Export Opportunities for SMEs- Incentives

Lakshmi Prasanna
Director-Regulatory Affairs
Pharmexcil

Role of Pharmexcil

FACILITATOR

- *Organises Export Promotional events and Trade delegations*
- *Industry's Voice* - Represents issues with concerned Agencies

ADVISOR

- *Make suggestions to Govt. of India & Regulators on policy issues relating to Pharma exports*

EDUCATE

- *Market / Regulatory reports of countries*
- *Importers / Distributors in overseas countries*

India's Pharma Credentials

India provides generic medicines to more than 200 countries.

9 out of 25 Global Generic companies are from India

Over **60%** Exports to Highly Regulated Markets

90% of WHO Pre-Qualified API's are sourced from India

65-70% of WHO's vaccine requirements are sourced from India

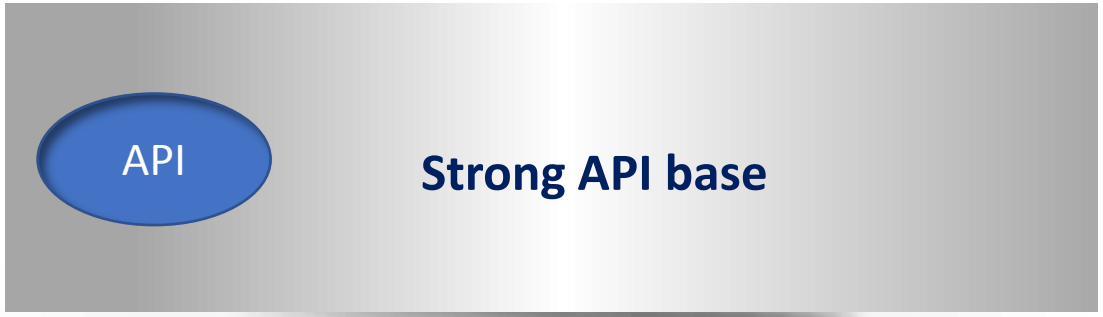
No. of USFDA approved sites: 703 (as of Apr 2023)

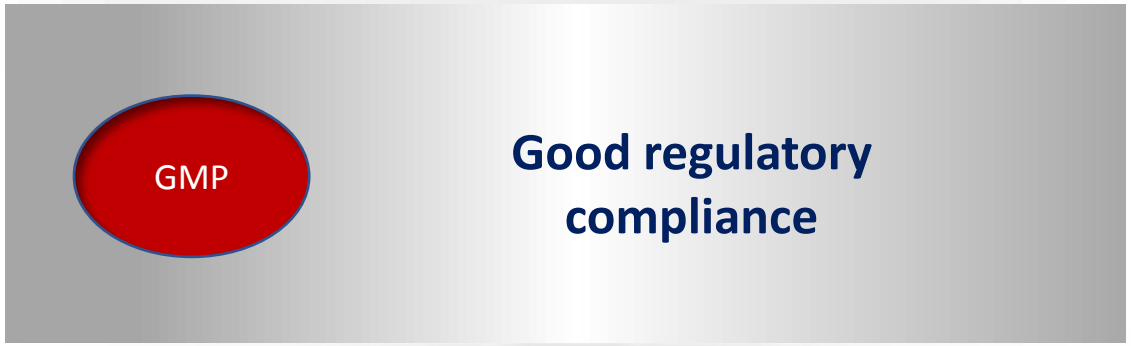
No. of ANDA Market Authorizations secured by Indian companies: 6316 (as on Apr 2023)

No. of EUGMP complied Units: 484 (as of Dec 2022)

