

# Support from the Pharmaceutical Industry

# The Pharmaceutical Security Institute, (PSI).

The **PSI** is a fact finding, non-profit organisation dedicated to:

*Protecting the public health*

*Sharing information on counterfeiting activity*

*Initiating enforcement actions with the authorities*

**PSI** gathers information about counterfeit medicines around the world and analyses that information turning it into intelligence, which it then shares with its members & the appropriate authorities. It is the only organisation that does this in order to understand the nature and scale of the problem.

**PSI** works closely with its **25** members, all are major international R&D pharmaceutical manufacturing companies as well as Law enforcement.



# Members ~ The PSI Network

 **ABBOTT  
LABORATORIES**

**AMGEN**

 **astellas**  
Leading Light for Life

**AstraZeneca** 

 **BAYER**

**Baxter**

 **Boehringer  
Ingelheim**

 **Bristol-Myers Squibb**

 **Eisai**

 **FOREST LABORATORIES, INC.**

 **gsk** GlaxoSmithKline

**Johnson & Johnson**

**Lilly**

 **Lundbeck**

 **MERCK**

 **MERCK**

 **NOVARTIS**

 **novo nordisk**

 **Pfizer**

 **PURDUE**

 **Roche**

 **sanofi aventis**  
Das Wichtigste ist die Gesundheit

 **SERVIER**

 **Takeda**

 **VERTEX**

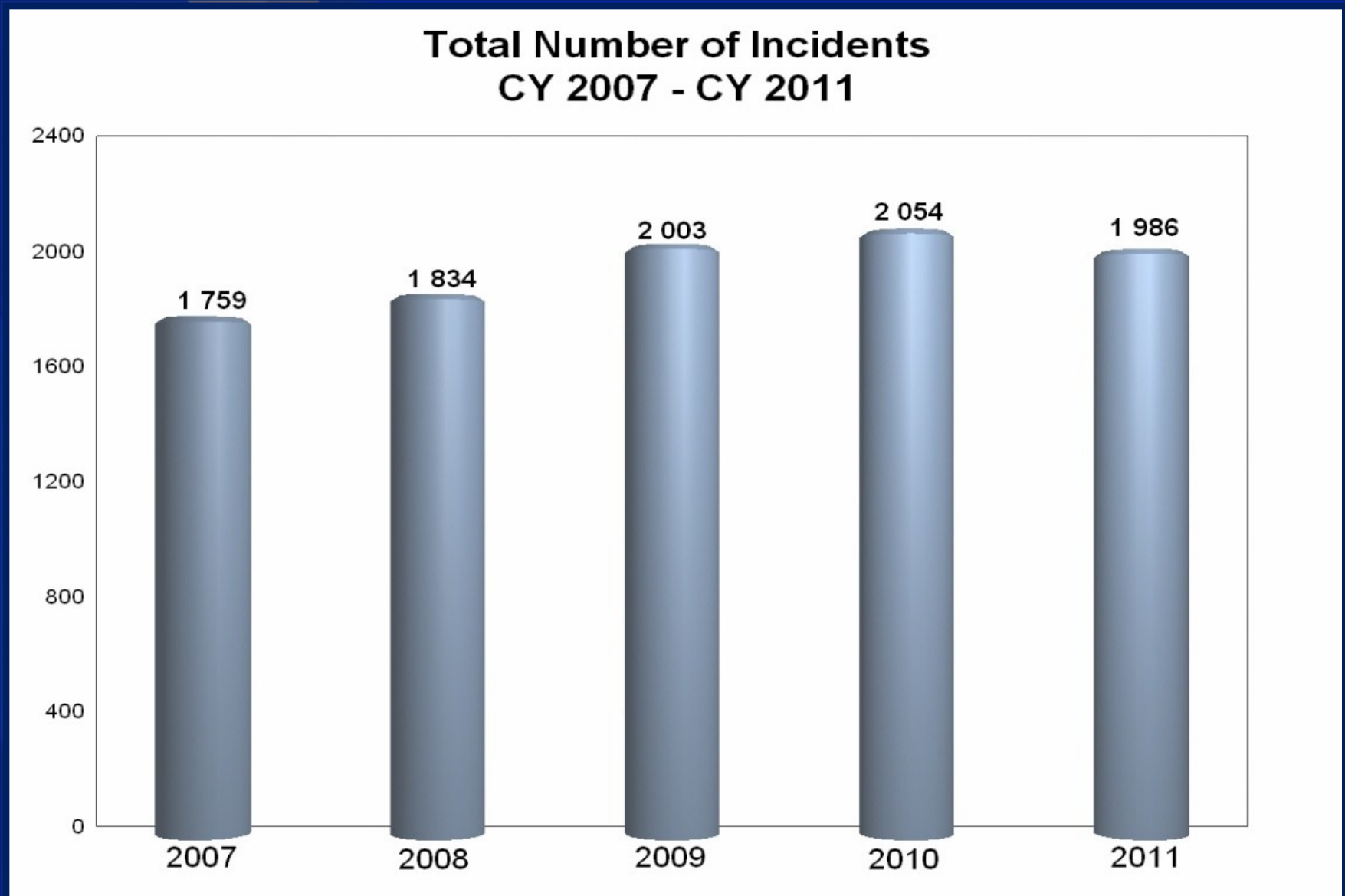


# PSI Counterfeit Incident System (CIS) ~ Information about Pharmaceutical Crimes

- **Collect and analyse information**
- **Provide the information to:**
  - Members
  - Drug Regulatory Authorities
  - Law Enforcement
- **Resulting in:**
  - Better informed risk analysis
  - More resources to address counterfeiting
  - Coordinated investigations
  - Dismantled/Disrupted counterfeiting groups



# Incident Trends



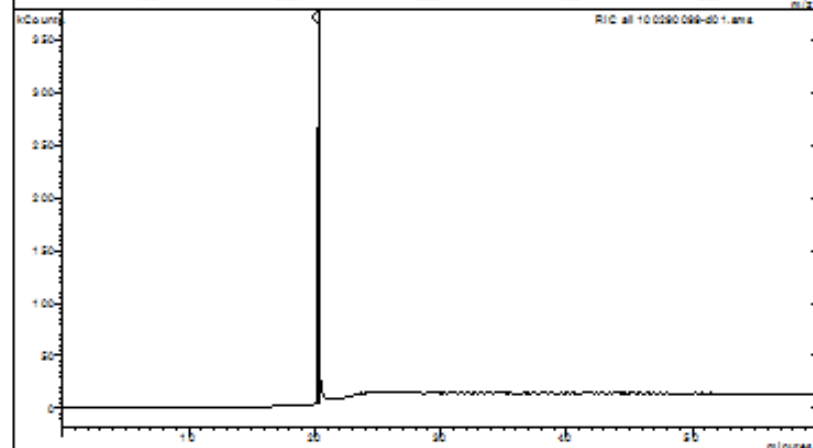
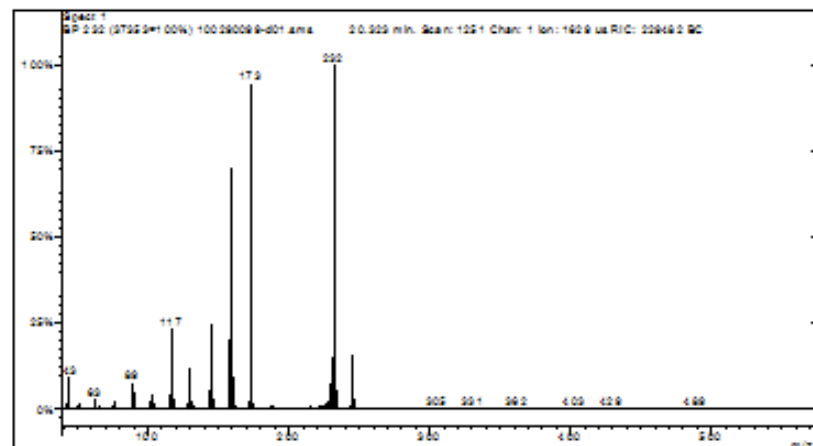
**3.3% decline in pharmaceutical crime incidents**

# PSI Members provide Scientific Analysis & Expert Witnesses

GC/MS Screen on Exhibit GW1A (MTS: 02/10/029/0099-D01) showing, left, Gas Chromatogram (bottom) and Mass Spectrum @ 20.32 mins (top) and, right, Library Search of Spectrum Showing Melatonin

