



# Orientation conference for investment in Pharmacy Sector towards 2020 in Vietnam



# Agenda



- **Great achievements of the Vietnamese pharmaceutical industry thanks to your support**
- **PharmaGroup presentation**
- **Continuous investment and support from Multinational Pharma companies**
- **Long term perspectives for Pharmacy sector in Vietnam**

# Great achievements of the Vietnamese pharmaceutical industry in recent years (1/2)



- More and more Vietnamese patients having access to Health Insurance (around 50%)
- Important and growing market evaluated USD bn 1.7 in 2009
- Excellent progress towards achieving Good Practices in numerous Pharmaceutical Fields:
  - Plan on rolling-out GPP in retail pharmacies to ensure patients safety and information
  - Regulations on GCP jointly worked with DST
  - Wide applications of GSP and GMP across Vietnam
  - Harmonization of registrations requirements with ASEAN guidelines (ACTD)
  - Perspective of increased administrative efficacy with Project 30

# Great achievements of the Vietnamese pharmaceutical industry in recent years (2/2)



- Thanks to MOH and other ministries support and action, Vietnam has become a key country for Pharmaceutical investments



# PharmaGroup presentation



- **Active since 1996**
- **Part of EuroCham sector committees**
- **Contributions to White Book published by EuroCham, and to Project 30**
- **25 members, Multinational Research and Development companies**
- **Monthly meeting**
- **Strong partnership with MOH / DAV on new regulations (eg: Trainings on clinical trials assessment, registration process, best practices sharing, ...)**



# R & D Pharma companies are willing to pursue investments in Vietnam (1/2)



- Scientific information provided to doctors and pharmacists across Vietnam
- Strong and permanent investments in Continuous Medical Education
- Sustained support to Hospitals and Medical Associations through trainings
- Large direct and indirect employment sector
- New innovative medicines for Vietnamese patients to benefit from best in class treatments
- Increased activities in local clinical trials



## R & D Pharma companies are willing to pursue investments in Vietnam (2/2)



- **With the support of MOH and other ministries, R&D Pharma companies are strongly willing:**
  - to explore opportunities for local sustainable investments such as partnerships, cooperations, FDI, ...
  - to invest in the development of the Pharmaceutical sector in Vietnam, and
  - become a long term partner for improving Vietnamese patients health



# 1. Accelerate access to medicine for Vietnamese patients



- Very good progress made in clarity and quality of registration process
- Harmonization with ASEAN guidelines in place

However:

- Fast track registration process for specific medicines answering unmet needs could be considered
- Benefit from international clinical trials (developed under FDA / EMEA standards) for NCE registration and avoid local duplication of trials whenever possible



## 2. Pursue drug quality improvement



- **GMP-WHO standard applied widely and consistently monitored**
- **GPP standard application in retail pharmacies by 2011**

**However, drug quality for Vietnamese patients can be further improved by:**

- **Running Bioavailability and Bioequivalence (BA/BE) test to ensure better patient safety; Increasing the number of molecules (today limited to 12 molecules in the latest circular 08)**
- **Strengthening the pharmacovigilance management**
- **Monitoring the drug quality and information in retail pharmacies with the strict GPP implementation**



### 3. Strengthen Intellectual Property enforcement for patient safety



- **New Data Exclusivity circular in place, granting 5 years data exclusivity for innovator**

However,

- **Data protection could be more comprehensive and ensure data confidentiality when relevant**
- **More severe penalties when patient safety can be at stake :**
  - **Trademark & patent infringement with no drug quality assurance**
  - **Counterfeit products threatening patient safety**
  - **Illegal parallel imports**



## 4. Implement import right and wider scope of activities for foreign companies:



- Since January 2009, in line with WTO agreement, 100% foreign owned Pharma companies can be set up

However,

- Very limited scope of activity of Licences still restrict foreign investments
- Granting import rights to Pharma companies would allow accelerated investment in FIE in Vietnam

Note : Distribution rights are not in scope of Pharma companies priorities



# Conclusion



**We are committed to a sustainable and long term investment in the Vietnam pharmaceutical sector in cooperation with local authorities and stakeholders.**