Mexico City
2009

Importance of International Cooperation

PHARMACEUTICAL
SECURITY
INSTITUTE

Overview

Briefing Objectives

- Introduction to PSI
- Identify Resources of PSI
- Practical ways to build international cooperation

PSI's Mission is in its Name

The Pharmaceutical Security Institute is a fact finding, non-profit organization dedicated to:

Protecting the Public Health

Sharing Information on Counterfeiting Activity

Initiating Enforcement Actions with the Appropriate Authorities

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PSI Structure 2009

The Institute

Unique non-profit in Vienna, Virginia

- Funded by innovative pharmaceutical manufacturers
  - 26 Security Directors
  - Most former senior law enforcement
  - Dedicated anti-counterfeiting resources
- Primary focus
  - Collect, analyze and share information
  - Improve coordination
  - Disrupt and dismantle counterfeiting groups

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PSI Members

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Building International Cooperation

Suggested steps

Presentations to increase dialogue –
Explain business operations

Information on counterfeiting
Strategic and operational intelligence

Laboratory Examinations
Can determine product authenticity

Liaison meetings to
Maximize result by working together

PILL

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P = Presentations

Coordinate LEA and DRA seminars:

- Identify information shortfalls
- Develop and provide seminars
- In 2008, briefing included:
  - —FBI, ICE, Health Canada
  - —Argentina, Canada, China, Japan, Singapore, Thailand

Goal – information exchanges help to:

- Foster understanding
- Improve enforcement efforts
- Build relationships

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Presentations: Briefing Materials

Multi-lingual training guides to alert the authorities

I = Information

- Operational Reports
  - Timely, case specific reports identifying investigative linkages
- Country Reports
  - Country or regional counterfeit, theft, and diversion analyses
- Special Projects
  - Customized projects or studies to match unique needs

L = Laboratory Examinations

AUTHENTICITY EVALUATION
ANALYTICAL TESTING REPORT

Impacted Product:	Our Drug
Samples:	Purported, 100-mg, Name Tablets and Packaging Obtained by the Public Health Service in the Country
Company Internal Identifications:	05974-642-S505598
Agency/ Submitting Country:	Self-Explanatory
Conclusions:	S505598: Counterfeit Drug Product Tablets and Packaging

Chain of Custody Information:

Received by (name):	Company Senior Analytical Chemist
Date Received:	Day/Month/Year, Internal Mail; EP S505598
Receiving Laboratory:	Counterfeit Testing Laboratories, Quality Operations, City, State, COUNTRY
Sample from (name/dept):	Top Notch Investigator (Global Security, Country)
Date(s) of Testing	Day/Month/Year

L = Laboratory Examinations

Description of sample, visual evaluation, and spectroscopic comparison:

Sample Description (see Figure 1):

The analytical sample **05974-642-S505598** was received from Global Security, COUNTRY, in sealed evidence bag S505598.

The subject sample **05974-642-S505598** consisted of one ten-tablet blister pack of purported Our Drug 100-mg tablets, an IFC and a PIL. The IFC and blister lot number and expiry are 832718474 and 08-2007 respectively.

The subject sample is a representative sample of 375 blisters, cartons and leaflets that were found in a hotel near a city in Asia.

Packaging Evaluation 05974-642-S505598 (see Figures 2-5):

Individual Folding Carton (See Figure 2): The subject sample **05974-642-S505598** IFC was received unformed but with the lot number, expiry date and manufacturing date already printed on the carton. The IFC is elegant and fully purports to be Our Drug 100mg manufactured by Our Company, USA. The IFC artwork and box codes are 8408120 and 103541 respectively.

These codes are valid for an Arabian market pack of 50-mg of Our Drug and not for a 100mg of Our Drug pack. The lot number 832718474 along with the manufacturing date of 08-2004 and the expiry date of 08-2007 are printed on the IFC and have been confirmed as not valid for any authentic Our Drug manufactured in the USA.

The carton shape is consistent with the code 103541 however there are errors in the artwork of the IFC including: 'Our Name' font in the logos is incorrect; the carton states "100mg" when the authentic is for 50mg and there is text missing from the back of the carton. There are no security features or box seals present.

C:\Users\TKubic\Desktop\Sample Lab Report 2008.doc

L = Liaison

Case Related seminars

Paris 2008

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L = Liaison

Derived from the Latin word meaning “to bind.”

Every international and national organization recognizes the need for public private partnerships to address counterfeit medicines

Shared responsibility to the patients of the world

Effective liaison leads to understanding the nature and extent of this threat - actions.

Effective liaison

- Better coordination of cases impacting over diverse geographic areas;
- Improved communication with manufacturers security departments;
- Increased opportunities to seize counterfeit medicines; and,
- Save lives and prevent harm to innocent patients.

Effective liaison in Latin America

WCO – Interpol Operation Jupiter:

- 2005 Multi-nation – Multi-product anti-counterfeiting operations in Latin America;
- 2006 Five countries – three month operation seized $35 M in counterfeit goods; and,
- 2007 More countries involved - Argentina, Bolivia, Brazil, Chile, Paraguay, Peru and Uruguay.

Investigator Comments

Many thanks for your fast response and the detailed report. Interesting stuff! – UK

Great job PSI. Thanks for the info I will share your work with my colleagues. – US LEA

Have a once-over and let me know ...I figure you know more than anyone else on this stuff. - DRA, Caribbean nation

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Conclusion

PSI can help you:

- reduce investigative time
- conserve resources
- build better cases

Call, fax or email – all services are available at no charge.

Conclusion

Remember the PILL

- Presentations
- Information
- Laboratory
- Liaison

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