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INTERPRETATIVE DOCUMENT OF THE COMMISSION SERVICES[1]

INTERPRETATION OF THE CUSTOMS UNION AGREEMENT WITH TURKEY IN THE FIELD OF MEDICAL DEVICES

This analysis concerns the interpretation of the legal obligations arising from the Customs Union Agreement signed between Turkey and the European Community in the field of medical devices.

In the framework of this Customs Union Agreement, four questions have been raised regarding the interpretation of the Turkish and EU obligation:

Firstly, there are two questions related to authorised representative[2]

Question 1. Do companies putting medical devices in *libre pratique* in Turkey have to designate one specific authorised representative for EU-27 in case their products are sent to the EU, even if they have already appointed an authorised representative in Turkey?

Question 2. Do manufacturers established in Turkey have the obligation to designate an authorised representative on the EU territory if they want to sell their products in the European Union?

Secondly, there are two questions related to notified bodies in Turkey.

Question 3. Does Turkey have the right to appoint notified bodies?

Question 4. Can a Turkish notified body be chosen by a Member State manufacturer instead of Member States notified body?

[1] This interpretative document is not legally binding. The ultimate interpretation of Community law lies with the European Court of Justice.

[2] Article 10a.2 of Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Article 14.2 of Council Directive 93/42/EEC concerning medical devices and Article 10.3 of Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices.

I. Regarding "authorised representatives"

On the first stage, we are going to present the legal texts related to the establishment of the customs union with Turkey. Afterwards, we present our conclusions following the interpretation of the legal texts.

- ***Legal texts concerning medical devices and Turkey in the framework of the Customs Union***

The establishment of the Customs Union has been done gradually.

Firstly, Article 9 of Decision 1/95 of the EC-Turkey Association Council on implementing the final phase of the Customs Union states "When Turkey has put into force the provisions of the Community instrument or instruments necessary for the elimination of technical barriers to trade in a particular product, trade in that product between the Parties shall take place in accordance with the conditions laid down by those instruments (…)".

Secondly, Decision 2/97 of the EC-Turkey Association Council was adopted in order to establish the list of Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey.

-Annex I of Decision 2/97 stipulates:

Regarding rights and obligations for the parties of the Customs Agreement

"Rights conferred and obligations imposed upon the EC Member States or their public entities, undertakings or individuals in relation to each other shall be understood also to be conferred or imposed upon Turkey, the latter also being understood, as the case may be, as its competent authorities, public entities, undertakings or individuals.".

In addition, it is indicated that references to territories shall be interpreted in a way that:

"Whenever the instruments referred to contain references to the territory of the 'Community` or of 'the common market` the references shall for the purposes of Decision No 1/95 be understood to include the territory of the Turkish Republic."

- Annex II of Decision 2/97 list the Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey. Directives concerning medical devices were mentioned in this annex.

Thirdly, Article 1 of Decision 1/06 of the EC-Turkey Association Council (annex 1) specifies the procedure for implementing Article 9 of Decision 1/95.

It indicates that "The Customs Union Joint Committee established by Article 52 of Decision No 1/95 shall be competent for ascertaining that Turkey has effectively put into force the provisions of the Community instrument or instruments necessary for the elimination of technical barriers to trade in a particular product. To this end, the Customs Union Joint Committee shall adopt a statement".

Finally, in 2006, a Customs Union Joint Committee Statement has been issued regarding the implementation of Article 1 of Decision 1/06 and Article 52 of Decision 1/95 (annex

2). It indicates that the Customs Union Joint Committee recognizes that the Turkish legislation takes over the Community *acquis* and that Turkey has put into force the provisions of the Community instruments necessary for the elimination of technical barriers to trade in the products covered by, among others, the three directives on medical devices (Council Directive 93/42/EEC of 14 June 1993, Council Directive 90/385/EEC of 20 June, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998).

In addition, this Statement indicates that the authorised representatives established in the Community have the same rights and obligations as those established in Turkey. One part of the Statement specifically concerns authorised representative in the field of medical devices, it specifically stresses that "(…) it is also understood that the designation of an authorised representative in Turkey or in the Community is mandatory and that these are therefore aligned with the EC legislation.".

- ***Following the analysis of the legal texts which have been presented:***

Firstly, companies putting medical devices in *libre pratique* in Turkey do not need to nominate two authorised representatives: one for Turkey and one for the EU territory. Once they have nominated one authorised representative, they can sell their product in the whole territory of the Turkey-EC Customs Union.

Indeed, according to the wording of the Statement issued pursuant to Decision 1/06, an authorised representative has to be nominated "in Turkey **or** in the Community".

