COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.10.2009
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2009/0155 (ACC)

Proposal for a

COUNCIL DECISION

on the conclusion of an additional Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, and the State of Israel on an Agreement between the European Community and the state of Israel on Conformity Assessment and Acceptance of Industrial Products (ACAA)

EXPLANATORY MEMORANDUM

I. THE PROTOCOL

1. BACKGROUND

Article 2.3.1.4: *Facilitate market access of industrial products*, of the European Neighbourhood Action Plan between the EU and Israel commits the Parties to "accelerate progress towards bilateral negotiations leading to an ACAA, taking into account the specific nature of the Israeli economy and building upon the Palermo Action Plan".

On the basis of the above, and negotiating directives included in the specific decision of the Council of 21 September1992 authorizing the Commission to negotiate agreements between the European Economic Community and certain third countries on mutual recognition relating to conformity assessment, as amended by the specific decisions adopted by the Council on 26 May 1997 and on 8 July 2002, the Commission has negotiated and initialled an additional Protocol to the Euro-Mediterranean Agreement with Israel on Conformity Assessment and Acceptance of industrial products (hereinafter referred to as "the Protocol").

The text of the Protocol is attached to this Memorandum. The Commission proposes that the Council authorises the signature of the additional Protocol to the Euro-Mediterranean Agreement on behalf of the Community.

2. ASSESSMENT OF THE PROTOCOL

The Protocol follows the general principles laid down in the Commission's Communication on Community External Trade Policy in the field of standards and conformity assessment (COM(96) 564 final. of 13.11.1996).

It has been decided, in consultation with the 133 Committee, to adopt this agreement as a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, signed on 20 November 1995 (OJ L 147, 21.06.2000, p.3) rather than as a stand alone Agreement.

The ACAA provides for an extension of certain benefits of the Internal Market in sectors already aligned. The ACAA thus facilitates market access by eliminating technical barriers to trade with respect to industrial products. Each ACAA consists of a framework agreement and one or more annexes, setting out the products covered, and the means adopted to extend the benefit of trade in that sector.

To this end, the ACAA provides for two mechanisms, first, for the recognition of equivalence in technical regulation, standardization and conformity assessment for industrial products subject to equivalent regulation in Community law and the national law of the partner country, and second, for the mutual acceptance of industrial products that fulfil the requirements to be lawfully placed on the market in one of the Parties.

Under the first mechanism, mutual recognition of products operates on the basis of the *acquis communautaire* that has been transposed by the partner country, in the same way as it would apply to products placed on the market of a Member State. It allows industrial products covered by it and attested as compliant according to the procedures of the European Union to

be placed on the Israeli market without having to undergo any further approval procedures, and *vice versa*. At present one sector is included: good manufacturing practice (GMP) for pharmaceutical products. Israel has taken over the Community technical legislation in the sector covered by the Annex to the Protocol and participates in the European organisations in the sector covered by it.

The second mechanism, i.e., the mutual acceptance of industrial products not commonly regulated, confirms that Articles 16 and 17 of the Euro-Mediterranean Agreement with Israel apply without other restriction in the product sectors covered by it. That is, Annexes applying this mechanism will provide that where no European technical regulations exist, industrial products listed under such Annexes lawfully traded in the market of either Party (i.e., on the territory of Israel or that of one of the Member States of the EU) may be lawfully traded in the other. No annexes making this mechanism operational are at present included.

3. THE FRAMEWORK AGREEMENT

Article 1: Purpose and means. This article establishes the purpose of the ACAA, namely the elimination of technical barriers to trade in respect to industrial products. The ACAA provides for two mechanisms, as described above.

Article 2: Definitions. This is self-explanatory.

Article 3: Alignment of legislation. This contains a commitment for Israel to take appropriate measures to take over and maintain measures to align with and maintain Community law, as it applies to products covered by the Agreement. For New Approach sectors (which will be explicitly identified as such in the Annexes that relate to them) there is also an obligation on Israel to maintain relevant transposed standards, in the same way as a Member State of the EU.

Article 4: Infrastructure. This commits Israel to establish and maintain a quality infrastructure equivalent to that of the EU for sectors covered by the Protocol.

Article 5: Mutual acceptance of industrial products. The principles of the two mechanisms underlying the mutual acceptance of products onto the market of the other Party, as described above, are detailed in this Article. There is also a provision that, unless otherwise agreed, the ACAA does not entail any obligation, for one Party, to accept product attested as compliant by bodies other than those of the Parties.

Article 6: Safeguard clause. This sets up the right of each Party to deny market access when that Party is able to demonstrate that a product might endanger legitimate concerns covered by legislation applicable to the products covered by an Annex (mainly to do with safety or public health). The Annexes will provide for the detailed procedures to be used in such cases.

Article 7: Extension of coverage. This sets out that the Parties may modify the scope and coverage of this Protocol through amendment of the Annexes or by the addition of new ones.

Article 8: Obligations of Parties as regards their Responsible Authorities and Notified Bodies. This article obliges the Parties to ensure that their reponsible authorities monitor the technical competence and compliance of their respective notified bodies and have power and expertise for designating, suspending, and withdrawing such bodies. In addition, it obliges the Parties to ensure that their notified bodies comply with the requirements of Community and

aligned national law, and maintain their technical competence to carry out the tasks for which they have been notified.

Article 9: Notified bodies. This describes the procedure for the notification of bodies to assess conformity in relation to the legal requirements specified in the corresponding annexes. The procedure is similar to the one applied within the Community. It also sets out the procedure for the withdrawal of notified bodies.

