Pharmaceuticals - Risk Assessment

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What are the two major reasons why insurance companies assess pharmaceutical risks?
Major reasons for pharmaceutical risk assessments

“We decided to recall our new drug because a common side-effect is lawsuit”
Casualty Risk Engineering
Service Offerings

Risk Engineering Services

Client

Broker

Underwriter

Casualty Regulations & Guidelines
- Industry Code
- Risk Band
- Trigger options
- Recommended exclusions
- Referral to Risk Engineering?

Risk Engineering

Desktop Analysis Report

Site Survey Report

Broker submission with variable levels of survey reports, assessments or risk rating.
Casualty Risk Engineering
Know-how / Specialist Areas

**Engineering Disciplines:**

- Civil Engineering
- Mechanical Engineering
- Electrical Engineering
- Chemical Engineering
- Environmental Engineering
  - Pharmacology (Dorothea Köppe)
  - Biotechnology/Genetic Engineering (Markus Kälín)
Questions from Underwriters to Risk Engineering?

Question 1:
Does Viagra have any side effects?

Answer:
Misuse might create some problems
Questions from Underwriters to Risk Engineering

Question 2:
Is Ritalin a drug or a dietary supplement?
XL’s tools to assess pharmaceutical risks

- Pharmaceutical know-how
- Submission information from clients and brokers
- Assessment of clinical trials (existing clients)
- Scientific Papers
- FDA MedWatch Safety Alerts
- Internet pages of US law firms (e.g. www.yourlawyer.com)
- XL Insurance Product Exclusion and Watch List
- Non governmental organisations (NGOs, e.g. Public Citizen)
FDA MedWatch Safety Alerts

- Changes in prescribing information (e.g. black box warnings)
- Early Communication About an Ongoing Safety Review (new)
- Dear Doctor Letters
- Recalls, Market Withdrawals and Safety Alerts

**PROZAC®**

**FLUOXETINE CAPSULES, USP**
**FLUOXETINE ORAL SOLUTION, USP**
**FLUOXETINE DELAYED-RELEASE CAPSULES, USP**

**WARNING**

Suicidality and Antidepressant Drugs — Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Prozac or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Prozac is approved for use in pediatric patients with MDD and obsessive compulsive disorder (OCD). (See WARNINGS, Clinical Worsening and Suicide Risk, PRECAUTIONS, Information for Patients, and PRECAUTIONS, Pediatric Use.)
Internet pages of US law firms

- List with 191 “Defective Drugs”
- Detailed chronology for each drug
- About 50 articles for Baycol case
- On-line form for free case review
Product Exclusion and Watch List

- Data base with 253 pharmaceuticals
- Detailed information set for each substance (e.g. side effects, litigation status, drug classes)
- Divers searching and reporting functions
Life Science Initiative by Risk Engineering

Definition of Life Science

- Pharmaceuticals
- Medical Devices
- Cosmetics
- Professional, Scientific and Technical Services
- Nutraceuticals
Life Science Initiative by Risk Engineering

Goal:

- Define parameters to select potential new Life Science clients
- Demonstrate profitability of the Life Science business by analysing XLI’s loss histories
- Convince Underwriting Management that pharmaceutical companies can be underwritten with profit
## Life Sciences Statistical Information

### Period 2000-2008 (world-wide)

<table>
<thead>
<tr>
<th>Category</th>
<th>Range of annual loss ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Pharmaceutical companies (&gt; $5 billion)</td>
<td>150% – 1200 % (2000-2003)</td>
</tr>
<tr>
<td>Other Pharma (&lt; $5 billion)</td>
<td>10% - 60%</td>
</tr>
<tr>
<td>Implant manufacturers</td>
<td>20%- 700%</td>
</tr>
<tr>
<td>Medical devices manufacturers (without implants)</td>
<td>10%- 70%</td>
</tr>
</tbody>
</table>
Major (Big) Pharma – What are the problems?

- Large US sales
- Several “blockbuster” drugs (sales per product > $1 billion)
- Target of consumer organisations and lawyers (deep pocket)
- Very fast growing products
- Large number of therapeutic areas (difficult to assess for RE)
- Reputation problems
Life Science Initiative – Preferred new clients

**Pharmaceutical Companies**
- Veterinary companies
- Phytotherapeutic companies
- Homeopathic companies
- Pharmaceutical/Biotech companies (sales < $1 billion and other criteria)
- Biotech companies with no products on the market
- Pharmaceutical wholesaler
- Clinical Research Organisations (CROs)
- Contract manufacturers

**Medical devices**
- Medical devices Class I and II companies
- In-vitro Diagnostics / Clinical Biomarkers companies
- Instruments and reagents for the Life-Science industry providing companies

**Cosmetic companies**
- Cosmetic companies of the luxury segment or niche market
Conclusions

- Most pharmaceutical companies are not as bad as their reputation
- Risks can be assessed like in any other industries
- Risk Engineering can be a differentiator in this business