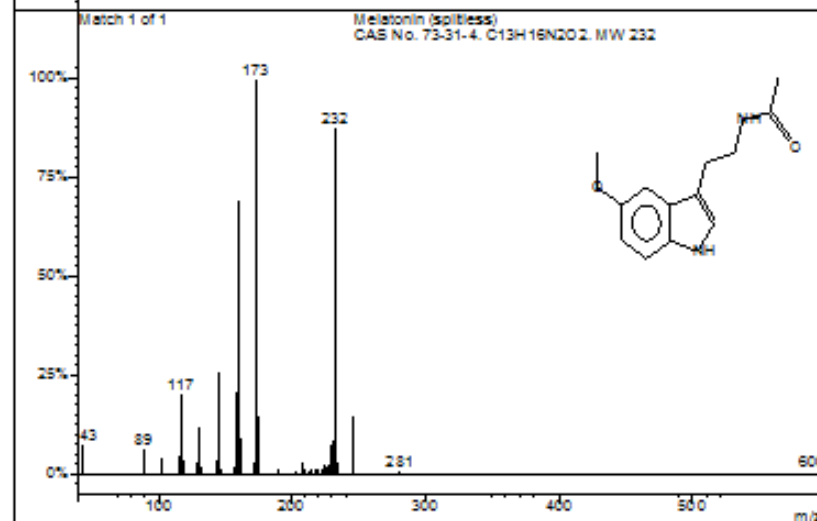
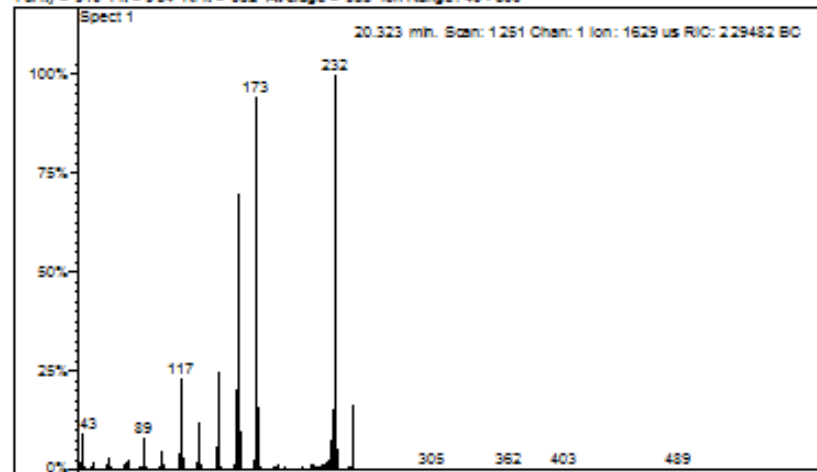
## Chromatogram Plot

File: c:\saturn\ms\data\100423 10-029 diazepam screen\100290099-d01.sms  
Sample: 100290099-D01 Operator: mc  
Scan Range: 1 - 3812 Time Range: 0.00 - 59.97 min. Date: 4/23/2010 10:50 AM  
Sample Notes: Exhibit GW1A - Vallium (Diazepam) 10mg Tab



Scan	Segment
1	1
1251	2
1972	2
2252	2
3172	2

Scan 1251 from c:\... \data\100423 10-029 diazepam screen\100290099-d01.sms  
Entry 402 from gomsscreendl.lib Saturn Library  
Purity = 910 Fit = 964 RFit = 932 Average = 935 Ion Range: 40 - 600



## **PSI works with:**

- 1. INTERPOL**
- 2. World Customs Organisation**
- 3. Europol**
- 4. National and international enforcement agencies**
- 5. EU Medicine Agencies WGEO**
- 6. Council of Europe**
- 7. Regional Pharmaceutical Industries & Associations**
- 8. Operation Pangea**

# PSI provides training:

- Raise awareness...
  - The issues
  - Where to find assistance
- PSI provides training to...
  - Law Enforcement
  - Drug Regulatory Authorities
  - Judiciary
- Outcomes...
  - Coordinated investigations
  - Better quality case preparation
  - Improved conviction rate





## Conclusion.

**“Information & Intelligence is no use unless it is shared with those that have the ability to use it! “**

# *Thank you!*

**Ashley HOW**

Director EMEA

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