Article 10: Verification of notified bodies. This article gives the right to one Party to request a verification of a body notified by the other Party. The verification may be done either by the authorities which have designated the body or together by the authorities of both Parties. The notified body would be suspended until a final decision is taken.

Article 11: Exchange of information. This transparency provision ensures uniform application and interpretation of the Protocol. It also provides for the Parties to encourage their notified bodies to co-operate to establish mutual recognition agreements in the voluntary sphere.

Article 12: Confidentiality. This standard provision prohibits disclosing information acquired under this Protocol.

Article 13: Management of the Agreement. This article provides that the Committee (defined in Art. 2 as the Association Committee set up under the Association Agreement, or any working group (subcommittee "Industry, trade and services") set up and designated for trade purposes under Article 73 of the Association Agreement) shall manage the Agreement, including adding and amending Annexes, appointing experts for verifications, considering new arrangements, and resolving questions related to the Protocol. It also provides for ultimate recourse to the disputes settlement procedure set out in Article 75 of the Association Agreement.

Article 14: Technical co-operation and assistance. This confirms the Community policy on technical co-operation and assistance with a view to properly implementing this Protocol.

Article 15: Agreements with other countries. Provides that the agreement can be extended to other countries by explicit agreement, and encourages - but does not force - Israel to make agreements similar to the Protocol, and covering the same products, that the EU might make with another country.

Article 16: Entry into force. A standard provision that provides the arrangement for the entry into force.

Article 18: Status of the Agreement. A standard provision establishing the status of the different language versions of the text.

4. THE ANNEXES

4.1 Annex on Mutual Acceptance of Industrial Products

There is one Annex, covering good manufacturing practice (GMP) for pharmaceutical products. It operates by the mechanism described above whereby mutual recognition of products operates on the basis of the *acquis communautaire* that has been transposed by Israel.

Coverage is determined by the relevant Community or Israeli national law, which will be notified by each Party to the other under *Section I*.

Section II deals with the scope. It lists the coverage and exclusions, and provides for an exchange of letters listing types of products to be covered. It also specifies that it applies to products covered by it irrespective of their origin. The ACAA will cover good manufacturing practice (GMP) for all products in the pharmaceutical field, with the exception of advanced therapy products, special medicinal products based on tissues and cells of human origin, and medicinal products that include blood products. The inclusion of these fields may be agreed between the Parties if the Israeli legislation governing them is brought into alignment.

Section III states that the Parties shall notify the identity of their responsible authorities to each other. Responsible Authorities are responsible for the GMP cetification process in the Parties (Notified Bodies are not relevant to GMP).

Section IV provides for the specific arrangements for these products. Clause 1 provides definitions. Clause 2 describes the mutual obligations of the Parties, to recognise the conclusions of compliance of manufacturers and importers with EU GMP and its Israeli equivalent. Clause 3 provides for an exchange of information on the authorisation status of manufacturers and importers and on the outcome of inspections. Clause 4 provides for an exchange of inspection reports. Clause 5 deals with the exchange of laboratory testing on reasoned request. Clause 6 makes similar provisions for exchange of information on batch release of products. Clause 7 fixes the format for information exchange. Clause 8 provides a safeguard mechanism, giving either Party the right to ask for a full inspection or testing report. Clause 9 commits Israel to participate in the Community alert system. Clause 10 provides for information exchange. Clause 11 provides for the notification of contact points who will monitor the implementation and operation of the Annex.

4.2 Annexes on Mutual Acceptance of Industrial Products no commonly regulated

No such annexes have been negotiated for the moment. The ACAA provides nevertheless the basis for such acceptance of products.

5. RELATIONS WITH EFTA /EEA MEMBER COUNTRIES

In accordance with the information and consultation procedures set out in the European Economic Area-Agreement and Protocol 12 of that Agreement, the Commission has informed EFTA/EEA Member Countries on the progress of the negotiations and the final result.

6. IMPACT

The Commission considers that the proposed ACAA creates an acceptable balance of benefits for all parties. In the sector covered the Community has secured effective market access in terms of access to procedures of the other party. The ACAA confirms that Israel has taken over the Community legislation. Commercial benefits will be achieved with the ACAA.

The Protocol will allow Community exporters, if they so choose, to test and certify their industrial products to the same (aligned) requirements prior to export, and then access that market without any further conformity assessment requirements. The certification procedures will only need to be carried out one time for both markets and against the same aligned

requirements or standards. The recognition of certification will permit savings and stimulate exports.

It has not always been possible to quantify the costs or time taken to obtain batch clearance for pharmaceutical products in Israel. The precise extent of savings in time, cost and market opportunity of this Protocol is therefore not feasible in every case to determine. This may only be possible once the Protocol has been in operation for some time.

See table I, attached, for figures for trade in pharmaceutical products between Israel and the EU. They have been supplied by the European Federation of Pharmaceutical Industries and Associations (EFPIA). It will be noted that the total trade in such products between the Parties to the proposed ACAA amounted in 2007 to close to €1bn.

In fact, most benefits are clearly not quantifiable, such as reduced time for accessing markets, better predictability, less protectionism, and harmonisation of systems. What can be ascertained is that any agreement provides reciprocal levels of market access, in terms of conformity assessment.

