Possible Impacts of Trans-Pacific Partnership Agreement (TPP) on Accessibility to Medicines

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Presentation Content

- Assessment Methodology
- Pharmaceuticals related provisions under TPP
- TPP's possible impacts on the accessibility and higher medicines prices

Assessment methodology

- Review secondary data
  - Joint Annual Health Review, National health Strategy, various reports from WHO, WB, MOH Departments, etc.
- Conduct in-depth interview with key informants from various organizations
  - MOH relevant Departments
  - National Office of Intellectual Property
  - Academia, Hospitals
  - Civil Society

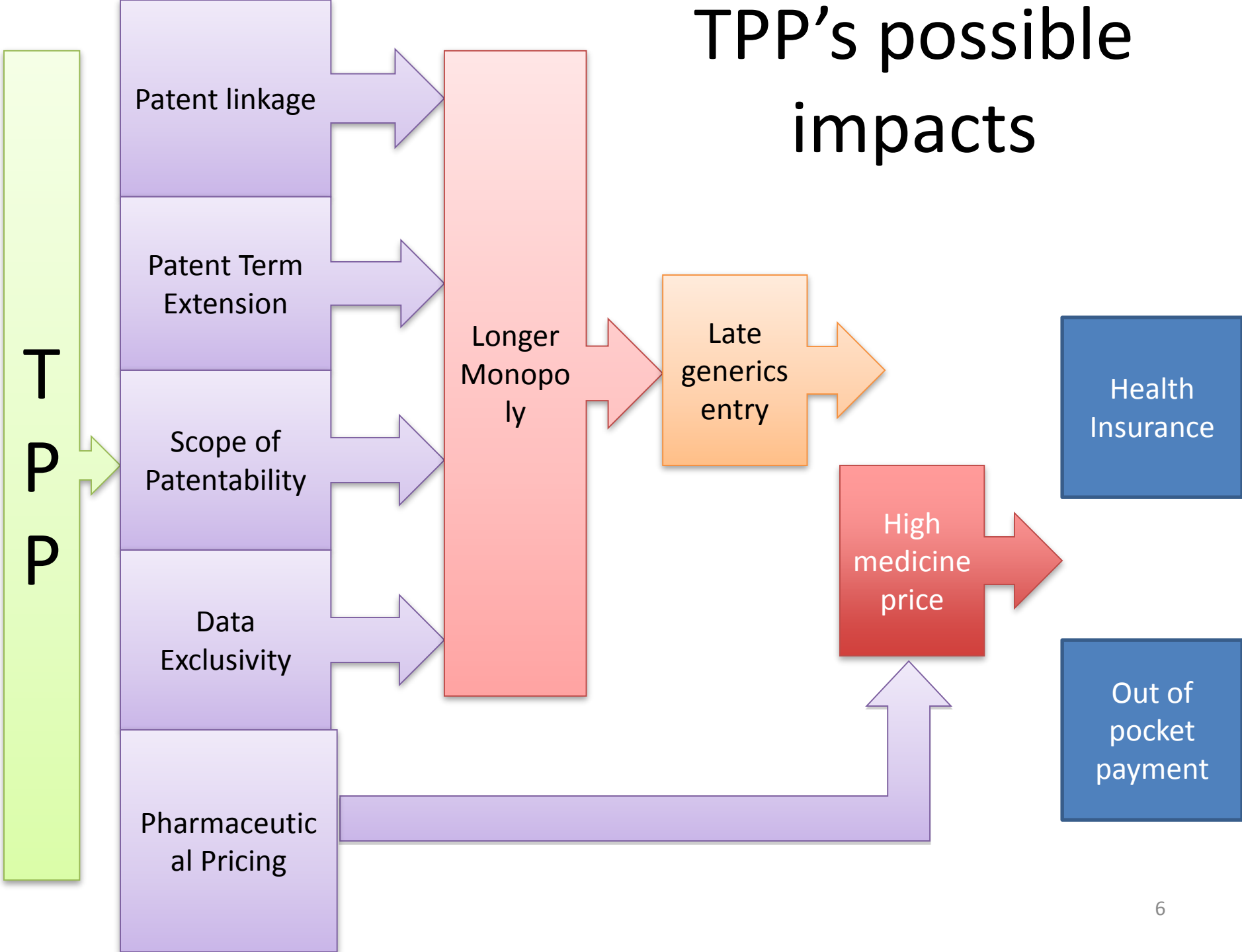
Trans-Pacific Partnership Agreement

- In TPP, **IPs emphasized during negotiation in TRIP+ direction**