Therefore, for goods put in *libre pratique* in Turkey, the current wording leads us to the interpretation that only one representative is necessary for the EU and Turkey.

Secondly, by analogy with the previous analysis, we consider that manufacturers established in Turkey have no obligation to appoint an authorised representative on the EU territory in order to sell their products in the European Union and vice versa.

In case they decide voluntarily to nominate an authorised representative, only one authorised representative for Turkey and EU-27 is necessary.

Conclusion

Question 1. Do companies putting medical devices in *libre pratique* in Turkey have to designate one specific authorised representative for EU-27 in case their products are sent to the EU, even if they have already appointed an authorised representative in Turkey?

Answer: No

Question 2. Do manufacturers established in Turkey have the obligation to designate an authorised representative on the EU territory if they want to sell their products in the European Union?

Answer: No

II. Regarding "notified bodies"

On the first stage, we are going to present the legal texts related to the establishment of the customs union with Turkey. Afterwards, we present our conclusions following the interpretation of the legal texts.

- ***Legal texts concerning medical devices and Turkey in the framework of the Customs Union***

We can apply *mutatis mutandis* the legal analysis presented above. This interpretation is confirmed by the specific articles related to notified bodies in Decision 1/06 adopted by the EC-Turkey Association Council.

Decision 1/06 of the EC-Turkey Association Council

Article 1 of Decision 1/06 of the EC-Turkey Association Council specifies the procedure for implementing Article 9 of Decision 1/95. It indicates that "The Customs Union Joint Committee established by Article 52 of Decision No 1/95 shall be competent for ascertaining that Turkey has effectively put into force the provisions of the Community instrument or instruments necessary for the elimination of technical barriers to trade in a particular product. To this end, the Customs Union Joint Committee shall adopt a statement".

Article 2 of the Decision 1/06 concerns the **notification of Turkish conformity assessment bodies:**

"1. Following the adoption of a statement as provided for in Article 1(1), Turkey shall notify the Commission and the Member States of the names and full details of any conformity assessment bodies that it has designated, specifying the subject matter and the conformity assessment procedure for which they have been designated.

2. The rules concerning the designation of conformity assessment bodies applicable to the Member States shall apply to Turkey. The Commission shall provide Turkey with detailed information on those rules and on the procedure for notifying those bodies to the Commission.

3. When the notification process has been completed, the results of the conformity assessment procedures carried out by Community bodies and by Turkish bodies shall be mutually recognised without repetition of these procedures or any additional requirements.".

Article 3 deals with obligation of Parties as regards their authorities and bodies.

Article 4 of Decision 1/06 aims to provide a procedure in case one party to the Agreement wants check the technical competence and compliance with relevant legal provisions of a notified body under the jurisdiction of the other Party or under the jurisdiction of a Member State of the Community.

Customs Union Joint Committee Statement

As it has been already stated, in 2006, a Customs Union Joint Committee Statement has been issued regarding the implementation of Article 1 of Decision 1/06 and Article 52 of Decision 1/95. It indicates that the Customs Union Joint Committee recognizes that the Turkish legislation takes over the Community *acquis* and that Turkey has put into force the provisions of the Community instruments necessary for the elimination of technical barriers to trade in the products covered by, among others, the three directives on medical devices (Council Directive 93/42/EEC of 14 June 1993, Council Directive 90/385/EEC of 20 June, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998).

- ***Following the legal texts which have been presented***

It appears that Turkey is entitled to notify notified bodies.

In addition, following Article 2(1) of the Decision 1/06 concerning the notification of Turkish conformity assessment bodies, it is possible for Turkey to notify more than one notified body.

There is no limitation concerning the use of Turkish notified body by EU manufacturers in the legal texts. Therefore, there is no reason to accept any limitation, and Member States are obliged to accept all certificates issued by Turkish notified bodies.

As a matter of consequence an EU manufacturer has to right to seek for the certification from a Turkish notified body, and Medical devices using Turkish certificate shall circulate freely around the European Union.

Conclusion

Question 3. Does Turkey have the right to appoint notified bodies?

Answer: Yes

Question 4. Can a Turkish notified body be chosen by a Member State manufacturer instead of Member States notified body?

Answer: Yes

ANNEXES

Annex 1:

Decision 1/06 of the EC-Turkey Association Council on the implementation of Article 9 of Decision No 1/95 of the EC-Turkey Association Council on implementing the final phase of the Customs Union

Annex 2:

Statement of Turkey – EC Customs Union Joint Committee on the implementation of Article 1 of Decision 1/2006