In terms of the benefits to Israel, the ACAA will facilitate access to the Community market. Israel regards the ACAA as a means to develop closer industrial relations with the EU and fully to integrate certain sectors with the Single Market.

Table I. Trade in pharmaceutical products between EU and Israel, the West Bank and Gaza

Notes.

1. "Imports" denotes imports from Israel, the West Bank and Gaza to the EU-27 for the period stated. "Exports" denotes exports from the EU-27 to Israel, the West Bank and Gaza for the period stated.

2. Amounts are given in millions of Euro.

3. The full point is used as the decimal marker.

4. Source: EFPIA.

Part 1 of 2: 2000 and 2005

PRODUCT	2000		Trade Balance	2005		Trade Balance
	Import	Export		Import	Export	
2936 - Provitamins	7.371	6.679	-691	7.796	2.697	-5.099
2937 - Hormones	467	1.517	1.050	3.008	3.173	166
2938 - Heterosides	1.728	121	-1.607	1.129	256	-873
2939 - Alkaloids	3.806	1.075	-2.732	512	955	444
2941 - Antibiotics	1.278	7.552	6.274	8.735	19.696	10.962
3001 - Pharmaceutical Products	2	1.260	1.258	20	159	140
3002 - Pharmaceutical Products	348.092	38.732	-309.359	134.778	52.921	-81.858
3003 - Pharmaceutical Products	1.925	17.192	15.268	122.469	8.278	-114.191
3004 - Pharmaceutical Products	45.949	275.486	229.537	230.340	321.602	91.261
3005 - Pharmaceutical Products	5.283	5.378	96	6.172	3.501	-2.671
3006 - Pharmaceutical Products	4.092	9.571	5.478	4.868	22.160	17.292
Total (2936-3006)	**419.992**	**364.563**	**-55.429**	**519.826**	**435.399**	**-84.428**
Total (3001-3006)	**405.342**	**347.620**	**-57.723**	**498.648**	**408.621**	**-90.027**

Table I continued

Part 2 of 2: 2007

PRODUCT	2007		Trade Balance
	Import	Export	
2936 - Provitamins	5.735	4.609	-1.126
2937 - Hormones	1.075	1.474	399
2938 - Heterosides	149	300	152
2939 - Alkaloids	5.180	1.418	-3.762
2941 - Antibiotics	1.242	6.959	5.717
3001 - Pharmaceutical Products	54	340	286
3002 - Pharmaceutical Products	8.465	53.419	44.954
3003 - Pharmaceutical Products	68.847	12.338	-56.509
3004 - Pharmaceutical Products	400.290	344.611	-55.679
3005 - Pharmaceutical Products	4.463	5.025	562
3006 - Pharmaceutical Products	5.483	27.137	21.654
Total (2936-3006)	**500.982**	**457.632**	**-43.350**
Total (3001-3006)	**487.602**	**442.871**	**-44.731**

II. THE DRAFT COUNCIL DECISION

A proposal for a Council Decision is attached.

It is concerned with the signature and adoption of the ACAA. Signature is required by Israel for the adoption of this Protocol. It is accordingly proposed that the President of the Council be authorised to designate the person empowered to sign the Protocol on behalf of the Community, on the basis of Articles 133 and 300 of the Treaty. In this context, the Council should, in line with previous Council Decisions on the conclusion of ACAAs and mutual recognition agreements, establish the appropriate Community procedures for the implementation and management of the Protocol.

In particular, the Council should confer on the Commission, in consultation with the special committee appointed by the Council, the necessary powers for the management and implementation of the Protocol. Moreover, the Council should delegate to the Commission, acting in consultation with the special committee, the necessary powers to determine the Community position with regard to this Protocol in the Association Committee, or, where the Association Council has in accordance with Article 73 of the Association Agreement delegated powers to a working group designated to cover trade issues, in that working group.

The delegation of powers to the Commission includes delegation of the power to add –after appropriate consultation with Member States in the framework of the 133 Committee- new Annexes, since, as indicated in the Preamble, the commitments in the Euro-Mediterranean Agreement include the use of best endeavours to approximate the laws of the Parties.

The Commission therefore proposes that the Council adopt the attached Decision on the signature and conclusion of the ACAA.

2009/0155 (ACC)

Proposal for a

COUNCIL DECISION

on the conclusion of an additional Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States and the State of Israel on an Agreement between the European Community and the state of Israel on Conformity Assessment and Acceptance of Industrial Products (ACAA)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 in conjunction the first sentence of the first subparagraph of Article 300(2) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel of the other part (hereinafter "the Association Agreement"),[1] entered into force on 20 November 1995;

(2) Article 47 of the Association Agreement provides, where appropriate, for the conclusion of a European conformity assessment agreement, and Article 55 of the same Agreement provides for the use of best endeavours to approximate the laws of the Parties;

(3) The Protocol to the Association Agreement on Conformity Assessment and Acceptance of Industrial Products (hereinafter "the Protocol") initialled in Brussels on 24 June 2009 should be signed;

(4) Article 70(2) of the Association Agreement provides that the Association Council may delegate to the Association Committee any of its powers, and Article 73 provides that the Association Council may decide to set up any working group or body necessary for the implementation of the Agreement;

(5) The appropriate internal procedures should be established to ensure the proper functioning of the Protocol;

[1] OJ L 147, 21.6.2000, p. 3.

(6) It is necessary to empower the Commission to make technical amendments to this Protocol and to take decisions for its implementation;

HAS DECIDED AS FOLLOWS:

Article 1

The Protocol to the Euro-Mediterranean Agreement with the State of Israel on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as "the Protocol"), is hereby approved on behalf of the European Community.

