of 22 March 2007 (D(2007) 7800), the involved notified bodies and institutes by letter of 21 March 2007 (D(2007) 7817), and MBS by letter of 11 June 2007 (D(2007) 16597). It furthermore consulted experts in the field of *in-vitro* diagnostic medical devices on various occasions and, *inter alia*, in a meeting on 31 January 2008.
- (7) Article 13 of Directive 98/79/EC (Particular health monitoring measure) has wider conditions than Article 8 (Safeguard clause) of this Directive. Article 13 of Directive 98/79/EC does not require the same level of certainty of the acting authority with regard to the existence of a risk.
- (8) The analysis of the initial notification and of the later correspondence of Infarmed and the consultation of the parties concerned have shown that that it can be ascertained that the device under examination, when correctly maintained and used for its intended purpose, may compromise the health and/or the safety of patients, users or other persons, in the meaning of Article 8 of Directive 98/79/EC, as the essential requirement of being 'state of the art' is not met.
- (9) As the test is slower and less reliable than other devices, it will detect less HIV infections than the other devices and may delay the start of an adequate anti-retroviral therapy. The test could also contribute to an increased risk of missing HIV infected blood donors. It also compromises health in as much as its late and poor detection of the HIV infection may increase the risk of transmission to third persons, for instance by sexual intercourse.
- (10) According to the European Court of Justice ⁽²⁾ the view given by the European Commission in accordance with Article 8.2 of Directive 98/79/EC binds the Member State which has taken measures. Accordingly, this legal act is to be qualified as a decision,

HAS ADOPTED THIS DECISION:

Article 1

The measures of the Portuguese authority Infarmed taken by letter of 29 July 2005 (DGREE/VPS/086/05 — Case No 9.5.1 — 329/2005) against the marketing of the *in-vitro* diagnostic medical device 'HIV 1 & 2 Ab' manufactured by the Italian company Medical Biological Service SRL are justified.

Article 2

This Decision is addressed to the Portuguese Republic.

Done at Brussels, 2 December 2008.

For the Commission
Günter VERHEUGEN
Vice-President

⁽¹⁾ Austrian authorities had asked the Paul-Ehrlich-Institut for this report after confiscating the modified test on the way from MBS to the Austrian company Dialab GmbH, the latter intending to market the test under its own name.

⁽²⁾ See, by analogy, Judgment of the Court (First Chamber) of 14 June 2007, Case C-6/05, ECR 2007, p. I-4557 Nos 58, 59.