The 8th AsiaPacific Pharmaceutical and Medical Devices Compliance Congress

Ethics and Compliance in Perspective

HOW, Ti-Hwei

Country President of AstraZeneca
President of Singapore Association of Pharmaceutical Industries (SAPI)
Chair, Healthcare Committee, EuroCham Singapore
Value of biomedical innovations...

...to patients

- Vaccines against communicable diseases
- Improvement of survival for cancer
- Cardiac stents for MI

...to economy

- Largest R&D investment
- Providing 8 million jobs in total
- Supporting economic growth
If a tree falls and no one is around to hear it, does it make a sound?
We can do better...

Imposed $3bn after bribing doctors to increase drugs sales

Under Investigation for ‘Sham’ Events
There were allegedly 80,000 sham events
William White, InvestorPlace Writer

Broke the Law by Promoting Drugs for Unapproved Uses

Fine $490m by China for bribery

CNN Money Business Markets Tech Pers
To pay $520

Million fine

Transparency International
Corruption in the Pharmaceutical Sector
Diagnosing the challenges
Compliance, Ethics and Integrity

**Compliance**
A state of being in accordance with established guidelines or specifications.

**Ethics**
A system of accepted beliefs that control behaviour, especially based on morals.

**Integrity**
Acting consistently on a set of values, ethical standards and principles.
“The right attitude and values can be worth more than the number of rules you put in place”

- Robert Smith
Thank you!
Medicines Are Some of the Most Powerful Tools to Treat and Cure Deadly Diseases

HEPATITIS C VIRUS

The leading cause of liver transplants and the reason liver cancer is on the rise – is now curable in more than 90% of treated patients with only 8-12 weeks of treatment.

+133% cure rate increase for patients in Europe¹

1st Generation (1999-2010)
2nd Generation (2011-2013)
3rd Generation (2013-2014)

41% CURE RATE 48 Weeks⁴
63-80% CURE RATE 12 Weeks²
90% CURE RATE 8-12 Weeks⁵
95-96% CURE RATE 8-12 Weeks⁵

IMPROVED TOLERANCE AND EASE OF TREATMENT

Interferon and Ribavirin (IFN-R) Injection
Protease Inhibitors with IFN Injection
Polymerase Inhibitors with IFN Injection
Oral Combination Therapies

¹Treatment duration.
Note: European Medicines Agency approval dates. Cure rates based upon clinical trial results reported in US Food and Drug Administration labels for interferon, telaprevir, boceprevir; simeprevir, sofosbuvir, ledipasvir and daclatasvir combination; and ombitasvir, paritaprevir, ritonavir, and dasabuvir combination.
Source: ¹PhRMA, 2014, 25 years of progress against hepatitis C. ²PhRMA, 2015, Biopharmaceutical research industry profile.
### The Innovative Biopharmaceutical Industry Has a Major Impact on Economies

The innovative biopharmaceutical industry has a significant impact on economies across the US, EU5, Japan, Korea, Mexico, Canada, and Australia. Here are the key statistics:

- **1,600,000** direct jobs
- **6,400,000** jobs downstream
- **8 million** total jobs

The breakdown by region is as follows:

<table>
<thead>
<tr>
<th>Region</th>
<th>Jobs</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>4,500,000 jobs</td>
</tr>
<tr>
<td>EU5</td>
<td>1,700,000 jobs</td>
</tr>
<tr>
<td>Japan</td>
<td>630,000 jobs</td>
</tr>
<tr>
<td>Korea</td>
<td>440,000 jobs</td>
</tr>
<tr>
<td>Mexico</td>
<td>680,000 jobs</td>
</tr>
<tr>
<td>Canada</td>
<td>80,000 jobs</td>
</tr>
<tr>
<td>Australia</td>
<td>64,000 jobs</td>
</tr>
</tbody>
</table>

**Source:** Health Advances analysis; PhRMA and TEConomy Partners LLC, 2016, The economic impact of the US biopharmaceutical industry: national and state estimates; EFPIA, 2015, Pharmaceutical industry in figures; JPMI, 2016, Pharmaceutical industry outlook; Invest Korea, 2016, Investment opportunities in Korea; Biopharmaceutical Industry Data, 2015; WifOR, 2016, Supporting the value proposition of the pharmaceutical industry in Mexico; Statistics Canada CANSIM Database (accessed January 2017); Australian Bureau of Statistics Australian Industry Database (accessed January 2017).
Biopharmaceutical Companies Have Invested Billions to Bring Innovative Therapies to Market

Worldwide Pharmaceutical R&D Investment

Over $1.4 trillion in R&D since 2006

Another $1 trillion in the next six years

“The most important challenge facing the global research community is ensuring that populations regard its contributions as positive, responsible and legitimate. R&D policy is not just about throwing money at scientists and engineers – it is also about ensuring that their innovations can be brought into use, which is a quite different challenge.”

– DOMESTIC CORPORATION, UK (DECEMBER 2013)

Source: Health Advances analysis; EvaluatePharma, 2016, World preview; Battelle, 2014, Global R&D funding forecast.