The text of the Protocol is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person empowered to sign the Protocol, on behalf of the Community. The President of the Council shall, on behalf of the Community, transmit the diplomatic note provided for in Article 16 of the Protocol.

Article 3

1. The Commission, after consultation with the special committee appointed by the Council, shall:

   (a) carry into effect the information, co-operation, notification, amendment, verification and management functions provided for in Articles 6, 7, 8, 9, 10, 11, 13, 14 and 15 of the Protocol;

   (b) carry into effect the information, co-operation, notification, amendment, verification and management functions provided for in the Annexes to the Protocol;

   (c) if necessary, reply to requests in accordance with the Annexes to the Protocol.

2. The position to be taken by the Community with regard to the Protocol in the Association Committee and, where applicable, in a body set up by the Association Council under Article 73 of the Association Agreement and designated to cover trade issues, shall be determined by the Commission, following consultation of the special committee referred to in paragraph 1 of this Article.

Done at Brussels,

For the Council
The President

PROTOCOL TO THE EURO-MEDITERRANEAN AGREEMENT ESTABLISHING AN ASSOCIATION BETWEEN THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES, OF THE ONE PART, AND THE STATE OF ISRAEL, OF THE OTHER PART, ON AN AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE STATE OF ISRAEL ON CONFORMITY ASSESSMENT AND ACCEPTANCE OF INDUSTRIAL PRODUCTS (ACAA)

THE EUROPEAN COMMUNITY

AND

THE STATE OF ISRAEL

Hereinafter referred to as “Israel”

Both together referred to as “the Parties”,

WHEREAS Israel is a party to the EURO-MEDITERRANEAN AGREEMENT ESTABLISHING AN ASSOCIATION BETWEEN THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES, OF THE ONE PART, AND THE STATE OF ISRAEL, OF THE OTHER PART, Hereinafter referred to as “the Association Agreement”[2],

RECOGNISING that the adoption and implementation of relevant Community law by Israel provides the opportunity to extend certain benefits of the internal market and to ensure its effective operation in certain sectors,

CONSIDERING that, in the sectors covered by this Agreement, Israel's national law is substantially aligned with relevant Community law,

CONSIDERING their shared commitment to the principles of free movement of goods and to promoting product quality, so as to ensure the health and safety of their citizens and the protection of the environment, including through technical assistance and other forms of cooperation between them,

DESIRING to conclude as a Protocol to the Association Agreement an Agreement on Conformity Assessment and Acceptance of Industrial Products (hereafter referred to as “this Agreement”) providing for the application of the mutual acceptance of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties, including where appropriate the mutual recognition of the results of obligatory conformity assessment of industrial products, noting that Article 47 of the Association Agreement provides, where appropriate, for the conclusion of a European conformity assessment agreement and that Article 55 of the same Agreement provides for the use of best endeavours to approximate the laws of the Parties,

NOTING the close relationship between the European Union and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel European Conformity Assessment Agreement between Israel and these countries equivalent to this Agreement,

BEARING IN MIND the Parties’ status as Contracting Parties to the Agreement establishing the World Trade Organisation, and conscious in particular of their rights and obligations under the World Trade Organisation Agreement on Technical Barriers to Trade,

HAVE AGREED AS FOLLOWS:

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[2] OJ L 147 of 21.6.2000, p. 3 and “Kitvei Amana” (Israel Official Publication Journal), 1034.

Article 1

Purpose and means

1. The purpose of this Agreement is to facilitate the elimination by the Parties of technical barriers to trade in respect of certain industrial products, listed in the Annexes to this Agreement, which form an integral part of this Agreement.

2. The means to this end are:

   (a) the adoption and implementation by Israel of national technical regulations, standards and conformity assessment procedures which are equivalent to those of relevant Community law;

   (b) the implementation by Israel of a regulatory and technical infrastructure which is equivalent to that in place in the Member States of the European Union;

   (c) the mutual acceptance on their markets by both Parties of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties, including where appropriate the mutual recognition of the results of obligatory conformity assessment of industrial products subject to relevant Community law and to the equivalent Israeli national law.

   (d) the acceptance on their markets by both Parties of industrial products which fulfil the requirements for being lawfully placed on the market in Israel and any one of the Member States of the European Union, on conditions analogous to those applying to trade in goods between the Member States of the European Union.

Article 2

Definitions

For the purpose of this Agreement,

(a) "Industrial products" means products, as defined by the scope of the Annexes to the present Agreement;

(b) "Relevant Community law" means any legal act and implementing practice of the European Union applicable to a particular situation, risk or category of industrial products, referenced in the Annexes to this Agreement;

(c) "National law" means any legal act and implementing practice by which Israel has aligned its legislation with relevant Community law applicable to a particular situation, risk or category of industrial products;

(d) "Responsible Authority" means a body under the jurisdiction of one of the Member States of the European Union or of Israel which is responsible for the effective implementation of

Community and national law in a specified industrial sector, and which where appropriate has the responsibility for notifying Notified Bodies;

(e) "Notified Body" means a body notified, by a Responsible Authority under the respective jurisdiction of one of the Parties to this Agreement, to the other Party, as competent to assess conformity in relation to requirements of Community or national law.

(f) "Committee" means the Association Committee set up under Article 70 of the Association Agreement or a body set up by the Association Council under Article 73 of the Association Agreement and designated to cover trade issues.

