International Journal of Advanced Research in Biological Sciences
ISSN: 2348-8069
www.ijarbs.com
(A Peer Reviewed, Referred, Indexed and Open Access Journal)
DOI: 10.22192/ijarbs Coden: IJARQG (USA) Volume 9, Issue 11 -2022

Review Article

DOI: http://dx.doi.org/10.22192/ijarbs.2022.09.11.001

Are Turkish Manufacturers of Medical devices requested to Appoint European Authorized Representatives?

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Abstract

Turkey, as a large country with a population of more than 82 million and a comprehensive public and private healthcare system designed to provide accessible and equitable healthcare to every resident, the potential for any life sciences-related sector in the country can easily be described as advanced. The Turkish medical device industry has grown rapidly over the last ten years - ranking third in Central and Eastern Europe and second in MENA with a value of $2 billion. Global medical device companies are in Turkey with important production and organization activities and mostly use Turkey as a center for regional market access. The average annual growth rate of the Turkish medical device market was 17% between 2010 and 2020. With the increasing number of medical device manufacturers over the last ten years, understanding of regulatory requirements of placing medical devices in marketplace become essential; yet the European market complying with the EU Medical Device laws including MDD 93/42/EEC and the current, upcoming into force; EU-MDR 745/2017.

Method: Reviewing of the current regulations and decisions published by the EU on the official website of Europe ec.europa.eu concerning medical devices and relationship between the EU and Turkey.

Findings: **In 1999**, at the Helsinki Summit in December, the European Council gives Turkey the status of candidate country for EU membership, following the Commission's recommendation in its second Regular Report on Turkey. In December 2005, the Council has accepted the new accession partnership document for Turkey. **In 2012**, following the release of MEDDEV 2.5/10 when reference is made to the EU, this is meant to include the EEA, Switzerland and Turkey complying with **2006/646/EC: Decision No 1/2006** of the EC-Turkey Customs Cooperation Committee of 26 September 2006 laying down detailed rules for the application of **Decision No 1/95** of the EC-Turkey Association Council. **In March-2022**, following the implementation date of EU-MDR 745/2017 in May-2021 and the transition of implementation till May- 2024, European commission has published a **NOTICE TO STAKEHOLDERS "EU-TURKEY CUSTOMS UNION AGREEMENT IN THE FIELD OF MEDICAL DEVICES,"** that was clearly referring to the same regulations of 2006/646/EC: Decision No 1/2006 of the EC-Turkey Customs Cooperation Committee of 26 September 2006 laying down detailed rules for the application of Decision No 1/95 of the EC-Turkey Association Council.

Conclusion: Turkey has been recognized as a candidate country to the EU since 1999, for which number of steps were progressed in the positive agenda launched in 2012 between the EU and Turkey following decision number 1/1995, 1/1999 and finally 1/2006. One of these steps is manufacturers established in Turkey have no obligation to designate an authorized representative on the EU territory to place medical devices on the EU market.

Another is manufacturers established outside the territory of the EU or Turkey only need to designate one authorized representative, either in the EU or in Turkey, in order to place medical devices on the market in the EU or in Turkey.

Keywords: Turkish Manufacturers, Medical devices, EU or Turkey, authorized representative.

History of the European Union

The European Union, previously known as European Community [1], originated from a concept brought forth in the formation of the European Coal and Steel Community (ECSC) in 1951, shortly after World War II. On May 9, 1950, Robert Schuman, French Foreign Minister, announced a plan conceived by Jean Monnet to consolidate the coal and steel production under a single authority in an attempt to prevent future war. The idea was accepted by the other nations, Belgium, the Federal Republic of Germany, Luxembourg, the Netherlands, and Italy, with the strong encouragement of the United States. Together, these six nations formed the ECSC. With their pooled resources and management, the coal and steel trade among the six nations increased by 129% within the first five years after the establishment of the ECSC. With the risk of another world war originating from Western Europe eliminated, the six nations soon undertook to integrate their military and political structures after the success of the ECSC. However, the union was rejected by the French Parliament in 1954. Not being frustrated with the attempt, the nations moved toward integration primarily on the economic front. The landmark meeting of these nations in Messina, Italy, in June of 1955 laid the framework to establish a common market. On March 25, 1957, two treaties that established the European Economic Community (EEC) and the European Atomic Energy Community (EAEC or Euratom) were signed in Rome [2]. The treaty that established the EEC is commonly referred to as the Treaty of Rome.

The EEC sought to join the nations into a common market to eliminate obstacles in the movement of people, goods, services, and capital among the nations. The EAEC aimed at promoting the peaceful use of nuclear energy. The Rome Treaties marked the official beginning in the consolidated effort for recovery and stimulation of economic growth. The ECSC, EEC, and EAEC collectively became known as the European Communities (EC) [3]. Nine additional nations have acceded to the EC since its inception: Denmark, Ireland, and the United Kingdom in 1973; Greece in 1981; Spain and Portugal in 1986; and Austria, Finland, and Sweden in 1995 [4]. In 2004 the accession of ten countries; Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia [5]. In 2007 another enlargement was made to include Bulgaria and Romania following by the last enlargement in 2013 and accession of Croatia. With the withdrawal of Norway and the UK from the EU, the current member states of The EU are 27 member states [6].

