# INDUSTRY ACTIONS TO IMPROVE REGULATORY SYSTEM



**VIETNAM'S EXPERIENCE** 

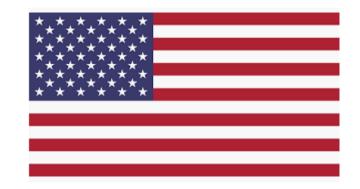
# REGULATIONS ARE CRUCIAL FOR SOCIETY BUT TOO MANY REGULATIONS MAY NOT BE GOOD

"whenever an executive department or agency (agency) publicly proposes for ... a new regulation, it shall identify at least two existing regulations to be repealed"

Donald J. Trump – President's. Executive Order 30 Jan 2017

In Vietnam: From 2016, the Prime Minister Nguyen Xuan Phuc calls for Administrative Procedures Reforms: "drastically cut administrative procedures, remove sub-licenses, in particular, better control of placing additional procedures...".

*Source:* <u>http://vpcp.chinhphu.vn/Home/Thu-tuong-Nguyen-Xuan-Phuc-lam-viec-ve-cai-cach-thu-tuc-hanh-chinh/20178/22271.vgp</u>





It needs contributions from whole society, especially from the Industry, to share the best international practices & harmonization.

# AMCHAM/US-ASEAN BUSINESS COUNCIL ACTIVELY SUPPORT VIETNAM TO IMPROVE REGULATORY SYSTEM

- November 23, 2015, the US-ASEAN Business Council signed the Memorandum of Understanding on Partnerships to Strengthen Healthcare in Vietnam with Vietnam MOH
- 2 projects completed, 7 projects are on-going, (plus 3 new projects suggested in 2019)
- 7/9 projects are focused on strengthening healthcare systems; and 2 are focuses on improving health status in a specific area

Source: US-ASEAN Business Council: 4<sup>th</sup> Health & Life Sciences (HLS) Industry Mission to Vietnam

# MEMORANDUM OF UNDERSTANDING

BETWEEN

THE US-ASEAN BUSINESS COUNCIL

AND

# THE MINISTRY OF HEALTH OF THE SOCIALIST REPUBLIC OF VIET NAM

For and on behalf of The US-ASEAN Business Council For and on behalf of The Ministry of Healthof the Socialist Republic of Viet Nam

Michael M. Michalak

Amb., Senior Vice President& Regional Managing Director US-ASEAN Business Council, Inc Pham Le Tuan
Vice Minister of Health

Amm

# HIGH LEVEL GOVERNMENT ENGAGEMENT TO SHAPE MOU PARTNERSHIP



Meeting with DPM Vu Duc Dam on Mar 18, 2016

Meeting with MOH Vice Minister Nguyen Viet Tien on **Apr 21, 2016**  Prof Luong Ngoc Khue, Director General, Medical Service Administration at Clinical Nutrition Symposium on May 14 – 15, 2016 MOU signing ceremony in the National TV

# STRENGTHEN FOOD REGULATORY SYSTEM

#### **TECHNICAL SUPPORT FOR POST-MARKET SURVEILANCE:**

PROJECT Improving Food Safety Testing Capacity (Abbott & National Institute of Food Control) has been completed in 2018, with many testing methods for food products have been standardized and expert exchange

#### STRENGTHEN SCIENTIFIC AND TECHNICAL UNDERPINING:

3 PROJECTS on nutrition (Abbott with Mother & Children Protection Dept; and Medical Service Administration-MOH) built 3 National Guidelines & implemented them nationwide:



- National Guideline of Prevent and manage Gestational Diabetes Mellitus
- National Guideline of Maternal nutrition
- \* Source: US-ASEAN Business Council: 4th Health & Life Sciences
- National Guideline of Clinical Nutrition
  - (HLS) Industry Mission to Vietnam

#### **IMPROVE FOOD REGULATIONS:**

In 2017, Industry (including Amcham) requested the Prime Minister to improve the food safety regulation, and worked intensively with the Government & MOH to build Decree 15 on Implementing Food Safety Law (it has been issued in Feb 2018), which focused on:

- Risk-based management: split foods into high and low-risk groups for different levels of controls.
- Post-market surveillance: simplifies paper requirements in granting certificates to reduce administrative burden, while clearly defines local health authorities responsibilities in post-market surveillance.
- Clearer regulatory requirements for easier implementation.