The terms used in this Agreement shall have the meaning given in relevant Community law and Israel's national law.

Article 3

Alignment of legislation

For the purpose of this Agreement, Israel agrees to take appropriate measures, in consultation with the European Commission, to align with and maintain relevant Community law as it applies to the placing on the market of products covered by this Agreement,

In sectors covered by this Agreement where relevant Community law is based upon the use of technical standards giving presumption of conformity with essential safety requirements (known as "New Approach" sectors) Israel agrees to take appropriate measures, in consultation with the European Commission, to align with and maintain relevant Community practice in the fields of standardisation, metrology, accreditation, conformity assessment, market surveillance, general safety of products, and producers' liability. "New Approach" sectors are indicated as such in the Sectoral Annexes.

Article 4

Technical infrastructure

For the purpose of this Agreement, Israel agrees to take appropriate measures, in consultation with the European Commission, to establish and maintain appropriate Responsible Authorities in accordance with Article 9.

In sectors covered by this Agreement where relevant Community law is based upon the use of technical standards giving presumption of conformity with essential safety requirements (known as "New Approach" sectors) Israel agrees to establish and maintain bodies that are capable of sustaining the functions of standardisation, metrology, accreditation, market surveillance, assessment of general safety of products, and assessment and enforcement of producer liability on its territory at a level broadly equivalent to those in place in the Member States of the Union.

Article 5

Mutual acceptance of industrial products including their conformity assessment

1. The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the Annexes on Acceptance of Regulated Products, fulfilling the requirements for being lawfully placed on the market of a Party, may be placed on the market of the other party, if, in particular, they fulfil:

   (a) the requirements of applicable legislative provisions related to the location in either of the Parties of the persons responsible for placing of products on the market; and

   (b) where appropriate, applicable provisions related to the location of the bodies that are responsible for assessing compliance.

2 The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the Annexes on Acceptance of Products Not Commonly Regulated, and for which no European technical regulations exist, may be traded between Israel and the European Union on the basis that a product lawfully traded in the market of Israel or of one of the Member States of the EU may be lawfully traded upon that of the other Party to this Agreement.

3. Where products are subject to obligatory conformity assessment procedures to be carried out in accordance with the Community and national laws listed in the Annexes, the Parties further agree to recognise the results of such procedures without requiring them to be repeated, nor with the imposition of any additional requirements for the purposes of accepting such conformity assessment.

4 Notwithstanding Paragraphs 5.1, 5.2 and 5.3, neither Party shall be obliged to accept products on to its market that have been lawfully placed on the market of the other Party as a consequence of an agreement similar in effect to this Agreement between either Party and a third country or party, or by virtue of a unilateral concession by either Party to a third country or party.

Article 6

Safeguard clause

Where a Party finds that an industrial product placed on the market on its territory by virtue of this Agreement, and used in accordance with its intended use, may compromise the safety or health of users or other persons, or any other legitimate concern protected by legislation identified in the Annexes, it may take appropriate measures to withdraw such a product from the market, to prohibit its placing on the market, putting into service or use, or to restrict its free movement.

The Annexes shall provide for the procedure to be applied in such cases.

Article 7

Extension of coverage

If Israel adopts and implements further national law aligning with relevant Community law, the Parties may amend the Annexes or conclude new ones, in accordance with the procedure laid down in Article 13.

Article 8

Obligations of Parties as regards their Responsible Authorities and Notified Bodies

1. (a) The Parties shall ensure that Responsible Authorities under their jurisdiction which are responsible for the effective implementation of Community and national law shall continuously apply it. Further, they shall ensure that these Responsible Authorities are able to ensure the conformity of industrial products with Community or national law or to require their withdrawal from the market and, where appropriate, to notify, suspend, remove suspension and withdraw the notification of Notified Bodies.

   (b) The Parties shall notify each other of the names and addresses of their Responsible Authorities, and shall maintain a list of such bodies.

2. (a) The Parties shall ensure that Notified Bodies, notified under their respective jurisdiction to assess conformity in relation to requirements of Community or national law specified in the Annexes, continuously comply with the requirements of such Community or national law. Further, they shall take all necessary steps to ensure that such notified bodies maintain the necessary competence to carry out the tasks for which they are notified.

   (b) The Parties shall notify each other of the names and addresses of their Notified Bodies, and shall maintain a list of such bodies.

Article 9

Procedures for the recognition of Responsible Authorities and the notification of Notified Bodies

1. The following procedure shall apply for the recognition of Responsible Authorities which are responsible for the effective implementation of Community and national law, to ensure the conformity of industrial products with Community or national law or to require their withdrawal from the market and, where appropriate, are able to notify, suspend, remove suspension and withdraw the notification of Notified Bodies:

   (a) a Party shall forward its nomination to the other Party in writing, stating the territory and title of the Annex to this Agreement under which the Responsible Authority is competent to carry out the tasks listed in Article 8.1, including as appropriate any limitations to such competence within the territory or the scope of the Annex;

(b) on the acknowledgement of the other Party, given in writing, the Responsible Authority shall be considered as competent to carry out the tasks listed in Article 8.1 in relation to the Annexes for which it has been recognised from that date.

