The Practice of Pharmacovigilance in Pharmaceutical Industry

DR. SIAN NG
PRESIDENT, THE HKAPI
4TH MARCH 2011
HKAPI
Hong Kong Association of Pharmaceutical Industry

- **Formed in 1968;**
- **Membership**
  - 38 full members
  - Research & Development based multinational pharmaceutical companies, with top 20 in global, such as Pfizer, GSK, AstraZeneca, Roche, Novartis, MSD, J&J, Sanofi-aventis
    - Supply 70% of prescription medicine in Hong Kong
  - Affiliate members: 2 R&D based multinational companies with no pharmaceutical product launched in HK
  - Associate members: 29 companies, medical devices companies, and some are providing services to our full members
## HKAPI Members

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Laboratories Ltd</td>
<td>Galderma Hong Kong Limited</td>
</tr>
<tr>
<td>Actelion Pharmaceuticals Ltd</td>
<td>GlaxoSmithKline Ltd</td>
</tr>
<tr>
<td>Alcon Hong Kong Limited</td>
<td>Janssen Pharmaceuticals</td>
</tr>
<tr>
<td>Allergan Hong Kong Ltd</td>
<td>Kyowa Hakko Kirin (Hong Kong) Ltd</td>
</tr>
<tr>
<td>Astellas Pharma Hong Kong Company</td>
<td>Lundbeck Export A/S</td>
</tr>
<tr>
<td>AstraZeneca Hong Kong Limited</td>
<td>Medinova AG</td>
</tr>
<tr>
<td>B. Braun Medical (H.K.) Ltd</td>
<td>Merck Pharmaceutical (HK) Limited</td>
</tr>
<tr>
<td>Bausch &amp; Lomb (HK) Ltd</td>
<td>Merck Sharp &amp; Dohme (Asia) Ltd</td>
</tr>
<tr>
<td>Baxter Healthcare Ltd</td>
<td>Novartis Pharmaceuticals (HK) Ltd</td>
</tr>
<tr>
<td>Bayer HealthCare Ltd</td>
<td>Novo Nordisk Hong Kong Ltd</td>
</tr>
<tr>
<td>Beaufour Ipsen International</td>
<td>Nycomed (Hong Kong) Ltd</td>
</tr>
<tr>
<td>Boehringer Ingelheim (HK) Ltd</td>
<td>Otsuka Pharmaceutical (H.K.) Ltd</td>
</tr>
<tr>
<td>Bristol-Myers Squibb Pharma (HK) Ltd</td>
<td>Pfizer Corporation Hong Kong Limited</td>
</tr>
<tr>
<td>CSL Biotherapies Asia Pacific Ltd</td>
<td>Reckitt Benckiser Hong Kong Ltd</td>
</tr>
<tr>
<td>Daiichi Sankyo Hong Kong Ltd</td>
<td>Roche Hong Kong Limited</td>
</tr>
<tr>
<td>Eisai (HK) Co Ltd</td>
<td>Sanofi-Aventis Hong Kong Ltd</td>
</tr>
<tr>
<td>Eli Lilly Asia Inc</td>
<td>Servier Hong Kong Ltd</td>
</tr>
<tr>
<td>Ferring Pharmaceuticals Ltd</td>
<td>Takeda Pharmaceuticals Taiwan, Ltd</td>
</tr>
<tr>
<td>Fresenius-Kabi H.K. Limited</td>
<td>UCB Pharma (Hong Kong) Ltd</td>
</tr>
</tbody>
</table>
HKAPI: Our Mission

- To ensure patients having expedient access to innovative and effective drugs
- To enhance better health and quality of life for the public
Role of R&D Based Pharmaceutical Companies Globally

- Investment in R&D of new compounds

- Commitment to bring new drug to market to enhance patients’ health and quality of life (can cost up to USD 1 billion* and take up to 15 years.)

