

# Drug Regulatory Authority of Pakistan (DRAP)



Performance Evaluation

Ministry of National Health Services, Coordination and Regulation  
(MNHSCR)



Drug Regulatory Authority of  
Pakistan (DRAP)

Licensing

Medical  
Devices

Pharmacy  
Services

Costing  
and  
Pricing

Administra  
tion

Quality  
Assurance

Biological  
Drugs

Health  
and OTC

MIS

Legal  
Matters

Controlled  
Drugs

Budget  
and  
Accounts

# Criterion for Analysis



- ❧ Quality of drugs and drug dispensing
- ❧ Consistency of Policies
- ❧ Ease of conducting/doing business
- ❧ Research and Development (R&D), and its supporting infrastructure
- ❧ Attracting Investment
- ❧ Are consumers better off than before?

# Quality of drugs and drug dispensing



- Issues pertaining to sub-standard medicines old, causing deaths
- Issues of drug malfeasance still persist

Year	Drug Recalls	Samples Tested	Substandard	Spurious	Unregistered	False Warranty	Misbranded Drugs
2015		43,933	538	252			
2016		74,071	813	97			
2017		53,371	446	63			
2018		41,435	2,527	42	497		
2019		51,194	490		587	1,710	222
2020	34						
2021	7						

- Official data reflects a comparatively better picture, but based primarily on batches bought for official health facilities
- DTLs and BE labs few, and not of international quality
- Drug dispensing techniques and quality still questionable- major portion of pharmacies still running without a quality pharmacist



# Consistency of Policies



- ❧ Policies being run, and modified, through SROs still a dominant mode of day-to-day operations
- ❧ Little, if any, improvement compared to pre-DRAP days
- ❧ E.g- April 2020 notification- holders of valid Drug Manufacturing Licenses (DML) to manufacture hand sanitizers
- ❧ Similar notifications- 10<sup>th</sup>, 14<sup>th</sup> and 17<sup>th</sup> April 2020
- ❧ 21<sup>st</sup> May 2020- all four notifications cancelled under Cabinet's directive! No reason mentioned

# Ease of conducting/doing business



## ❧ Considerable challenges still persist

- ❧ **Pricing-** Still the most contentious issue
- ❧ From 'Price Freeze' to new drug policies (2015 and 2018)
- ❧ Despite changes, pricing still a Govt. level prerogative, with Cabinet's decision mandatory
- ❧ Controlled prices- black market expansion, non-production of essential drugs, etc.
- ❧ **Production-** Large number of steps required to set up and conduct business
- ❧ Can take anywhere b/w 3 to 4 years to get approval for production plant
- ❧ Drug registration and approval process can still take many years
- ❧ Contract Manufacturing- \$11 billion in India; not even \$5 million in Pakistan
- ❧ 13 basic steps involved in contract manufacturing
- ❧ **Charges and Taxes-** Littany of charges, for work performed by DRAP or getting approval
- ❧ Large number of taxes on product, including FED, VAT, Import duty, Income tax, clearing charges, port charges, etc.