Developed indigenous vaccines for Covid-19

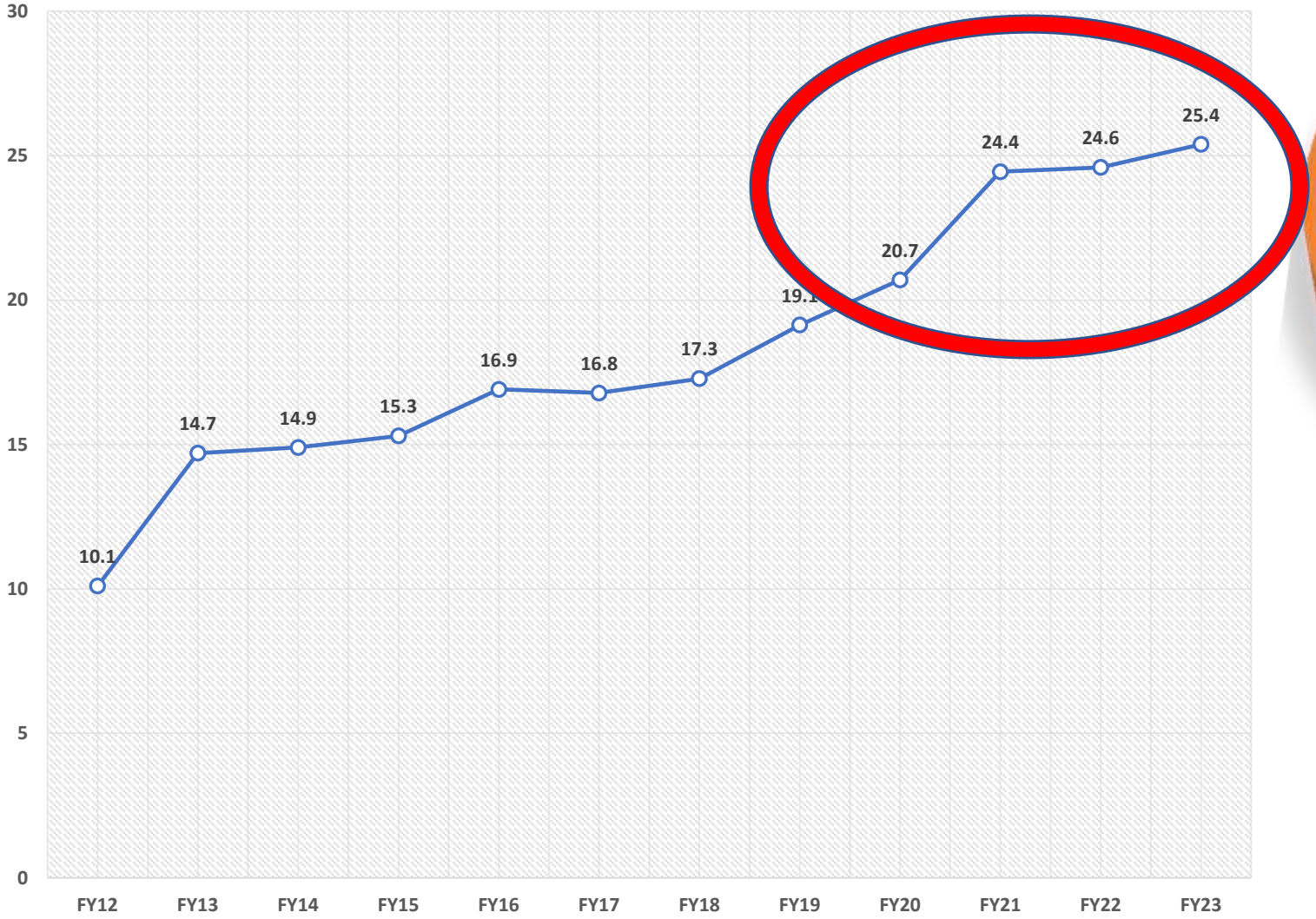
Indian Pharmaceutical Industry has the Advantage of Backward Integration