- Strict governance to conduct clinical trials and product development activities

- Conduct relations with patients and healthcare professionals in accordance with ethical and legal principles

Role of our industry in Hong Kong

- Ensuring broader and expedient patient access to innovative therapies through evident-based discussion with healthcare stakeholders
- Addressing public safety concerns about pharmaceuticals, which includes - manufacture of quality drugs, carry out pharmacovigilance reporting system, stop counterfeit and unregistered drugs
- Providing education to patients on healthcare and treatment options (“right to know...”), by partnering with healthcare professionals, such as doctors and pharmacists
The Practice of Pharmcovigilance within the industry
Pharmacovigilance

Definition:

“The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”

(WHO)

Pharmacovigilance is a standard in drug Development in each of the following phase:
- Research Phases (Phases I, II, III)
- Post Marketing Phase
Pharmacovigilance during clinical research

Adverse events during clinical studies (Requirement by law to conduct the followings-)

- Submit to regulatory authorities within specified time frame
- Notify all investigators and ethics committees
- Safety review by independent Drug Safety Monitoring Boards
- Provide annual reports (EU: Annual Safety Reports)
  - summary and analysis of all the serious adverse events
  - new safety findings from animal studies
  - Evaluations of benefit and risk
Pharmacovigilance when the product is marketed

Safety reporting is an obligation for companies in Marketing Phase

Include:

- Phase IV Studies (Post authorization studies)
  - Clinical trials (intervene disease management )
  - Pharmacoepidemiological studies (non-interventional or observational)
- Risk Management Plan
- Periodic Safety Updates Report (PSUR)
- Spontaneous Reports
Risk Management Plan (RMP)  
(Mandatory in EU and US FDA)

- RMP – a strategic safety program designed to decrease product risk

- Three main elements
  1. Safety reports in pre-clinical and clinical phases
  2. Pharmacovigilance Plan - company must indicate how to resolve the uncertainties (e.g., extra studies)
  3. Risk minimization plan – how the company propose to reduce the severity or frequency of known adverse reactions (e.g., special communication programmes, or educational exercises, registration programmes for patients or pharmacists)

   - Indicate timelines for those plans
Periodic Safety Update Reports (PSUR)

- Overview of the safety of the product, including all Adverse Drug Reports
- Summary of the worldwide registration and usage status
- Actions taken about safety issues
- A regulatory requirement for authorized medicine in EU
- Generated every 6 months for the first 2 years of launch, then annually for 5 years
Spontaneous Reporting

- Spontaneous reporting
  - Reporting by HCPs
  - Any serious adverse reactions: Legal obligations on the company to report within a specified time frame to the regulatory authority
  - Non-serious reactions: included in periodic safety update reports
  - Entered on the data base of company and regulatory body

- Literature screening on weekly basis
A dedicated team in R&D companies

- Each R&D international company has a dedicated Department (namely, Global Clinical Safety Department...) for:
  - Overseeing the above plans
  - Signal detection from ADR reporting
  - Perform trend analysis

- Local Office of R&D company has dedicated regulatory/medical affairs expert for looking after the local pharmacovigilance plans and coordinating with the global team
The existing ADR system in Hong Kong
The existing ADR system in Hong Kong
Better flow?

1. ADR reports from patients, doctors, and pharmacists.
2. Different channels for reporting.
3. A centralised database under the Department of Health.
4. Data analysis with reference from other health authorities and manufacturers.
5. Actions taken: communicate to which stakeholders via proper channel.
Suggestions to improve the pharmacovigilance system in HK

- To increase the awareness of healthcare professionals and the public on the understanding of importance of pharmacovigilance
- Develop and promote an effective channel for ADR reporting, such as online reporting system
- All the parties involved in pharmacovigilance reporting are coordinated under a platform from the Department of Health
- A centralized database for safety reports to facilitate systematic follow up and detailed analyses
- Improve communication among stakeholders in the reporting of adverse events such as, a single contact point from the regulator, the Hospital Authority, manufacturer for pharmacovigilance
R&D Pharmaceutical companies are committed in pharmacovigilance processes
Each product phases (from research to post-marketing) are highly regulated
Suggest areas for improvement – Centralized database, awareness, education and communication to all stakeholders
THANK YOU