# Research and Development (R&D), and its supporting infrastructure

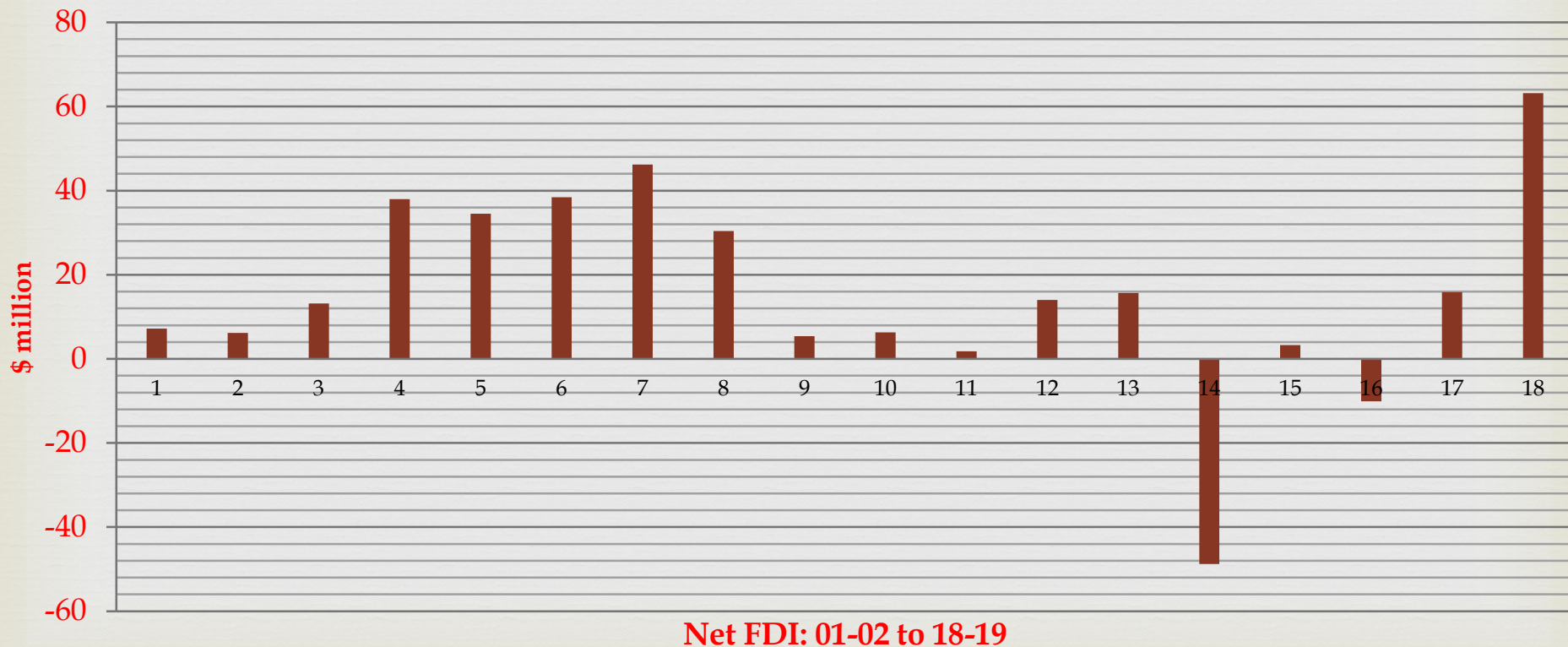


- ❧ Without R&D, new and effective drugs/ variants not possible
- ❧ But R&D needs supporting infrastructure and policies
- ❧ Both are non-existent in Pakistan
- ❧ No FDA approved lab; no top DTL; few BE labs
- ❧ Govt. charging tax equal to 1 percent of industry gross sales
- ❧ Where did all the money go?
- ❧ No research
  - ❧ 95 percent APIs have to be imported
  - ❧ Until COVID-19 struck, not a single vaccine manufactured/assembled
  - ❧ Industry doing little or no research since Govt. has taken it upon itself
  - ❧ New API research expensive endeavor; industry unwilling to indulge b/c copyright laws weak

# Attracting Investment



On net, only \$280 million received as FDI by the pharmaceutical sector in almost 2 decades