- TRIP+ requires higher monopoly protection than signed TRIP Agreement
- TPP considered “New agreement generation”, “high standard” among 12 countries (both developed and developing countries).
- The developed partners want to impose “higher IP standards” for all partners

Provisions under TPP

- Application of new regulations:
  - Patent linkage
  - Patent term extension
  - Data exclusivity
  - Scope of patentability
  - Pharmaceutical pricing

TPP's possible impacts



Impact of Patent term extension

- Article 8.6: Require of an extensions beyond patent term of 20 years to make up for unreasonable delays during
  - Regulatory Review
  - Patent examination
- Unreasonable delays:
  - delays longer than 4 years in granting patents since application submission in new territories, or
  - 2 years since patent granting request, whichever later.

Impacts of Patent linkage

- Article 9.5: Links registration of drugs with the existence of a patent for a pharmaceutical product to the extent of a single claim.
- Vietnam has yet any regulations in its IP law
- Would require the Government to delay marketing approval of generics on behalf of MNCs
- Facilitate ever-greening of patent holders, eliminate competition

Impacts of Broaden Scope of Patentability

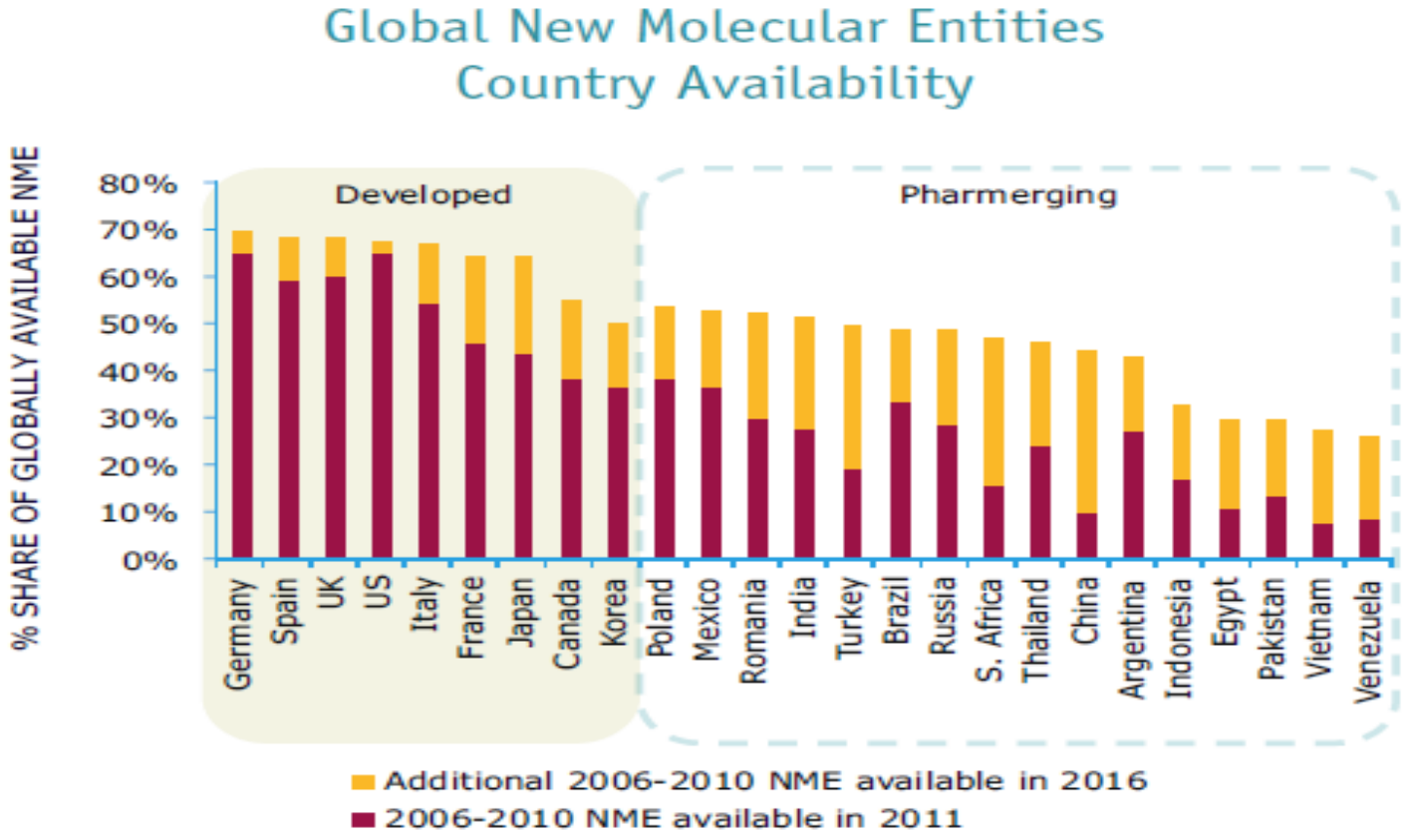
- Article 8.1: Broaden patentability scope to include new forms, new formulations, change in doses, second uses, etc., regardless whether there is any added value to the existing patent or not
- Drawbacks:
  - Would facilitate ever-greening, thus prevent generics competition
  - Limit access to new healthcare technology and products
  - Increase healthcare cost