2. The following procedure shall apply for the notification of Notified Bodies to assess conformity in relation to the requirements of Community or national law specified in the Annexes:

(a) a Party shall forward its notification to the other Party in writing, stating the title of the Annex to this Agreement under which the Notified Body is competent to assess conformity, and as appropriate any limitations to such competence within the scope of the Annex;

(b) on the acknowledgement of the other Party, given in writing, the body shall be considered as notified and as competent to assess conformity in relation to the said requirements specified in the Annexes from that date.

3. If a Party decides to withdraw the notification of a Notified Body under its jurisdiction, it shall inform the other Party in writing. The Notified Body will cease to assess conformity in relation to the said requirements specified in the Annexes from the date of its withdrawal at the latest. Nevertheless, conformity assessment carried out before that date shall remain valid, unless otherwise decided by the Committee.

Article 10

Verification of notified bodies

1. Each Party may request the other Party to verify the technical competence and compliance of a notified body, or a candidate notified body, under its jurisdiction. Such request shall be justified, in an objective and reasoned manner, in order to allow the Party responsible for the notification to carry out the requested verification and report speedily to the other Party. The Parties may also jointly examine the body, with the participation of the relevant responsible authorities. To this end, the Parties shall ensure the full cooperation of bodies under their jurisdiction. The Parties shall take all appropriate steps, and use whatever available means may be necessary, with a view to resolving any problems which are detected.

2. If the problems cannot be resolved to the satisfaction of both Parties, they may notify the Committee of their disagreement, giving (a) the reasons for the request supported by relevant evidence to verify the technical competence and compliance of the notified body; (b) the reasons why the problems cannot be resolved to the satisfaction of both Parties and (c) evidence showing there exists an imminent and real threat to human health and safety when relevant. The Committee may decide on appropriate action.

3. Unless and until decided otherwise by the Committee, the notification of the body and the recognition of its competence to assess conformity in relation to the requirements of

Community or national law specified in the Annexes shall be suspended in part or totally from the date on which the disagreement of the Parties has been notified to the Committee.

Article 11

Exchange of information and cooperation

In order to ensure a correct and uniform application and interpretation of this Agreement, and to encourage trade in industrial goods between them, the Parties, shall:

(a) notify each other of relevant proposed and actual legislative amendments, and exchange information concerning the implementation of law and practice, including in particular on procedures to ensure the compliance of Notified Bodies on their territory with the rules applicable to them;

(b) invite each other to take part in their relevant mechanisms of information exchange, in regards to mechanisms dealing with sectors covered by the Annexes to this Agreement unless specified otherwise in the Annexes. The EU will explore the possibility of inviting Israel to participate in relevant European networks and bodies;

c) encourage their Notified Bodies to cooperate with a view to establishing mutual recognition arrangements in the voluntary sphere.

Article 12

Confidentiality

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Agreement.

Article 13

Management of the Agreement

1. Responsibility for the effective functioning of this Agreement shall be borne by the Committee. In particular, it shall have the power to take decisions regarding:

   (a) amending and withdrawing Annexes;

   (b) adding new Annexes;

   (c) appointing experts to verify the technical competence of a notified body and its compliance with the requirements applicable to them, in accordance with Article 10.1;

(d) exchanging information on proposed and actual amendments to the Community law and national law referred to in the Annexes;

(e) considering new or additional conformity assessment procedures affecting a sector covered by an Annex;

(f) resolving any questions relating to the application of this Agreement;

(g) referring questions for decision to the disputes settlement mechanism set out in Article 75 of the Association Agreement or any other relevant dispute settlement mechanism set up by agreement between the Parties pursuant to the Association Agreement.

2. The Committee may delegate the above responsibilities set out under this Agreement.

3. Amendments to the annexes shall enter into force as the Committee shall decide.

Article 14

Technical cooperation

The Parties shall cooperate where necessary in order to support the effective implementation and application of this Agreement.

Article 15

Agreements with other countries

1. This Agreement may, by explicit agreement between the Parties, including by a decision of the Committee, be extended to cover the acceptance of industrial products from third countries or parties with which the European Union has concluded an Agreement similar to this Agreement in corresponding sectors.

2. Where the European Union notifies Israel that it has made an Agreement similar to this Agreement with a third country or party, that covers the acceptance of industrial products in corresponding sectors, Israel shall consider making an Agreement with the third country or party that provides for such an extension.

Article 16

Entry into force

This Agreement shall enter into force 30 days after the date of the later written communication, through diplomatic channels, by which the parties have notified each other that their respective internal legal requirements for the entry into force of this agreement have been fulfilled.

Article 17

Duration

The Agreement is concluded for an unlimited period. Each of the Parties may denounce the Agreement by notifying the other Party. The Agreement shall cease to apply twelve months after the date of such notification.

During the period between the denunciation of the Agreement by one Party and its ceasing to apply, the termination of this Agreement shall not adversely effect or in any way prejudice any right or obligation accrued to or to be incurred by virtue of the application of this Agreement prior to the effective date of such termination.

Article 18

Status of the Agreement

This Agreement is drawn up in two originals in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish, Swedish and Hebrew languages, each text being equally authentic.

Done at

ANNEX ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

Pharmaceutical Good Manufacturing Practice (GMP)

SECTION I

COMMUNITY AND NATIONAL LAW

Community law**:**	Community legislation and provisions that the European Commission has notified to Israel and published in connection with this Annex.
Israeli National law:	Israeli legislation that Israel has notified to the European Commission and published in connection with this Annex.

