Life Sciences Symposium
Key Topics in the Pharmaceutical Sector in Vietnam and Southeast Asia

Presented by Tilleke & Gibbins
AmCham Business Luncheon
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Avenues for Foreign Pharma

Activities allowed for foreign pharmaceutical companies doing business in Vietnam
Pharma business forms

Entities that may conduct marketing and other activities related to drugs:

- **Representative offices** of foreign drug companies that have registered with the MOH
- **Licensed drug companies**
Rep offices may:

- Function as liaison office, conduct market research, and monitor performance of contracts
- Employ drug introducers
- Register and provide drug information documents to HCPs
- Register and conduct drug information seminars
- Register drug advertisements
Rep offices may **not**: 

- Conduct sales activities
- Conduct promotional activities, nor hire third parties to conduct them
- Conduct advertisement, unless through a licensed third party
Licensed drug companies

Currently, establishing a licensed drug company is **NOT** an option because of:

- Lack of import procedures per Article 3.2 of Circular 47/2010/TT-BYT
- Barrier to obtaining CSC per Article 24.1 of Decree 79/2006/ND-CP
- Inability to get GSP per Article II.10.(c), subsection 4 per Circular 2/2007/-BYT
Licensed drug companies may:

- Engage in all activities of ROs
- Manufacture drugs
- Import drugs if it manufactures one or more drugs
- Warehouse imported drugs
- Sell to licensed distributors
- Conduct promotional activity to drug traders not to consumers
Licensed drug companies may not:

- Sell directly to retailers (pharmacies and hospitals)
- Sell directly to consumers
Drug Processing Activities

New opportunities for foreign pharmaceutical companies in Vietnam
Key changes for foreign drugs

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<tr>
<th>Circular 06/2004/TT-BYT</th>
<th>Circular 23/2013/TT-BYT</th>
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<td>All stages of manufacturing process must be processed, except for some special pharmaceutical dosage forms.</td>
<td>May be manufactured and processed in one, multiple, or all stages of the manufacturing process.</td>
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<td>Allowed to choose only one processing manufacturer</td>
<td>Allowed to choose one or a number of processing manufacturers</td>
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<td>Processed non-MA license drugs are not allowed to be marketed in Vietnam</td>
<td>Processed non-MA license drugs can obtain a processing MA license and be marketed in Vietnam</td>
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In Vietnam, we have had an ongoing presence in Ho Chi Minh City since 1992 and in Hanoi since 1994, and now have a team of more than 70 professionals, including nearly 30 lawyers and consultants, across the two offices.

Our high-caliber intellectual property practice is widely recognized as one of the best in the country, while our corporate and commercial practice has been highly ranked in commercial transactions and M&A, labor and employment, tech/media/telecom, and regulatory affairs by such surveys as Chambers Asia Pacific, The Legal 500 Asia Pacific, Asialaw Profiles, and Asian Legal Business.