European Union’s approach in Medical device regulation

The EU medical device law is prescribed in three Directives. The first Directive, Directive 90/385/EEC on Active Implantable Medical Devices, was published on July 20, 1990 [7]. The second Directive, Directive 93/42/EEC on Medical Devices, was published on July 12, 1993 [8]. The Medical Devices Directive has broad applicability to almost all medical devices [9] other than the active implantable medical devices, and in vitro diagnostic medical devices.

Under Medical Devices Directive, the label or outer packaging or instructions for use shall contain the name and the address of the authorized representative where the manufacturer does not have a registered place of business in the Community [10]. This regulatory requirement was comprehensively implemented by all manufacturers who are located outside The EU since the medical device directive was firstly published on 12-July-1993 [11].

The new medical devices regulations (2017/745/EU) (MDR) will replace the existing medical devices Directive (93/42/EEC) (MDD) and the active implantable medical devices Directive (90/385/EEC) (AIMDD). The MDR was published in May 2017, marking the start of a four-year period of transition from the MDD and the AIMDD. During the transitional period the MDR will come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the MDR. The transitional period will end on 26 May 2021, the "Date of Application" (DoA) of the Regulation. From that date the MDR will apply fully [12], [13].

History of EU and Turkey

Turkey was one of the first countries, in 1959, to seek close cooperation with the young European Economic Community (EEC) [14]. This cooperation was realized in the framework of an "association agreement", known as the Ankara Agreement, which was signed on 12 September 1963. An important element in this plan was establishing a "Customs Union" so that Turkey could trade goods and agricultural products with EEC countries without restrictions [15].

The main aim of the Ankara agreement was to achieve "continuous improvement in living conditions in Turkey and in the European Economic Community through accelerated economic progress and the harmonious expansion of trade, and to reduce the disparity between the Turkish economy and … the Community" [16].

Key Milestones in EU - Turkey Relations Include

1987 Turkey submits application for full membership on 14 April.

1993 The EU and Turkey Customs Union negotiations start.

1996 The Customs Union between Turkey and the EU takes effect on 1 January.

1999 At the Helsinki Summit in December, the European Council gives Turkey the status of candidate country for EU membership, following the Commission's recommendation in its second Regular Report on Turkey.

2001 The European Council adopts the EU-Turkey Accession Partnership on 8 March, providing a road map for Turkey's EU accession process. On 19 March, the Turkish Government adopts the NPAA, the National Programme for the Adoption of the Acquis (acquis means EU law), reflecting the Accession Partnership.

2001 At the Copenhagen Summit, in September, the European Council decides to increase significantly EU financial support through what is now called "pre-accession instrument" (IPA).

2004 On 17 December, the European Council decides to open membership talks with Turkey.

2005 Accession Negotiations open on 3 October.

In October 2005, the "Screening Process" which is the analytical examination of compliance with acquis has begun under 35 titles.

In December 2005, the Council has accepted the new accession partnership document for Turkey.

In September 2006, the Council has issued decision 1/2006 OF THE EC-TURKEY CUSTOMS COOPERATION COMMITTEE.

In January 2012, European Commission DG Health and Consumer, has drafted a guideline for medical devices "GUIDELINE FOR AUTHORIZED REPRESENTATIVES MEDDEV 2.5/10 January-2012"; answering questions related to application of EC-Directive on medical devices.

In May-2017, Publishing of New regulations of Medical Devices MDR 2017/745,

In March-2022, At Brussels, European Commission has published "NOTICE TO STAKEHOLDERS; EUTURKEY CUSTOMS

UNION AGREEMENT IN THE FIELD OF MEDICAL DEVICES"

Conclusion

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[8] Council Directive 93/42/EEC, 1993 O.J. (L 169) 1, (amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 L 247).

[9] Council Directive 93/42/EEC, article 1 paragraph 1 and 2, 1993 O.J. (L 169); definition of a "medical device"

[10] MEDDEV 2.5/10 issued on January-2012 "GUIDELINE FOR AUTHORISED REPRESENTATIVES"

[11] Council Directive 93/42/EEC, as commonly called Medical Device Directive MDD, annex I, section 13.3a.

[12] https://health.ec.europa.eu/system/files/2020-09/md_manufacturers_factsheet_en_0.pd, ©European Union, [2020] Reuse is authorised provided the source is acknowledged. The reuse policy of European Commission documents is regulated by Decision 2011/833/EU (OJ L 330, 14.12.2011, p. 39). Funded under the Third EU Health Programme ISBN: 978-92-79-89702-3 DOI: 10.2873/66341

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Website: www.ijarbs.com

Subject: Medical Devices Regulations

Quick Response Code

DOI:10.22192/ijarbs.2022.09.11.001

How to cite this article:
Mohamed REDA, Lama Al Shallah, Aysu Uluöz, Melda Ulaşer Köktürk. (2022). Are Turkish Manufacturers of Medical devices requested to Appoint European Authorized Representatives?. Int. J. Adv. Res. Biol. Sci. 9(11): 1-5.
DOI: http://dx.doi.org/10.22192/ijarbs.2022.09.11.001