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 Conformity Assessment and Acceptance of Industrial Products (CAA)

THE EUROPEAN UNION,

hereinafter referred to as "EU"

and

THE STATE OF ISRAEL,

hereinafter referred to as "Israel",

hereinafter 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" ([1]),

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

CONSIDERING the shared commitment of the Parties 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 a Protocol to the Association Agreement on Conformity Assessment and Acceptance of Industrial Products (hereafter referred to as "this Protocol") 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 Association Agreement provides for the use of best endeavours to approximate the laws of the Parties,

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

NOTING the close relationship between the European Union and Iceland, Liechtenstein and Norway under 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 those countries equivalent to this Protocol,

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:

Article 1

Purpose and means

1. The purpose of this Protocol 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 Protocol, which form an integral part of this Protocol.

2. The purpose set out in paragraph 1 shall be met through:

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

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

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

(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 EU 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 EU, on conditions analogous to those applying to trade in goods between the Member States of the EU.

Article 2

Definitions

For the purpose of this Protocol,

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

(b) "Relevant EU 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 Protocol;

(c) "National law" means any legal act and implementing practice by which Israel has aligned its legislation with relevant EU 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 EU or of Israel which is responsible for the effective implementation of EU 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 Protocol, to the other Party, as competent to assess conformity in relation to requirements of EU 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 Protocol shall have the meaning given in relevant EU law and Israel's national law.

Article 3

Alignment of legislation

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

In sectors covered by this Protocol where relevant EU 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 EU 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 Protocol, 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 Protocol where relevant EU 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 EU.

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 EU 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 Protocol.

3. Where products are subject to obligatory conformity assessment procedures to be carried out in accordance with the EU 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 1, 2 and 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 Protocol 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 Protocol, 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 EU 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 EU 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 EU 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 EU or national law specified in the Annexes, continuously comply with the requirements of such EU 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 EU and national law, to ensure the conformity of industrial products with EU 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 Protocol 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 that 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 EU 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 Protocol under which the Notified Body is competent to assess conformity, and as appropriate any limitations to such competence within the scope of that 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 EU 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 Protocol, 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 Protocol 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 Protocol 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 Protocol.

Article 13

Management of this Protocol

1. Responsibility for the effective functioning of this Protocol 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 EU 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 Protocol;

(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 Protocol.

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 Protocol.

Article 15

Agreements with other countries

1. This Protocol 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 EU has concluded an Agreement similar to this Protocol in corresponding sectors.

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

Article 16

Entry into force

This Protocol 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 Protocol have been fulfilled.

Article 17

Duration

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

During the period between the denunciation of this Protocol by one Party and its ceasing to apply, the termination of this Protocol 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 Protocol prior to the effective date of such termination.

Article 18

Languages

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

Съставено в Брюксел на шести май две хиляди и десета година.

Hecho en Bruselas, el seis de mayo de dos mil diez.

V Bruselu dne šestého května dva tisíce deset.

Udfærdiget i Bruxelles den sjette maj to tusind og ti.

Geschehen zu Brüssel am sechsten Mai zweitausendzehn.

Kahe tuhande kümnenda aasta maikuu kuuendal päeval Brüsselis.

Έγινε στις Βρυξέλλες, στις έξι Μαΐου δύο χιλιάδες δέκα.

Done at Brussels on the sixth day of May in the year two thousand and ten.

Fait à Bruxelles, le six mai deux mille dix.

Fatto a Bruxelles, addì sei maggio duemiladieci.

Briselē, divi tūkstoši desmitā gada sestajā maijā.

Priimta du tūkstančiai dešimtų metų gegužės šeštą dieną Briuselyje.

Kelt Brüsszelben, a kétezer-tizedik év május havának hatodik napján.

Magħmul fi Brussell, fis-sitt jum ta' Mejju tas-sena elfejn u għaxra.

Gedaan te Brussel, de zesde mei tweeduizend tien.

Sporządzono w Brukseli dnia szóstego maja roku dwa tysiące dziesiątego.

Feito em Bruxelas, em seis de Maio de dois mil e dez.

Întocmit la Bruxelles, la șase mai două mii zece.

V Bruseli šiesteho mája dvetisícdesať.

V Bruslju, dne šestega maja leta dva tisoč deset.

Tehty Brysselissä kuudentena päivänä toukokuuta vuonna kaksituhattakymmenen.

Som skedde i Bryssel den sjätte maj tjugohundratio.

נעשה בבריסל ביום כ"ב באייר התש"ע לפי הלוח העברי, שהוא יום 6 במאי 2010

За Европейския съюз
Por la Unión Europea
Za Evropskou unii
For Den Europæiske Union
Für die Europäische Union
Euroopa Liidu nimel
Για την Ευρωπαϊκή Ένωση
For the European Union
Pour l'Union européenne
Per l'Unione europea
Eiropas Savienības vārdā –
Europos Sąjungos vardu
Az Európai Unió részéről
Għall-Unjoni Ewropea
Voor de Europese Unie
W imieniu Unii Europejskiej
Pela União Europeia
Pentru Uniunea Europeană
Za Európsku úniu
Za Evropsko unijo
Euroopan unionin puolesta
På Europeiska unionens vägnar

בשם האיחוד האירופי

За Държавата Израел
Por el Estado de Israel
Za Stát Izrael
For Staten Israel
Für den Staat Israel
Iisraeli Riigi nimel
Για το Κράτος του Ισραήλ
For the State of Israel
Pour l'État d'Israël
Per lo Stato d'Israele
Izraēlas Valsts vārdā
Izraelio Valstybės vardu
Izrael Állam részéről
Għall-Istat tal-Iżrael
Voor de Staat Israël
W imieniu Państwa Izrael
Pelo Estado de Israel
Pentru Statul Israel
Za Izraelský štát
Za Državo Izrael
Israelin valtion puolesta
För Staten Israel

בשם מדינת ישראל

ANNEX

ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

Pharmaceutical Good Manufacturing Practice (GMP)

SECTION I

EU and national law

EU law: EU 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 Protocol in relation to this Annex, the Parties agree to inform each other about Agreements similar in effect to this Protocol, 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 EU law set out 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 Protocol 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

EU

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

Israel

Bodies which have been designated by Israel in accordance with Israeli national law set out in Section I, notified to the EU in accordance with Article 9 of this Protocol 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 EU or Israel as referred to and regulated by pharmaceutical legislation and guidelines of the EU, 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 EU, 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 EU and Israeli national laws set out in Section I.

(d) The provisions in points (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 points (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 Protocol, 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 EU 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 EU.

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 EU.

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 Protocol, 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 EU.

10. Information and Cooperation

The Parties to the Protocol 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 EU 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 EU, 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 EU and Israeli national law.

Requests for cooperation 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 EU 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.