Access to DAAs from an Asian perspective

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Outline

- Thoughts from three days
- Treatment provision in the region
- Direct-acting antivirals (DAAs) in the region
- Pricing and availability
- How governments & people are accessing DAAs
- Conclusion
- Considerations

Thoughts from last three days

- PWID can adhere and SVR as good.
- The better the drugs the lower the re-infection
- SVR brings positive changes in life
- DAAs are the way forward: Treatment as Prevention
- Diagnostics- How do we find 180 million or 10 million PWID?
- Elimination by 2030?
- Pricing- is this an issue?
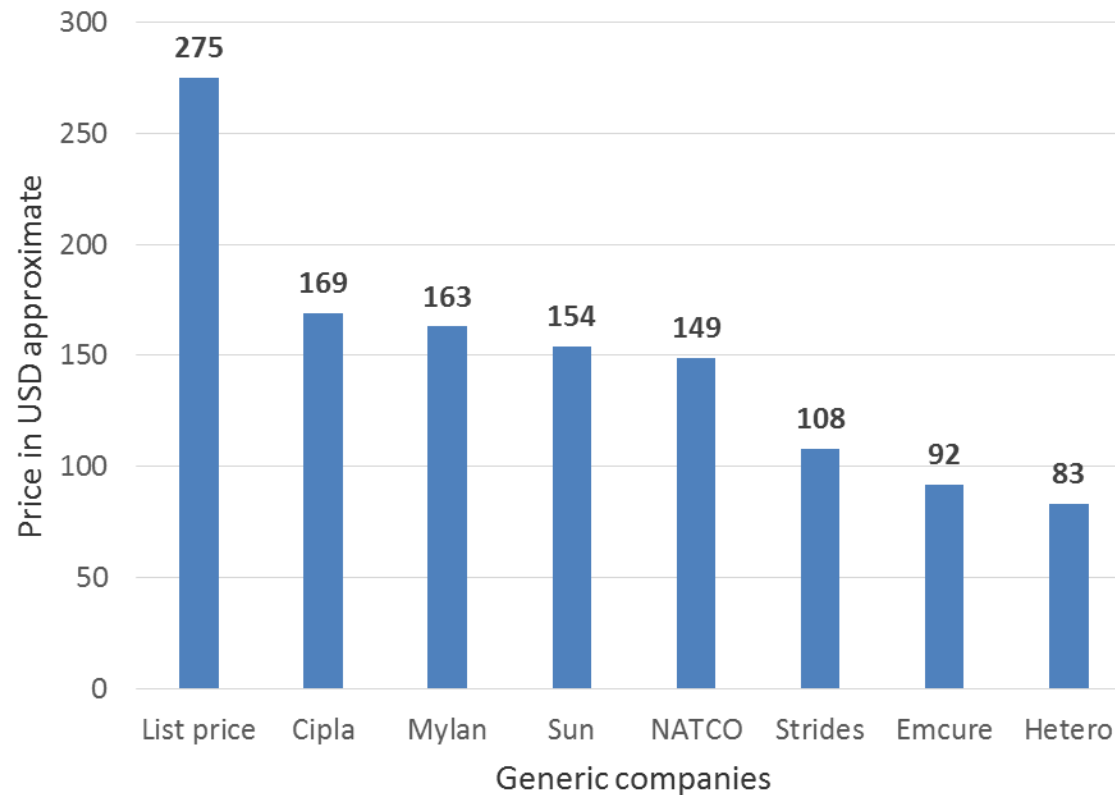- Western Europe: only 4 countries with no criteria for Tx?
- Special interventions?