Impact of Data Exclusivity

- Article 9.2:
  - Requests protection of clinical data at least 5 years upon new market registration even there is no patent in place
  - Prevent registration by reference to market access certificate
- Prevent use of compulsory license during the patent term, delay generics market access thus against ethical values

Impact of Data Exclusivity

- Since launch date of medicines in Vietnam is often long after first launch worldwide, term of data exclusivity will exceed patent term



Source: IMS Institute for Healthcare Informatics, May 2012

Late registration results in Data Exclusivity running beyond the Patent Term

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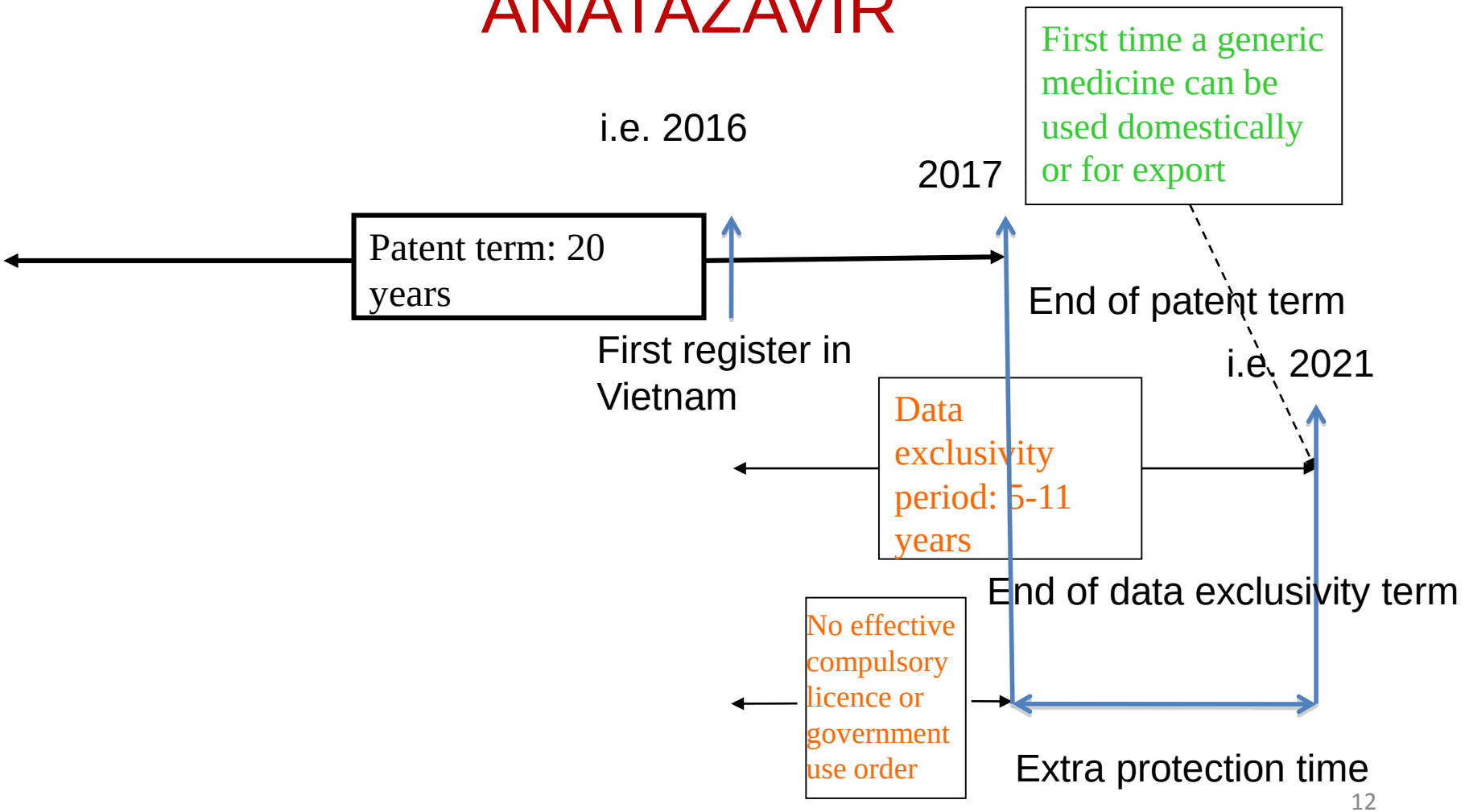


Medicines Pricing

- TPP would limit the ability of the Government in the future to manage medicines prices.
  - By enabling drug companies to interfere with and influence drug reimbursement decisions.
  - Seeks to require that regulators set reimbursement prices on the basis of "competitive market-derived prices in the Member's territory".

Spending on patented drugs is projected to double between 2008- 2014

- f = forecast

Index	2006	2007	2008	2009	2010f	2011f	2012f	2013f	2014f
Value (billion USD)	0.23	0.27	0.34	0.37	0.4	0.44	0.49	0.57	0.65
Market share (%)	24.30	24.40	24.10	23.80	23.43	23.04	22.54	22.02	21.55

