

A Model of Pro-active Advocacy



2017 Priorities

PG priorities	Outcomes and highlights
Equal Access - Tendering Circular	● <i>From OPO to SPN</i> ● <i>Freeze of reimbursement list less likely</i>
Fast Access - Pharma Law	● <i>Removal of Local Clinical Trial requirement (in progress)</i> ● <i>Collaboration with DAV on Registration Circular</i>
Legal entity/ Trading rights	● <i>Legal base for Import FIE with ability to strategically partner</i> ● <i>Risks to current RO structure, but likelihood of Roadmap to address concerns</i>
Innovative Lifesciences Sector Development	● <i>Strong expression of interest from Government</i> ● <i>Government (MOH and DPM Hue) workshop in December</i>
IP Rights	● <i>Compulsory Licensing remains off the table</i>

Evolution of Pharma Group Engagement

“Partnering for the long term: Shaping the environment through dialogue by showcasing the value of innovation and our commitment to Vietnam’s development”

	2012-13	2014	2015	2016	2017
PG Strategy	Strong Advocacy Position (Resistance)	Win-Win Strategy Focused Approach (4-Pillars)	Win-Win Strategy Focused Approach	Win-Win-Win approach and seat at the table	Win-Win-Win approach and seat at the table
Legislation	Drafts Circular 1, 36, 37/VMFVP	Pharma Law/Pharma strategy/2614	Pharma Law/Tender Circular/Toll Manuf	Pharma Law/Tender Circular/IP	OPO merger/Decree 54/Tender Circular/Registration Circular
PG Lever	N/A – Individual Company Approach	Innovation/Quality/EVFTA	Innovation/Quality/EVFTA/USTPP/FDI/IMS Data	Innovation/Quality/FILM/FTAs/IMS Data	Innovation/Quality/Visa extensions/FILM/FTAs
Outcome	No Impact on Circulars (yet in 2013 Importance of Quality Discussion (Circular 37 Created)	Rejected (Patient Focused) MoH	Positive Outcomes: MoH/MPI	Very positive developments: DPM level, Politburo FIE, Clinical Trials, engagement, BUT with some new developments VSS	Positive developments: DPM engagement, Politburo FIE, Clinical Trials, engagement, BUT VSS further strengthened and MOH issues
PG Involvement in Policy decision	Low	Low-Med	Med	Med-High	Med-High

No Lever
(Hoping)



Quality
Story



Innovation
Messaging &
EVFTA/USTPP



FDI
IMS Data



International
engagement and WWW
partnership

**Reactive Adversaries
“Dealing With Issues”**



**Proactive Partnership
“Creating Value and Optionality”**

A Model of Pro-active Advocacy

- *Goals:*

- Evolving from retro- to proactive
- Ultimate goals:
 - Accountability and responsibility in Regulatory environment and enforcement
 - Stakeholders regularly meet proactively re decrees, enforcement issues
 - Contribute CSR for greater good through our combined efforts
- Level playing field for international companies
- US Commerce and State Dep't cooperation
- Networking and supporting each other
- Informational events and workshops