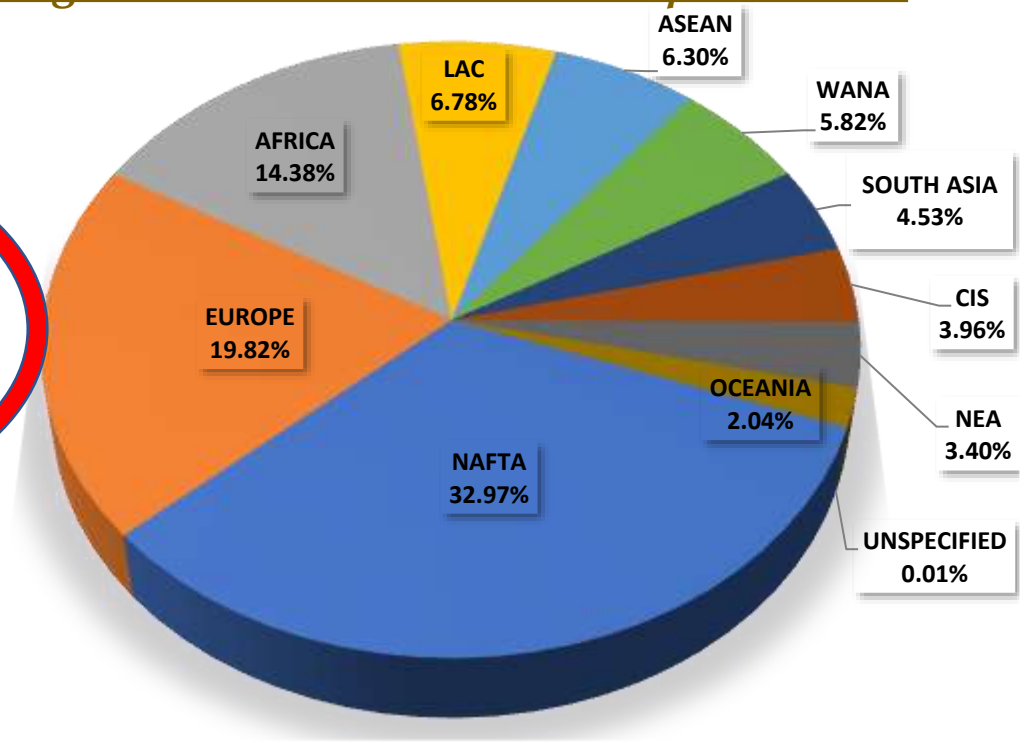


Pharma Exports

Pharma Exports from India (USD in bn)



Region wise India's Pharma Exports FY 23



Top 10 Export Destinations, FY23

1. USA
2. Belgium
3. South Africa
4. U K
5. Brazil
6. Netherland
7. Russia
8. France
9. Germany
10. Nigeria

Changing scenario

- Maximising capacity
- Assuring quality
- Offering affordability
- Coping up with regulatory capability

