IV ABILITY TO ASSUME THE OBLIGATIONS OF MEMBERSHIP

CHAPTER 1 FREE MOVEMENT OF GOODS

Priority 1.1 Abolishment of import permits or licence requirements, as well as disproportionate requirements for certificates in respect of products other than used motor vehicles

1 Schedule of legislative alignment

Table 1.1.1

No	EU legislation in force	Draft Turkish legislation	Scope	Institution in charge	Publication date
1	EC Agreement, Article 28	Amendment to the Communiqué No. 2007/6 on Products Which Can Only be Imported With a Guarantee Certificate.	Abolishment of the requirement of import licences for the import of goods in free movement gradually until 2013 in the framework of the obligations originating from the Customs Union.	Ministry of Industry and Trade Undersecretariat for Foreign Trade	2009 [1]
2	EC Treaty, Article 28	Communiqué No.2008/13 on Imports of Some Materials which Affects Safety at Work and Health of Workers	Abolishment of the requirement of import licences for the import of goods in free movement in the framework of the obligations originating from the Customs Union,	Ministry of Labour and Social Security	After 2011

2 Schedule of institutional capacity building requirements necessary for legislative approximation and implementation

No institutional capacity building requirement is envisaged under this priority at this stage.

3 Financial requirements and resources

No financial requirement is envisaged under this priority at this stage.

[1] Gradual alignment has been started by 1 January 2008 and the practice is aimed to be gradually annulled until 2013.

Priority 1.2 Submission to the Commission a plan for abolishing import permits on used motor vehicles

1 Schedule of legislative alignment

Table 1.2.1

No	EU legislation in force	Draft Turkish legislation	Scope	Institution in charge	Publication date
1		Performing an Assessment for the Used Motor Vehicles in the Article 7 of Import Regime	Assessment of abolishing the import permits on used motor vehicles	Undersecretariat for Foreign Trade	To be considered for the period after 2011 in the framework of impact analysis.

2 Schedule of institutional capacity building requirements necessary for legislative approximation and implementation

No institutional capacity building requirement is envisaged under this priority at this stage.

3 Financial requirements and resources

No financial requirement is envisaged under this priority at this stage.

Priority 1.3 Completing the identification of measures contrary to Articles 28 to 30 of the EC Treaty, drawing up a plan for their removal and introducing the mutual recognition clause into the Turkish legal order

1 Schedule of legislative alignment

Table 1.3.1

No	EU legislation in force	Draft Turkish legislation	Scope	Institution in charge	Publication date
1	Communication No. 2003/C 265/02 Decision No. 3052/95/AT	Implementing Regulation of the Council of Ministries on Mutual Recognition in the Non-harmonized Area	In the interpretative communication dated 4 November 2003, the European Commission declared that, in the non-harmonized area, the Turkish products would also be subjected to the same treatment with the products of any EU Member State origin, and demanded that, in principle, products manufactured in Turkey or products put in free movement in Turkey despite they are of third country origin should not be subject to checks at the Community customs. In this framework; laying down the procedures and principles for the incorporation of the mutual recognition clause in the national technical regulations in order to ensure free movement of goods in the non-harmonized area between Turkey and the EU, and for the notification of national measures, which prevent the free movement of goods between Turkey and the EU.	Undersecretariat for Foreign Trade	2009

2 Schedule of institutional capacity building requirements necessary for legislative approximation and implementation

No institutional capacity building requirement is envisaged under this priority at this stage.

3 Financial requirements and resources

No financial requirement is envisaged under this priority at this stage.

Priority 1.4 Addressing the remaining issue on regulatory data protection for pharmaceutical products