Government treatment programs in the region for hepatitis C

- **India:** Covered in certain states for specific populations

- **Indonesia:** Covered "100%" under national health insurance using Peg-IFN

- **Thailand:** Provided under Universal Health Care using Peg-IFN

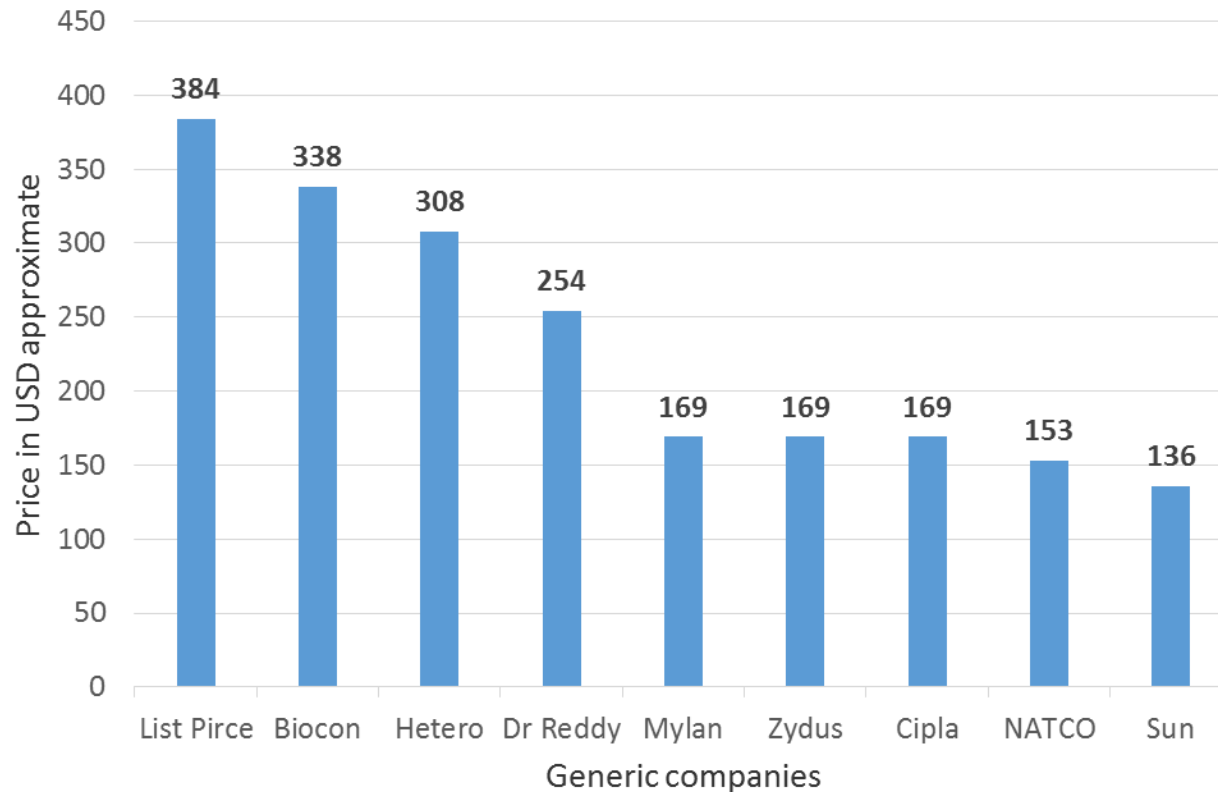- **Vietnam:** Reimbursement up to 30% on Peg-IFN cost

