


The New Israeli Legislation and International Agreements

PDA Annual meeting
10.12.2008

Mimi Kaplan
Institute for Standardization and Control of
Pharmaceuticals



קצת היסטוריה...

- הבקשה להתקבל לארגון PIC/S הוגשה 27/5/2004 על ידי מנהלת המכון באותה תקופה ד"ר רחל קרפל.
- במקביל החלו מגעים אם האיחוד האירופאי להכרה הדדית בנושא GMP.
- נדרשנו לבנות מערכת איכות ולשנות את החקיקה בישראל ולהתאימה לחקיקה האירופאית, כך שרישוי יצרני תרופות יעשה על ידי משרד הבריאות ולא להסתפק ברישיון עסק של הרשות המקומית.
- התקנות אושרו על ידי ועדת הכנסת ביוני 2008 והתפרסמו ב-6.11.08.
- כניסה לתוקף שנה מיום פרסומן.
- ביקורת האיחוד האירופאי וארגון PIC/S אוגוסט 2008



PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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PS/L 25/2008

12 November 2008

Dear Dr. Kaplan,

**ACCESSION OF ISRAEL'S INSTITUTE OF STANDARDISATION
AND CONTROL OF PHARMACEUTICAL TO THE PIC SCHEME**

I have the honour of informing you that on 12 November 2008, the PIC/S Committee, convening in Geneva (Switzerland), accepted the PIC/S membership application made by Israel's Institute of Standardisation and Control of Pharmaceutical.

The PIC/S membership of Israel's Institute of Standardisation and Control of Pharmaceutical will become effective as from 1 January 2009.

I attach the document "Pharmaceutical Inspection Co-operation Scheme", as contained in PIC/S 1/95 (Rev. 4) of 19 November 2007, whose provisions should be applied by Israel's Institute of Standardisation and Control of Pharmaceutical from 1 January 2009.

I hope that Israel's Institute of Standardisation and Control of Pharmaceutical will contribute to the effective operation of the PIC Scheme by means of constructive co-operation with the other PIC/S Participating Authorities.

In my capacity as Secretary to the PIC/S Committee, I would like to welcome Israel's Institute of Standardisation and Control of Pharmaceutical to the PIC Scheme. I take this opportunity to congratulate you for the successful application process and to thank you for all the efforts made to ensure that Israel's Institute of Standardisation and Control of Pharmaceutical complies with the Scheme's requirements.

Yours sincerely,



Daniel Brunner

PIC/S' mission

“To lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards

and

quality systems of inspectorates in the field of medicinal products.”



PIC/S Publications

Guidelines:

- PIC/S GMP GUIDE

Recommendations:

- PI 002-3 2007-09-25 QUALITY SYSTEM REQUIREMENTS FOR PHARMACEUTICAL INSPECTORATES
- PI 005-3 2007-09-27 GUIDANCE ON PARAMETRIC RELEASE
- PI 006-3 2007-09-25 VALIDATION MASTER PLAN INSTALLATION AND OPERATIONAL QUALIFICATION NON-STERILE PROCESS VALIDATION CLEANING VALIDATION

PIC/S Publications

➤ Recommendations:

- PI 021-2 2007-09-26 AIDE MEMOIRE ON GMP PARTICULARITIES FOR CLINICAL TRIAL PRODUCTS
- PI 023-2 2007-09-25 AIDE MEMOIRE ON INSPECTION OF QUALITY CONTROL LABORATORIES
- PI 025-2 2007-09-25 AIDE-MEMOIRE ON MEDICINAL GASES

PIC/S Publications

Newly adopted:

- AIDE-MEMOIRE ON PACKAGING (PI 028-1 adopted 31/10/08)
- AIDE MEMOIRE ON INSPECTIONS OF API (PI 030-1)

Members of PIC/S

- There are currently 34 Participating Authorities in PIC/S (Convention and Scheme taken together).
- Argentina, Australia, Austria, Belgium, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lichtenstein, Malaysia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, South Africa, Spain, Sweden, Switzerland, UK.

PIC/S membership: Benefit to Industry

- Reduced duplication of inspections
 - Cost savings
 - Export facilitation
 - Enhanced market access
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PIC/S membership: Benefit to Regulatory Authority

- Training opportunities
- International GMP harmonization
- Networking
- High standards
- Sharing of information
- Rapid alert system
- Facilitating the conclusion of other agreements

ACAA with EU: EU Agreements with 3rd Countries

- Mutual Recognition Agreements (MRA)
 - Canada, Japan, CH, Australia, NZ, (US-non operational)
- Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA)
 - Israel

Benefits of MRA

- Mutual recognition of GMP inspections through certification
 - Batch certification without re-testing at import
 - Reduced foreign inspections
 - Information exchange
 - Enhance bilateral regulatory cooperation maintaining confidence in each other GMP systems.
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Timetable for ACAA

- Assessment visit 3-7/8/2008
- Audit report distributed to European officials 1/9/2008
- Institute's CAPA plan agreed upon including amendments to legislation and to quality system
- No official objection to the agreement by EU MS
- Official opening of negotiations of the agreement 10/12/2008
- Agreement expected to be signed before mid 2009.

הערכות המכון לביקורת PIC/S-EU

המישורים שנבחנו:

- חקיקה מתאימה
- ידע מקצועי של הצוות
- מערכת איכות
- משאבים מתאימים לעמידה בדרישות

As a result of his evaluation on behalf of the PIC/S, the rapporteur:

- **recommends the PIC/S committee of officials to accept the Institute as a new member to the PIC/S**
- sees no necessity to perform a follow-up audit on site
- recommends to coordinate the follow-up of the corrective actions in legislation with the EC

תודות

- להנהלת משרד הבריאות ולמגר' בתיה הרן על תמיכתה לאורך כל הדרך.
- לעו"ד יואל ליפשיץ ועו"ד נילי חיון-דיקמן
- למפעלי דקסל פארמה וכימאגיס על הנכונות לקיום ביקורת מלווה.
- לכל עובדי המכון לביקורת ותקנים שבלעדיהם כל זה לא היה קורה.