Source: DAV, MOH

Other TPP provisions

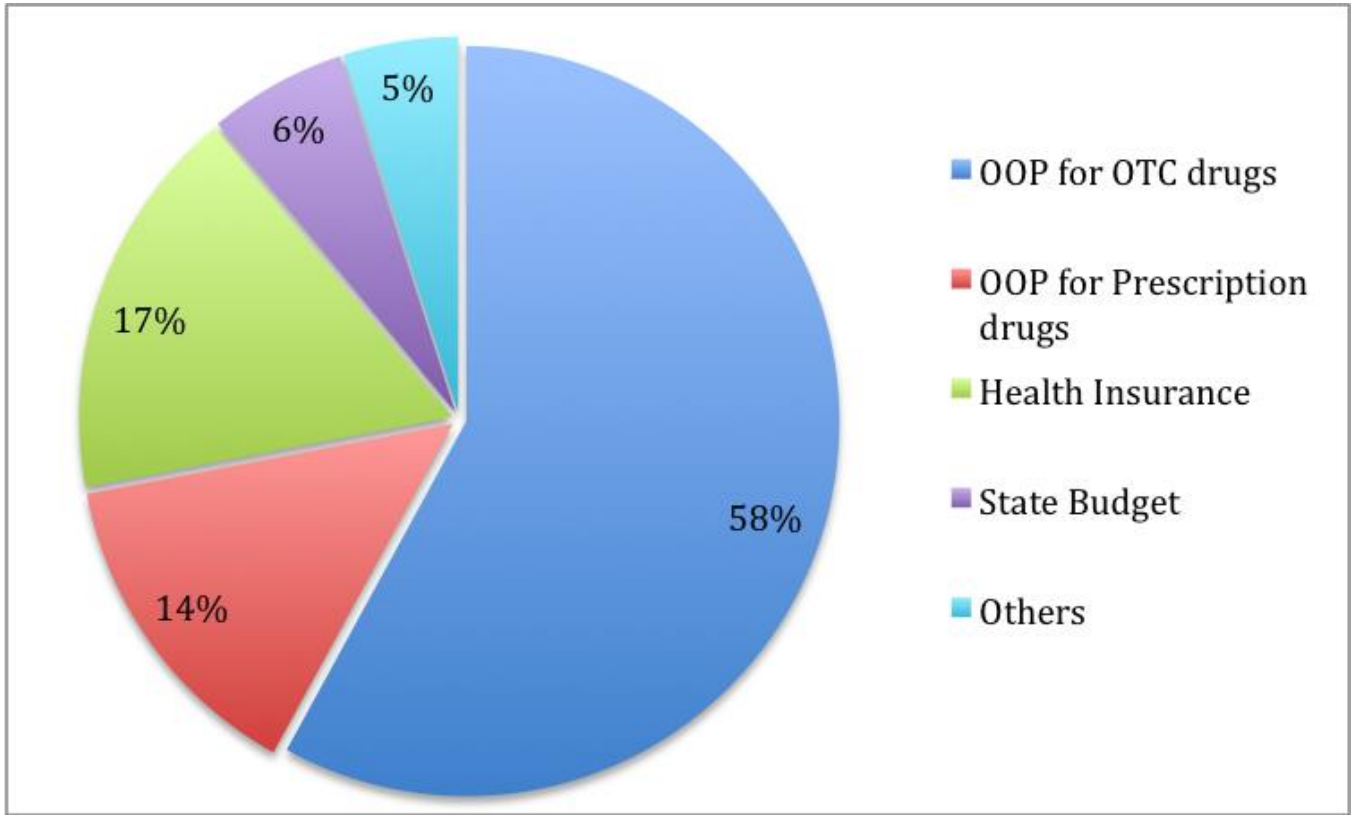
- Broaden of patent standard object (Article 8.2) to:
  - Plants and Animals
  - **Prevention, diagnostic and treatment methods to human and animals.**
- This would
  - Increase healthcare cost (pay for patent cost)
  - Against ethical value

Other TPP provisions

- Elimination of pre-grant opposition (Article 8.7)
  - This tool allows third parties to provide patent office with patentability or merits of a patent application
- This would
  - Undermine the ability of developing countries to ensure quality and efficiency of patent examination process.
  - Threatens access to market rights of generics manufacturers, hinders competitiveness of generics

Impacts of Medicine Price Increase

- On National Health Insurance
- On Out of Pocket Payment



Source: DAV, MOH

Impacts of High Medicine Price

- On Health Insurance
  - Currently, the National Health Insurance is facing challenges in controlling medicine expenditure proportion (60%) in hospital expenditures.
  - The HI fund is unable to set medicine prices or limited capacity to mandate rational use
  - The HI fund faced negative balance from 2006 to 2008. From 2009, insignificant positive balance has been maintained.
- In case of medicine price increase, National Health Insurance fund would have to
  - Increase Premium
  - Reduce Benefit Package

  Would eventually influence HI Universal Coverage target

Impacts of High Medicine Price (cont')

- Out of Pocket Payment for Medicines for several chronic diseases would substantially influence access to quality health services of patients, namely
  - HIV/AIDS
  - Hepatitis B and C

Impacts of High Medicine Price (cont')

- ARV for HIV/AIDS
  - In 2010, 73.4% of total expenditure for HIV/AIDS in Vietnam was funded by international donors
  - However, as Vietnam becomes a middle income country, foreign assistance will decline – including from US PEPFAR
  - National health insurance fund is meant to cover ARV costs, but it is not yet clear if sufficient funding is secured in the future