DAAs in the region

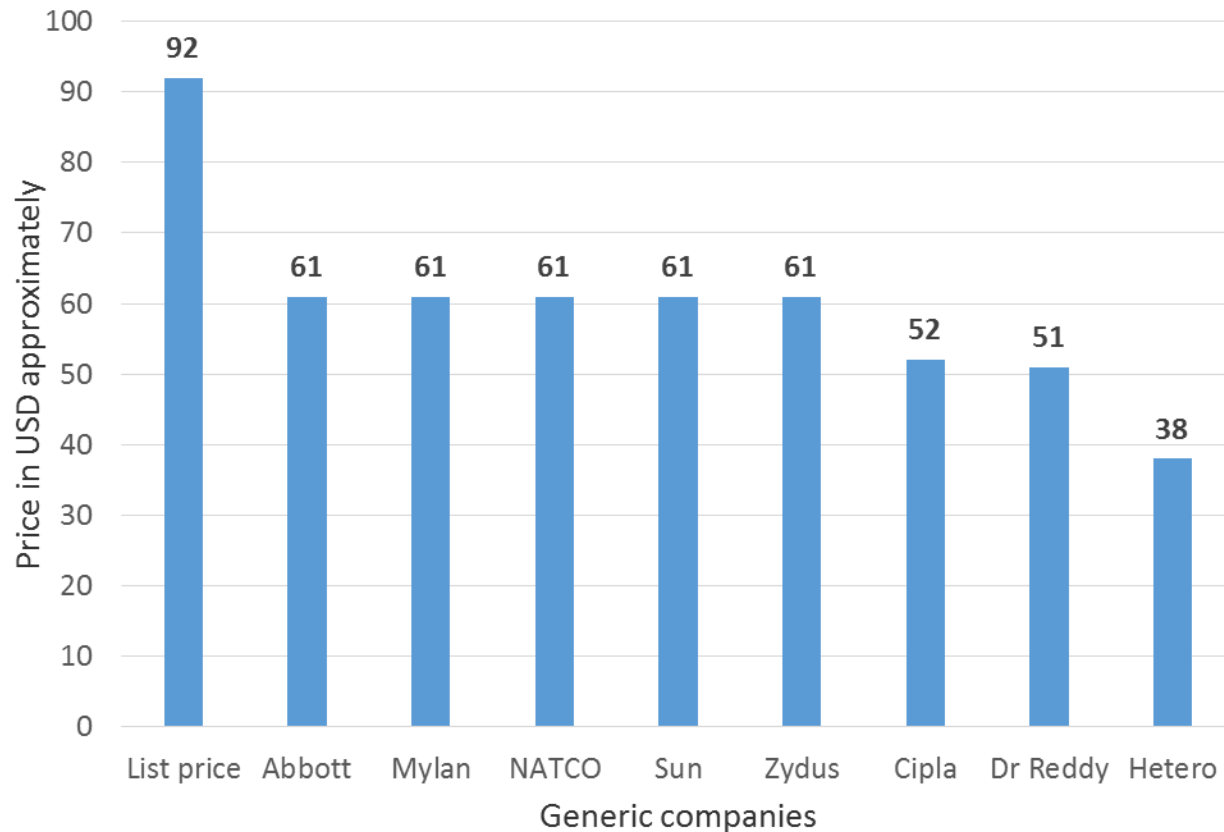| Country	Medicines	Status
Thailand	Sovaldi & Daklinza	Registration for both approved in August 2015
Cambodia	Sofosbuvir & Ledipasvir + sofosbuvir	• Generics approved in 2015 and 2016 beginning
Pakistan	Sofosbuvir (Sovaldi)	• Registration approved in February 2015 • February 2016, marketing approval to 9 generic companies.
Philippines	Sofosbuvir (Sovaldi)	• Registration approved in October 2015
Indonesia	Sofosbuvir Ledipasvir + sofosbuvir	• Sovaldi and generic sofosbuvir approved • Other DAAs in process of special import
Bangladesh	Sofosbuvir, daclatasvir Ledipasvir + sofosbuvir	• All generic forms available including sof+dac co-formulated tablets
Vietnam	Sofosbuvir ledipasvir + sofosbuvir	• Sovaldi filed for registration in January 2016 • Need for local trial is an issue • Generic sofosbuvir and Sof+ldv available under special import
Malaysia	ombitasvir, paritaprevir/ ritonavir ± dasabuvir (Vikierax) Sovaldi	• Registration approved in June 2015 • Available at approximate 13300 USD/ month • Registered in September 2015, DE uptil 2018
Myanmar	Sofosbuvir	• Generics approved
Nepal	Sofosbuvir, daclatasvir ledipasvir + sofosbuvir	• Generic forms available
India	Sofosbuvir	• Sovaldi available • 15 companies marketing generic versions
	ledipasvir + sofosbuvir	• 10 companies marketing generic versions
	Daclatasvir	10 companies marketing generic versions

Generic sofosbuvir pricing in India

- 15 companies now markets licensed sofosbuvir
- Lowest price is 83 USD per bottle

Generic sofosbuvir/ledipasvir pricing in India

- 10 companies marketing licensed sofosbuvir and ledipasvir co-formulation in India
- Lowest price is 136 USD per bottle

Generic daclatasvir pricing in India

- 10 companies marketing licensed daclatasvir in India
- Lowest price is 38 USD per bottle

How governments & people are accessing DAAs

- **State/Provincial programs**
- **At hospital level**
  - Special import license
- **At patient level**
  - "Named patient import"
  - Buyers' clubs
  - Large pharmacies in India

Conclusion

- Government programs begun but need to expand-280 USD (SOF+DAC) and 320 USD (SOF+LDV) for 12 weeks

- Patient groups: 363 USD for 12 weeks SOF+DAC and 408 USD for SOF+LDV- 12 weeks

- Some physicians: 325 USD/12 wks with diagnostics

- Patients are slowly being able to access treatment with generic DAAs

- Broader access will first require registration of the DAAs by national regulatory agencies

- Generics works: ILC Barcelona, Glasgow, CROI

- Pricing will need to become even lower if national programs are expected to adopt large-scale treatment programs

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Please consider

- We have lost 1233 people in these three days

- Many across the world continue to wait

- Are we willing to assist in monitoring the patients?

- As researchers, physicians, can we talk about how much our health system can absorb at current cost?

- Is our governments or ourselves negotiating enough with the industry?

- What special interventions for those who needs and wants to be on treatment?

Thank you