1 Schedule of legislative alignment

Table 1.4.1

No	EU legislation in force	Draft Turkish legislation	Scope	Institution in charge	Publication date
1	Directive No. 2004/27/EC	Amendment to Implementing Regulation on the Authorization of Medicinal Products for Human Use	Alignment of data exclusivity, which is currently being implemented in accordance with the Directive No 2001/83/EC, with the data exclusivity provisions of Directive No. 2004/27/EC	Ministry of Health	To be enacted within the framework of full membership perspective
2	Directive No. 2004/24/EC	Implementing Regulation on Simplified Licensing of Traditional Herbal Medicinal Products	Surveillance of traditional use and prevention of adverse effects on public health through identifying the products of which traditional use is supported bibliographically or by expert proofs according to their content in which one or more of the active substances is combined with one or more preparates or one or more this kind of herbal preparates	Ministry of Health	2009
3	Directive No. 2001/83/EC	Implementing Regulation on the Storage and Wholesale Distribution of Medicinal products	Laying down the procedures and principles regarding purchase, sale, storage, shipment and distribution of social medicine products licensed/permitted to protect social health or veterinary medical products used in veterinary medicine, and the procedures and principles for the conduct of such operations under appropriate conditions in order to ensure the provision of these products safely and at the desired quality, and withdrawal of false and spoiled products from the market when necessary.	Ministry of Health	2009
4	Directive No. 2001/83/EC	Law Amending Medicinal and Pharmaceutical Products Law No. 1262	Permission of publicity of out-of-prescription medicinal products for human use.	Ministry of Health	To be enacted within the framework of full membership perspective

Table 1.4.1 (Continued)

No	EU legislation in force	Draft Turkish legislation	Scope	Institution in charge	Publication date
5	Regulation No. 141/2000	Implementing Regulation on Orphan Drugs	Within the scope that patients suffering from illnesses arising from rare conditions that have right to be treated on equal conditions with other patients and therefore medicine industry should search, develop and introduce to the market drugs necessary for those rare illnesses; identifying procedures and principles for licensing of orphan drugs designed for diagnosis, prevention and treatment of a condition which threatens the life or weakens the patient chronically; or in case that the drug is designed for diagnosis, prevention and treatment of a serious and chronic condition which threatens the life or weakens the patient chronically but marketing the medical product can not produce enough profit to compensate the cost of investment without any incentive.	Ministry of Health	To be enacted within the framework of full membership perspective
6	Regulation No. 847/2000	Implementing Regulation on the Specification and Application of Criteria for Identifying a Medicinal Product as Orphan Drug, and Definitions of "Similar Medicinal Product" and "Clinically Superior"	Specification of drugs used for diagnosis, prevention and treatment of rare diseases and conditions; classifying them according to the cost of production and prevalence; determining the responsibility for using the terms of "equivalent" and "clinically superior" in terms of production and consumption; and prompting manufacturers to develop these kind of drugs and introduce to the market.	Ministry of Health	To be enacted within the framework of full membership perspective

2 Schedule of institutional capacity building requirements necessary for legislative approximation and implementation

Table 1.4.2

No	Requirements	Year
(Ministry of Health)		
1	Institutional capacity building by establishment of Turkish National Pharmaceuticals and Medical Device Institution	2009-2013

3 Financial requirements and resources

Table 1.4.3 **(Euro)**

Requirements (Ministry of Health)	Year	National Budget	EU sources	Other	Total
I- Investment					
Computer Network	2009-2013	10,000	30,000		**40,000**
Software (setting up a database, supplying MedDRA terminology and ensuring its sustainability, providing Micromedex and other periodical literature)	2009-2013	10,000	30,000		**40,000**
Establishment and Sustainability of Vigibase online	2009-2013	425	1,275		**1,700**
LEC Network	2009-2013	10,000	30,000		**40,000**
Software (intended for database)	2009-2013	7,500	22,500		**30,000**
II- Legislative approximation and implementation					
- Personnel					
- Training					
Training, internship and attending international meetings on pharmacovigilance	2009-2013	30,000	145,000		**175,000**
Training, internship and attending international meetings on certification of pharmaceuticals	2009-2013	15,000	15,000		**30,000**
Training, internship and attending international meetings on quality control of pharmaceuticals	2009-2013	50,000	250,000		**300,000**
Training, internship and attending international meetings on clinical trials of pharmaceuticals	2009-2013	50,000	50,000		**100,000**
- Consultancy					
Expertise	2009-2013		25,000		**25,000**

Table 1.4.3 (Continued) **(Euro)**

Requirements (Ministry of Health)	Year	National Budget	EU sources	Other	Total
- Translation					
Translation and publication of WHO books and booklets on drug safety	2009-2013	10,000			**10,000**
Translation of ICH and EU guidelines	2009-2013		35,000		**35,000**
- Other					
Reference books	2009-2013		5,000		**5,000**
Total		**192,925**	**638,775**		**831,700**