TPP Impacts on ARV

- **Prolong pharmaceutical patent protection** (20 years + patent application examination time)
- Limit generics registration due to **requests of patented medicines' clinical data protection** (+ 5-11 years)
- **Evergreening tricks** (+7-10 years)

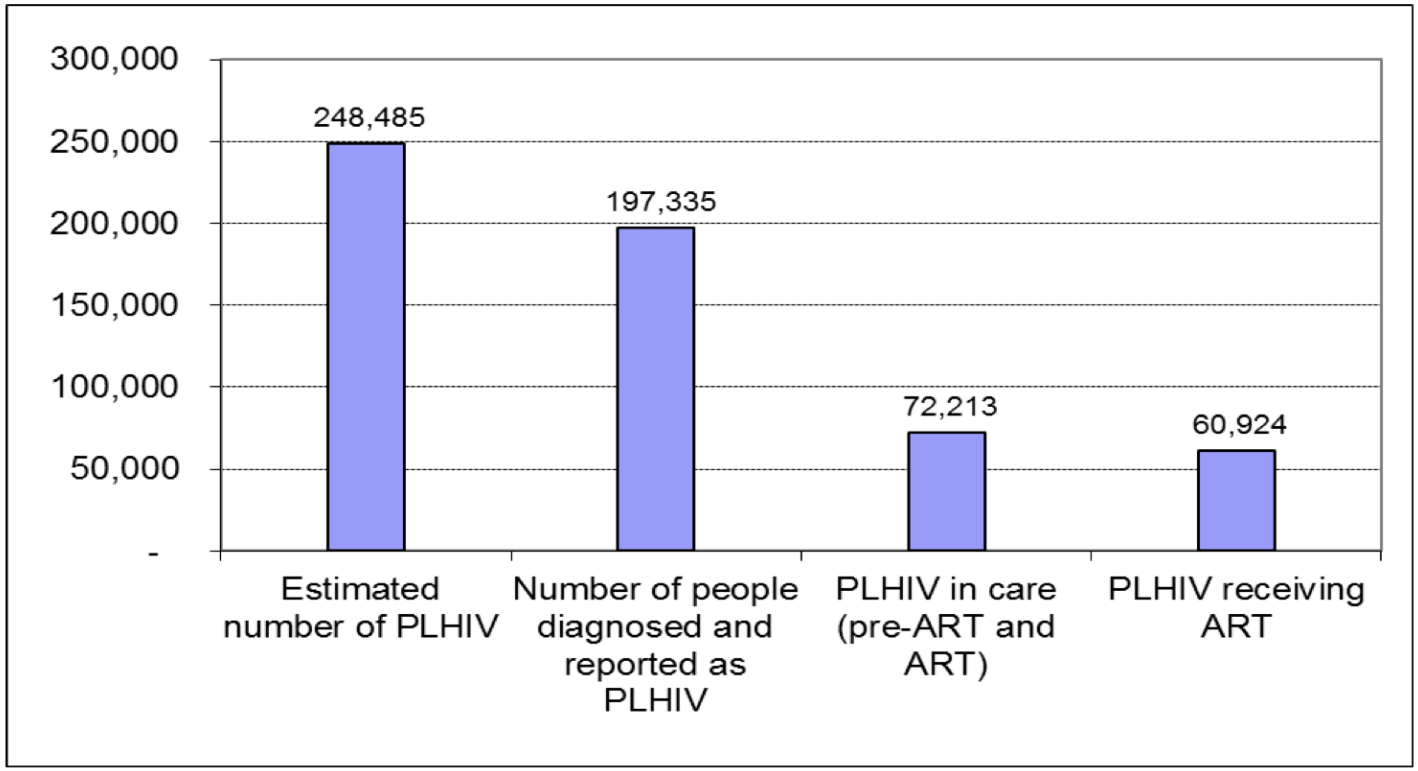
TPP Impacts on ARV

- ARV for H
  - First line … nd USD 312 for subseq… ne cost substantially higher (USD … for Lopinavir/Ritonavir)
  - Majority of patients receive 1st line medicines. Approximately 2.7% of patients are receiving 2nd and 3rd line medicines. Those number is expected to increase in the future due to treatment failure
  - First line medicines IP enforcement is not applicable in Vietnam by holders, thus generics can be imported and/or produced locally however 2nd and 3rd line medicines situation is not.

