



MUTUAL RELIANCE MECHANISM

FOR FACILITATED ACCESS OF MEDICAL
PRODUCTS

IDMA EXPECTATIONS

Dr. Viranchi Shah

National President – IDMA

21 Sep. 2022

Why INDIA

1st

India leads the world

No 1 Generic Drug Manufacturer
Amongst top 5 net exporters in
terms of net BoP
Most affordable source of quality
pharmaceuticals
Highest SRA approved site



Leadership position

Third largest manufacturer of
formulations
11th largest manufacturer in terms
of value
Maximum number of ANDA
approvals (40%) in US are from
Indian companies



Size and Scale

Around \$50 Bn USD Industry
with equal share of Domestic &
Export market
India's exports in FY 21-22 is USD
24.6 Bn

Why INDIA



Quality Credentials

- ~700 US FDA Sites. Highest in any country outside the US
- ~650 EU GMP certified sites
- 1800+ WHO GMP certified units
- 10500+ Manufacturing sites
- 3000+ Manufacturers
- ~60000 Formulations



Exports

- Supply essential medicines to over 200 countries
- Largest supplier to UN and WHO under various procurement schemes
- ~45% of exports goes to US and EU



Government Initiatives

- Constantly improving EODB
- Product Linked Incentives
- Aysuhman Bharat
- Jan Aushadhi
- Atmanirbhar Bharat

Why INDIA



Availability

- > 200 countries
- Largest WHO & UN vendor
- R&D, API, FDFs
- Sterile, Non-Sterile, Oral – Solids & Liquids, Ointments, Ophthalmic
- APIs, FDFs, Drugs, Vaccines, Serra, Supplements, Herbs



Affordability



Source: 2019 Medicine Price Index compiled by Medbelle
Read more at:

http://timesofindia.indiatimes.com/articleshow/72196203.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cpps

t



Quality

- 1800 + sites have WHO GMP
- Most regulated and accountable industry
- Very high number of sites with regulatory approvals- highest in developing world
- National Survey of almost 50000 samples showed NSQ and Fake/Falsified/ Spurious results to be below global average

IDMA
Since 1961



THE VOICE OF THE NATIONAL
PHARMACEUTICAL SECTOR

1100+
Manufacturers

8 State
Boards

Headquarters
- Mumbai
Delhi Office

Gujarat ,Haryana,
Himachal Pradesh &
Uttarakhand,
Karnataka,
Madhya Pradesh,
Tamil Nadu, Kerala &
Puducherry,
Telangana,
West Bengal

IDMA
Since 1961



THE VOICE OF THE NATIONAL
PHARMACEUTICAL SECTOR

24 TECHNICAL COMMITTEES

1. AECMP
2. Bulk Drugs
3. Contract Manufacturing
4. Digital Initiatives
5. Employee Relations & Development
6. AECMP

7. Excise & Taxation
8. Finance & Administration
9. I P R
10. Industry Trade Matters
11. Industry Institutes Interaction
12. International Trade

13. Marketing
14. Medical
15. Membership and Constitution
16. MSME
17. NDPS
18. Nutraceuticals

19. Pricing / Consumer Affairs
20. Public Relations
21. Publications
22. Quality Management & Technical
23. Regulatory Affairs
24. Research & D and Innovation

IDMA
Since 1961



**THE VOICE OF THE NATIONAL
PHARMACEUTICAL SECTOR**

INTERNATIONAL CO-OPERATION

MoUs :

- ❖ Toyoma Pharmaceutical Association (TPA), Japan
- ❖ National Chamber of Pharmaceutical Manufacturers, Sri Lanka
- ❖ China Pharmaceutical Industry Association (CPIA)

UNIDO:

Part of the on-going UNIDO/GoI study titled "National Manufacturing Innovation Survey 2021"

INTERACTIONS:

- US FDA India & US Offices
- EDQM
- USP – India & US Office
- IPC
- ANVISA (Brazil)
- Ethiopia FDA
- Kenya FDA
- FDAC Nigeria

SUPPORT TO:

- API
- FDF
- Drugs
- Nutraceuticals
- Vaccines
- Environment related issues
- Stakeholder consultation

IDMA
Since 1961



**THE VOICE OF THE NATIONAL
PHARMACEUTICAL SECTOR**

WHO

1. Presentation made on 'Pharmaceutical Perspective on Current Status of Trade of Medical Products, Regulation and Suggestions on Policies and Procedures to improve quality and for Regional Cooperation' during Regional meeting for Promoting Cooperation for Regulations in Trade of Medical Products, held during 22-24 September 2015 at New Delhi.