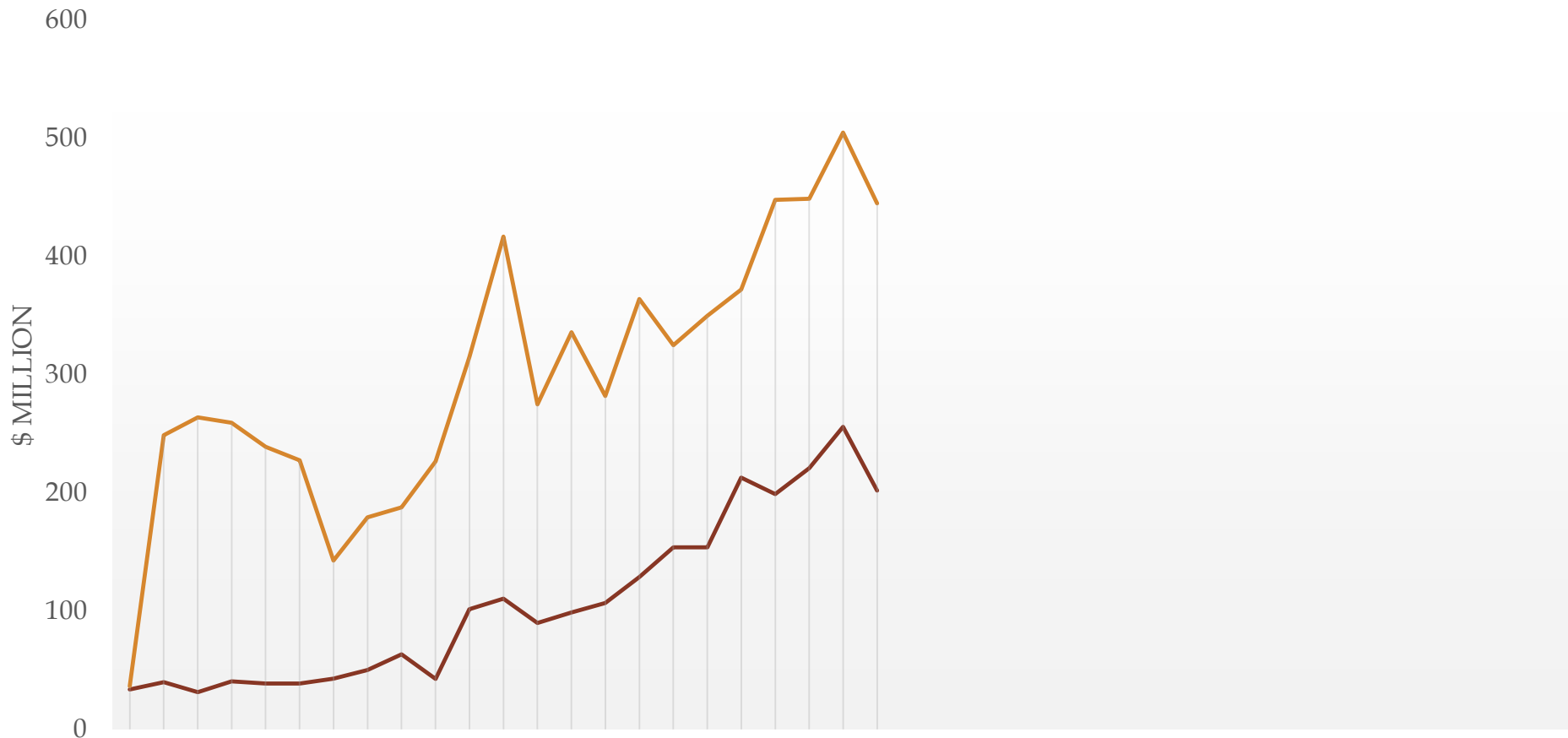




# Attracting Investment



Exports vs Imports: 1996-97 to 2018-19



# Are consumers better off than before?



## ❧ OOP expenses on drugs

Year	Expenses on drugs as percentage of total health expenses	Per Capita expense on drugs
2004	25	
2008	56	Rs. 900
2010	56	Rs. 920
2012	50	Rs. 822
2014	53	Rs. 1,338
2016	50	Rs. 1,400
2018	51	Rs. 1,580

❧ Black market in drugs still very active

❧ Drug shortages still a norm

❧ Pharmacovigilance unsatisfactory and pharmacy practices still lack quality

# The Aggregate Sum



- ❧ 2001 National Health Policy (NHP) envisaged major improvements over previous regulatory practices
- ❧ Two decades on, overall improvement but most of the challenges still remain
- ❧ Would need a major shift in thinking about regulation to optimize upon the potential of the industry



Thank you