Already benefited from Abbot special policy for developing countries regardless of middle income country status. Otherwise, 1000 USD pppy

HIV/AIDS: significant burden remains

Figure 22: Cascade of HIV diagnosis, treatment and care in Viet Nam (2011)



Source: Number of people diagnosed and reported as living with HIV (case reporting system); PLHIV in care and PLHIV receiving ART (Programme Monitoring Routine Reporting System); estimated number of PLHIV (EPP 2011 preliminary results). VAAC, Ministry of Health.

TPP Impacts on ARV

- **No compulsory license issuance** during **data exclusivity term**
- **ARV second line generics would not be manufactured in Vietnam** due to **prolonged patent protection**

Impacts of Medicine Price (cont')

- Medicines for Hepatitis B and C
  - Prevalence: Hep B anywhere from 20-30%; Hep C probably from 1.7% to 4.3%
  - In 2008, cost of treatment and addressing complications of Hep B would in 4.4 billion USD if patients were treated in Vietnam. 75% of treatment cost is OOP meaning many patients go without full treatment. Chronic HBV infection cost on average 450 USD per year, and carcinoma cost 1880 USD per year
  - Cost of Hepatitis C treatment is very expensive – 10,000 USD for 48 weeks of treatment
  - Government could improve prices through direct negotiations for pharmaceutical price negotiations

Cost of Hepatitis C treatment drugs as working days

Agent/ Dose	Medicine name	Manufacturer	Origin	Unit	Price/unit VND	Treatment cost VND	No of working day
Interferon 3 MIU	Roferon A Inj. 3MIU/ 0,5ml	Roche	Swiss	Tube	447300	64411200	1288
Interferon 3 MIU	Superferon 3MIU/ml	IVAC	Vietnam	Bottle	210000	30240000	604
Interferon 3 MIU	Heberon Alfa R 3M	Heber Biotec S.A	Cuba	Bottle	220400	31737600	635
RIBAVIRIN 200mg	Rebetol Cap 200 mg 70's	Schering-Plough	USA	Tablet	50214	84359520	1687
RIBAVIRIN 500 mg	Flazol 500	SPM	Vietnam	Tablet	9800	6585600	132
RIBAVIRIN 500mg	Syntervir 500	SYNMEDIC LABORATORIES	India	Tablet	10200	6854400	137

Source: HSPH – Oxfam research on prospective impacts on TPPA on A2M in Vietnam 2012

Conclusions

- Monopoly increases medicine prices and reduce accessibility to medicines of the people, especially of highly vulnerable groups (HIV/AIDS, tuberculosis, bacteria/virus infected, and chronic diseases: cardiovascular, diabetes, etc.)

- IP related provisions in TPP proposal deplete and delay opportunities for local pharmaceutical to exploit expired APIs which lead to delays in bringing generics to market.

Recommendations

- "TRIP+ is **inappropriate** for public health benefits of Vietnamese people at the **present** and in the **future,** therefore, TRIP+ pharmaceuticals related provisions in TPP Agreement should be **strongly limited.**"
- "Vietnam pharmaceutical business community and the people expect the negotiation delegates to have **strong negotiating position** to ensure that if **TRIP+ provisions, if passed, are minimized in TPP Agreement**"

Recommendations

- Role of:
  - The legislature authorities,
  - Related Ministries and Industries to Public Health goals,
  - Civil society- professional organizations.
- "Find sound negotiating strategies to balance benefits vs risks, positive vs negative impacts among all economic and social aspects"

Recommendations

• Local pharmaceutical industry are strongly encouraged to

– Understand throughout IPs-related provisions in TPP,

– Enhance science and technology capacity,

– Exploit IPs legally and protect our own IPs to develop local manufacturing industry,

to provide high quality and affordable local manufactured drugs for public health goals.

THANK YOU VERY MUCH!