2. Combating Antimicrobial Resistance: Public Health Challenges and Priority, 23-25 February, 2016

3. 1st World Conference on Access to Medical Products and International Laws for Trade and Health, 21-23 November, 2017, New Delhi (IDMA appearing in 'Acknowledgements')

4. Part of the First World conference on Access to Medical Products achieving the SDGs 2030, October 2018, New Delhi – (IDMA appearing in 'Acknowledgements')

5. Part of the Second World conference on Access to Medical Products achieving the SDGs 2030, November 2019, New Delhi (IDMA appearing in 'Acknowledgements')

IDMA
Since 1961



**THE VOICE OF THE NATIONAL
PHARMACEUTICAL SECTOR**

IDMA THEMES

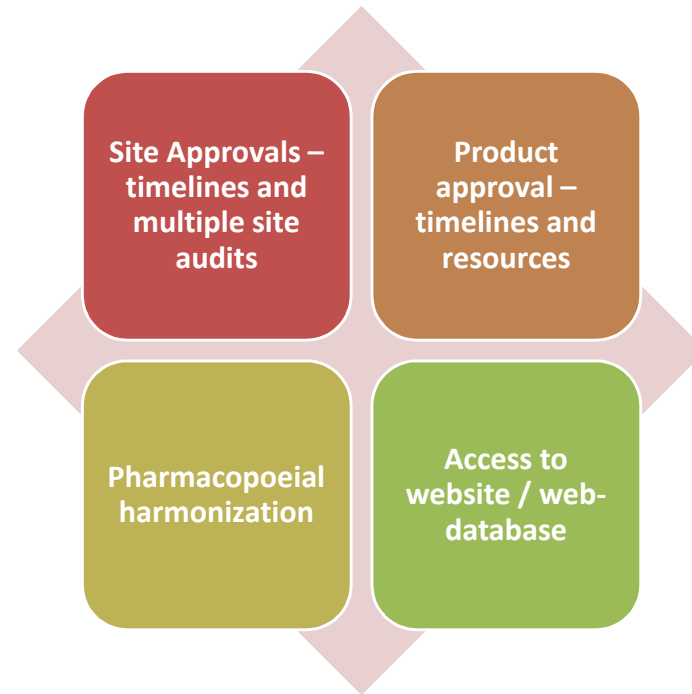
IDMA Themes in the last decade:

- Indian Pharma – Global Health Care: 2022
- Indian APIs and Formulations for Global Healthcare: 2020-2021
- Indian Pharmaceuticals – Nation’s Pride: 2017-2019
- Pharmaceuticals for Patient Benefit: 2016
- If it is Pharmaceuticals it is India: 2015
- Indian Pharmaceuticals for Global Health: 2014
- Affordable Efficacious Medicines All Roads lead to India: 2013
- Indian Pharma Inc. Creating a Global impact: 2012
- Healthcare of People Always in all Ways: 2011
- India – The Generics Pharma Capital of the World: 2010
- India’s Quality Affordable Generics For Global Healthcare: 2009