# IMPROVING FOOD SAFETY REGULATIONS



Industry discussed Food safety improvement in the Dialogue meeting of Government Consulting Committee of Reforming Administrative

VCCI/CIEMs raised the need of improving Food Safety Regulations in the Government Cabinet Meeting

Supported by several symposia chaired by VCCI



with lot of participants from authorities & industry



widely discussed in media



Industry met with Prime Minister during Vietnam Business Summit

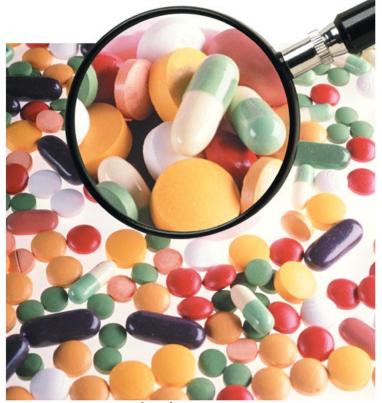
## STRENGTHEN DRUG REGULATORY SYSTEM

#### **BUILDING REGULATORY AGENCY:**

GSK's Leadership Program for ASEAN Senior Healthcare policymakers to build capacity on healthcare policies in terms of financing, health technology assessment, health outcomes, etc. (completed in 2018)\*

#### STRENGTHEN SCIENTIFIC AND TECHNICAL UNDERPINING:

Lilly's Public Private Partnership Project to empower the community to better diabetes management.\*



#### **IMPROVE DRUG REGULATIONS:**

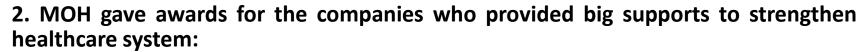
Industry contributed to build Decree No. 155/2018 / ND-CP issued in 12 Nov 2018 which significant changes drug import requirements toward simplification and harmonization.

\* Source: US-ASEAN Business Council: 4<sup>th</sup> Health & Life Sciences (HLS) Industry Mission to Vietnam

## RECOGNITION

- 1. On 26/12/2018, Vietnam MOH recognized the administrative procedures reforms is 1 of 9 outstanding events of Healthcare sector in 2018, with following conclusion:
- + **DRUG**: "Decree No. 155/2018 / ND-CP cuts down: 1363/1871 business investment conditions (72.85%); 169/234 administrative procedures (72.22%)".
- + **FOOD**: "Decree No. 15/2018 / ND-CP cuts down 98% of government inspection for 5 groups of imported foods".
- + FINANCIAL BENEFIT: "The total estimate after cutting down the business investment condition, administrative procedures and the list of specialized inspected goods under the Ministry of Health's management has saved more than 8.5 million working days / year, about VND 3,332.5 billion / year (> \$130 MM)".

Source: Vietnam National Television: https://vtv.vn/suc-khoe/9-su-kien-tieu-bieu-nganh-y-te-nam-2018-20181226172802943.htm



Source: Abbott

 Minister of Health Nguyen Thi Kim Tien: "2018 was a very special one for the healthcare sector, with many breakthrough achievements made, thus contributing to increasing access to healthcare for rural people, increasing the quality of examinations and treatment, developing the public-private partnership (PPP) model, and further facilitating business activities."





Source: https://english.vietnamnet.vn/fms/society/217722/the-clear-path-to-a-healthier-vietnam.html

### **LESSON LEARN**

- Healthcare industry plays an important role in improving the healthcare regulatory system, based on it's scientific expertise and sharing international best practice.
- <u>Set common goal</u> with the Government to improve public health, focus to address their main concerns.
- Work as a team, together with the local industry, with right strategy and investment.
- <u>Well communicate</u> with all involving authorities & parties, not limited in Health Authorities, to get the best alignments & supports.
- Open & Transparent communication to Media & Public is crucial.