SECTION II

SCOPE AND COVERAGE

1. Scope

Except as provided for in clause 2, Exclusions, the provisions of this Annex cover medicinal products, active pharmaceutical ingredients, pharmaceutical excipients or mixtures thereof, for human or veterinary use, to which Good Manufacturing Practice (GMP) requirements apply and that are governed by the requirements of relevant legislation notified by each party to the other under Section I of this Annex directly distributed by the manufacturer or importer of one Party to the importer of the other party.

This includes chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, and herbal medicinal products.

The provisions of this Annex shall apply to products covered by it irrespective of their origin.

2. *Exclusions*

Medicinal products derived from human blood or human plasma, advanced therapy medicinal products, investigational medicinal products, homoeopathic medicinal products, medicinal gases and veterinary immunologicals are excluded from the coverage of this Annex.

The possibility of extending the coverage of this Annex to medicinal products derived from human blood or human plasma, investigational medicinal products and veterinary immunologicals shall be discussed by the Parties two years from the entry into force of this Annex.

3. Maintenance, publication and extension of coverage and exclusion

Upon entry into force of this Annex, the Parties shall establish by exchange of letters a list of types of products and activities that it covers, and may also specify products to be excluded.

In addition, for the implementation of Article 5.4 of this Agreement in relation to this Annex, the Parties agree to inform each other about agreements similar in effect to this Agreement, and any unilateral concessions to a third country or party having a similar effect to an agreement of this type, the scope of products and procedures covered therein, and their intention as to whether or not to accept products onto their markets while derogating from certain obligations (notably those in Section IV.2) in relation to such agreements and unilateral concessions.

The Parties may, through the contact points specified in clause 11 of Section IV, following an assessment of legal and implementing provisions and practices in compliance with Community law specified in Section I, add or exclude further types of products and activities. Following such procedure the list may be amended as appropriate by exchange of letters between the Parties.

The Parties will make publicly available: (1) the list of types of products and activities covered by this Annex, (2) a list of any agreements similar in effect to this Agreement for which the derogation in Section IV clause 2(e) has been applied by the other Party and (3) a list of any unilateral concessions to a third country or party having a similar effect to an agreement of this type for which the derogation in Section IV clause 2(e) has been applied by the other Party.

SECTION III

RESPONSIBLE AUTHORITIES

European Union

Bodies which have been designated by the Member States of the European Union in accordance with Community law of Section I, notified to Israel in accordance with Article 9 of this Agreement and which have been made public by the European Commission.

Israel

Bodies which have been designated by Israel in accordance with Israeli National law of Section I, notified to the European Union in accordance with Article 9 of this Agreement and which have been made public by Israel.

SECTION IV

SPECIFIC ARRANGEMENTS

1. Definitions

For the purpose of this Annex the following definitions apply:

Official Medicines Control Laboratory (OMCL): Laboratory designated by a Member State of the European Union or Israel as referred to and regulated by pharmaceutical legislation and guidelines of the Community, the Council of Europe and Israel to perform laboratory testing for a competent authority, independently from the manufacturer, for medicinal products prior to and/or after marketing for the general surveillance of medicines in relation to the safety of human patients and/or animals.

Official Control Authority Batch Release (OCABR): Requirement by a Party, as referred to and regulated by pharmaceutical legislation and guidelines of the Community and the Council of Europe and Israel, that an Official Medicines Control Laboratory determines the conformity of a batch with the approved specifications as laid down in the marketing authorisation before the competent authority of the Party will allow that batch to be marketed. The examination includes testing on a schedule as defined in the guidelines referred to above.

Re-control: Testing of medicinal products imported from a third country or the other Party including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.

2. Obligations of the Parties

(a) For products covered by this Annex, each Party shall recognise the conclusions of inspections of compliance of manufacturers and importers with the principles and guidelines of EU GMP and equivalent Israeli GMP carried out by the relevant inspection services of the other Party on its own territory or in a third country in compliance with provisions on inspections as documented through the granting or refusal to grant a GMP certificate. The relevant provisions are listed in Section I.

(b) For medicinal products covered by this Annex, each Party shall recognise the relevant manufacturing and import authorisations confirming compliance with legislation on manufacture and importation and with the principles and guidelines on EU GMP and equivalent Israeli GMP.

(c) Certification of the conformity of each batch to its specifications by either the manufacturer established in one of the Parties, or the importer, shall be recognised by the other Party without re-control at import from one Party to the other. However, the additional responsibilities of the qualified person or the responsible pharmacist of the importer in each Party, with respect to the certification of each batch as set out in Section I above, remain in accordance with the provisions of the Community and Israeli National laws set out in Section I.

(d) The provisions in paragraph (a), (b) and (c) shall apply to finished or intermediate medicinal product imported from a third country and further exported to the other Party, only (1) if each batch of the medicinal product has been subject to re-control by either the importer from a third country or a manufacturer located in one of the Parties and (2) if the manufacturer in the third country has been subject to an inspection by the competent authority of either Party of which the outcome has been that for the product or product category the manufacturer complies with Good Manufacturing Practice.

(e) However, the provisions in paragraphs (a), (b) and (c) do not apply to products imported from a third country, that have exclusively been tested in and inspected by a competent authority of that or another third country. Any derogation from this provision on the basis of an agreement by one Party similar in effect to this Agreement, or any unilateral concessions by one Party to a third country or party having a similar effect to an agreement of this type shall be subject to the consent of the other Party.