Mutual Recognition

The way forward

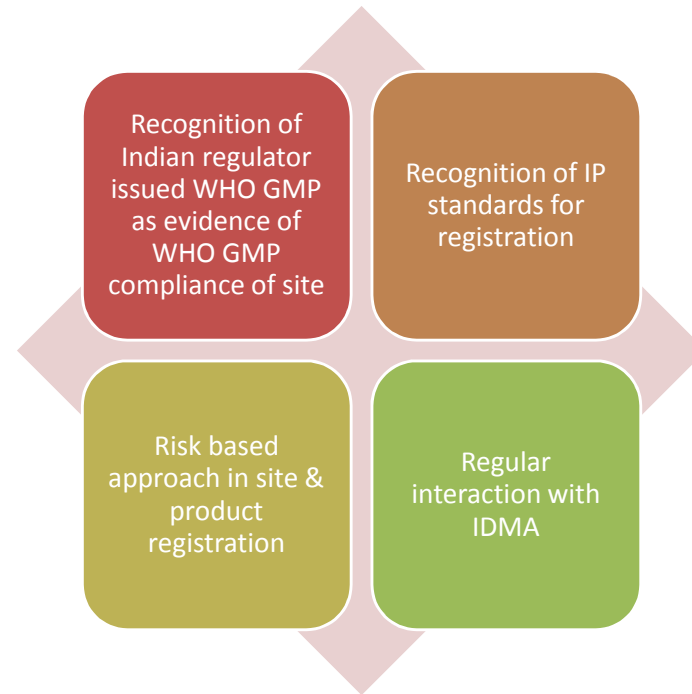
Areas of concern- IDMA



Mutual Recognition

The way forward

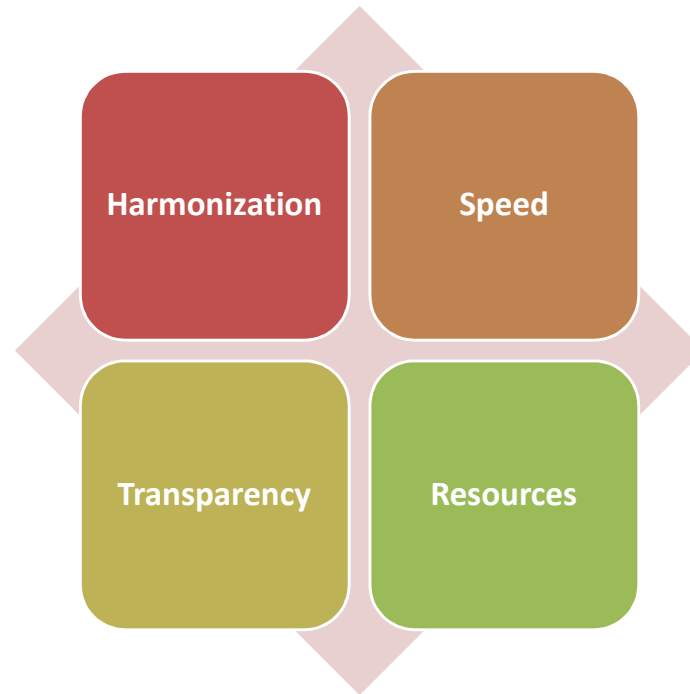
IDMA Expectations



Mutual Recognition

The way forward

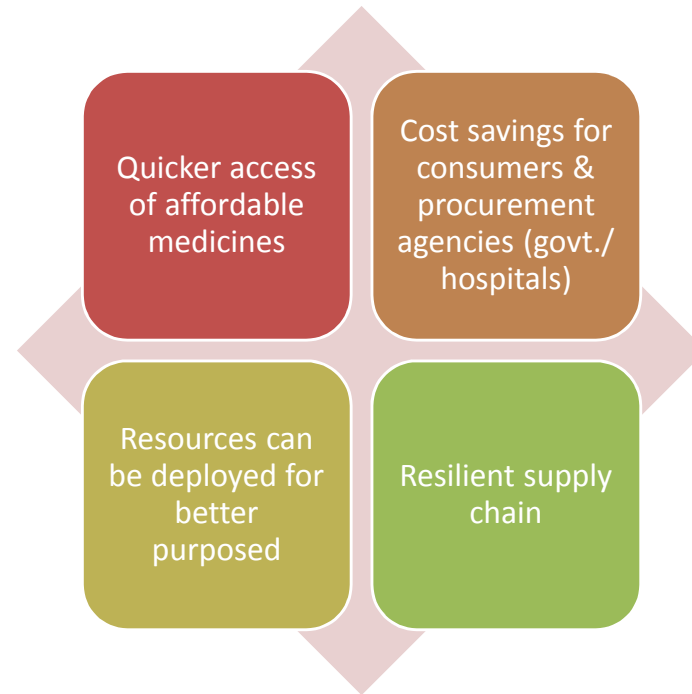
Benefits



Mutual Recognition

The way forward

Benefits to all the stakeholders



Mutual Recognition

The way forward

Mutual recognition of WHO GMP



Thank you!

Feel free to approach me
if you have any questions.



Dr. Viranchi Shah
National President - IDMA
president@idmaindia.com

Opinions expressed in this presentation are my personal opinions and not attributed to the organizations or the companies that I represent.

Some data are based on media news, IDMA database, Pharmexcil database and internet based sources.

While care has been taken to verify the authenticity and accuracy of data presented, I do not claim them to be absolute facts.