(f) When one party requires a competent authority or an Official Medicines Control Laboratory to carry out an Official Control Authority Batch Release, such checks carried out by an authority of a Party will be recognised as valid by the other Party through certificates documenting compliance with specifications laid down in the marketing authorisation.

(g) Each Party will ensure that each product batch exported to the other Party will be accompanied by a batch certificate. Batch certificates for medicinal products will be duly signed by the qualified person or responsible pharmacist of the manufacturer or importer of the appropriate Party.

3. Exchange of manufacturing/import authorisations and GMP compliance information

The Parties shall exchange information on the authorisation status of manufacturers and importers and on the outcome of inspections, in particular by entering authorisations, GMP certificates and information on GMP non-compliance into the database on GMP managed by the European Medicines Agency (EMEA).

4. Exchange of inspection reports

Upon reasoned request by a Party, the relevant inspection services of the other Party shall forward a copy of the last inspection report of the manufacturing or importing site or, in case analytical operations are contracted out, also of the contract site. This shall in particular apply when the inspection included an assessment of compliance of manufacture and control tests for a medicinal product in accordance with the particulars and documents submitted for a marketing authorisation or when the inspection was performed in response to a quality defect. Each Party shall deal with these inspection reports with the degree of confidentiality requested by the providing Party. Parties will ensure that inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 days should a new inspection or re-control be carried out.

5. Exchange of results of laboratory testing performed by OMCLs

Upon reasoned request by a Party, the relevant authorities of the other Party shall forward a copy of the results of laboratory testing performed as part of market surveillance activities. This shall in particular apply when such testing is performed in relation to a quality defect or when there is a suspicion that the product could be falsely represented as an authorised product with respect to its identity, history or source.

6. Exchange of results of Official Control Authority Batch Release (OCABR)

When an OCABR procedure is applied, the results of such procedures carried out by a competent authority of the exporting Party shall be accepted as valid by the other party under the conditions defined in Community legislation and implementing provisions. The competent authority of the exporting Party shall on request make the certificate or the results of non-compliance available to the importing Party.

7. Format of Information exchange

Authorisations, inspection reports, GMP certificates and information on GMP non-compliance shall follow the format in accordance with the procedures published by the Community.

Certificates on OCABR as well as notices of non-compliance shall follow the format in accordance with the procedures on OCABR published by the Council of Europe.

Batch certificates for medicinal products that accompany each batch shall document at least the date of manufacture, the date of expiry, results of the qualitative and quantitative analysis and the name and address of the laboratory where such analysis was performed, the name and address of the manufacturer(s) and, where applicable, the importer. They shall also include a reference to the GMP certificate issued for the manufacturer and, where applicable, the importer. Batch certificates shall follow the provisions in accordance with the procedures published by the Community.

8. *Safeguard clause*

Each Party shall have the right to ask for the full inspection report or the full testing report by an OMCL and conduct its own inspection and its own OCABR. Except for situations mentioned in clause 4, recourse to this provision should be an exception, and the cause identified to the other Party in an objective and reasoned manner. Such requests shall be notified in advance to the other Party, which shall have the option of joining the activity.

9. *Alert System*

On the entry into force of the present Agreement, Israel shall participate in and contribute to the Community information and rapid alert system related to quality defects, counterfeiting and batch recalls.

The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing or import authorisation, based on non-compliance with GMP, are communicated to each other with the appropriate degree of urgency as laid down in the procedures published by the Community.

10. Information and Cooperation

The Parties to the Agreement shall regularly exchange information on the implementation and operation of this Annex.

They shall keep each other informed on training sessions for inspectors and scientists from Official Medicines Control Laboratories. Such sessions, organised by one Party, shall where practicable be made accessible to the other Party.

Representatives of Israel are encouraged to participate regularly in the discussions on GMP and quality related topics of working groups coordinated by the European Medicines Agency and the network of OMCLs coordinated by the European Directorate for the Quality of Medicines and Healthcare (EDQM) under the auspices of the Council of Europe. In addition, Israel is encouraged to participate in coordinated inspection activities in third countries.

As part of its implementation of relevant Community law, Israel shall participate in the operation of the Community database on GMP managed by the European Medicines Agency.

For the purposes of demonstration of capability and compliance of GMP inspection systems and OMCLs with European standards and requirements in the evolving regulatory systems, the parties shall participate in the Joint Audit Programme of the Member States of the European Union, as published by the EMEA, and the Mutual Joint Audit Programme, as established by the EDQM and any future comparable audit programme.

Additional specific information shall on request be supplied by a Party in relation to its official inspection service and Official Medicines Control Laboratories. Such specific information may include training, observed audits, general information and document exchange, transparency of agency audits, exchanges of external assessments and review reports relating to official inspection services.

Parties agree to facilitate information exchange and interdisciplinary cooperation in cases when actors in the manufacturing and distribution chain are suspected of contravening the legislation..

With respect to medicinal products covered by the scope of this Annex, but not covered under Section II.3, the Parties may cooperate in planning and performing inspections and in exchanging information on such inspections.

The Parties will agree to meet upon reasonable request of either party to discuss issues of preparation, implementation of and compliance with relevant Community and Israeli National law.

Requests for co-operation under this clause should be made through the contact points referred to in clause 11.

11. Contact points

Each Party shall notify to the other Party its contact points for the purposes set out in this Annex.

The contact points shall jointly monitor the implementation and operation of this Annex, in particular the assessment of relevant Community and Israeli National law and implementing provisions and practices, and shall agree on the list of types of products and activities specified in clause 3 of Section II.