Post COVID scenario for MSME

Change in COST

Change in Freight

Erratic demand pattern

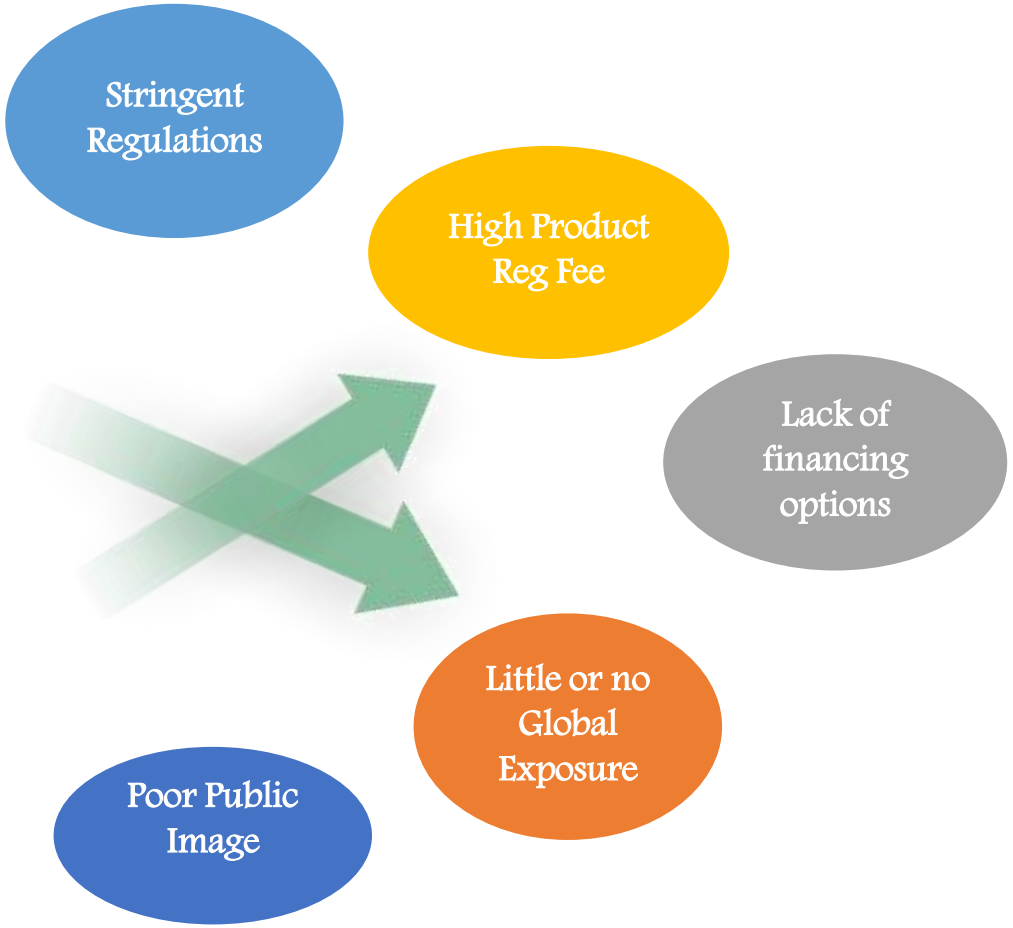
Regulatory delay

Uncertainty of recovery of payment

SME– Backbone of Pharma Industry

SME in Exports ?

CHALLENGES



EMERGING MARKET REGIONS

Latin America

Africa and Middle East

Russia and CIS

Asia Pacific

LATIN AMERICA MARKET OVERVIEW

- Have approximately **650 million** people lived in LATAM.
- **8.28%** of the total world population.

- The LA pharma market which accounts **4.89 % share in the global market is with USD 69.65 bn in 2022**.

- The LA Generic market which was valued at USD 17.96 bn in 2022 holds a share of 4.25 % in the global generic market. The generic market in LA is expected to be USD 16.96 bn.

- **Exports FY23: USD 1.72 bn | Apr-Sep FY24: USD 915.67 mn**

➢ LA has become one of the most attractive locations for international clinical trials. LA supports about 10% of clinical research worldwide. According to the Pan American Health Organization (PAHO), 202 (10.2 percent) of the global COVID-19 clinical trials were conducted in Latin America.

➢ Brazil, Argentina, Colombia, Chile, Peru and Venezuela leading markets

LATIN AMERICA – REGULATORY REQUIREMENTS

	Brazil (ANVISA)	Argentina (ANMAT)	Chile (ISP) and Colombia (INVIMA)	Mexico (COFEPRIS)	Peru (DIGEMID) and Venezuela (INHRR)
Dossier Format	**CTD**	**Country specific**	**CTD – electronic and paper**	**Country specific**	**Country specific**
Registration fees	5100 Rias	2300 Rias	USD 2231 – Chile USD 150 - Colombia	60,100 Mexican pesos 160,000 pesos (Fast Track)	USD 125 - 175
Labelling	Portuguese	Spanish	Spanish	Spanish	Spanish
Documents	COPP – Country Specific Stability at 30/75. Repetition of release testing during commercialization	COPP – Country Specific Stability at 30/75. Repetition of release testing during commercialization	COPP – Country Specific Stability at 30/75. Repetition of release testing during Commercialization. Not required at Colombia	COPP – Country Specific Stability at 25/60 Repetition of release testing during commercialization	COPP – Country Specific Stability at 25/60. Performed by certified laboratory as part of registration at Venezuela

RUSSIA AND CIS MARKET OVERVIEW

Russia and CIS markets have 4% of global share- $36.97Bn) share with 246 mn population

Government aiding in Healthcare

India's exports to the CIS region in FY23 was USD 1 bn. During Apr-Sep FY24 was USD 473 mn

RUSSIA AND CIS MARKET

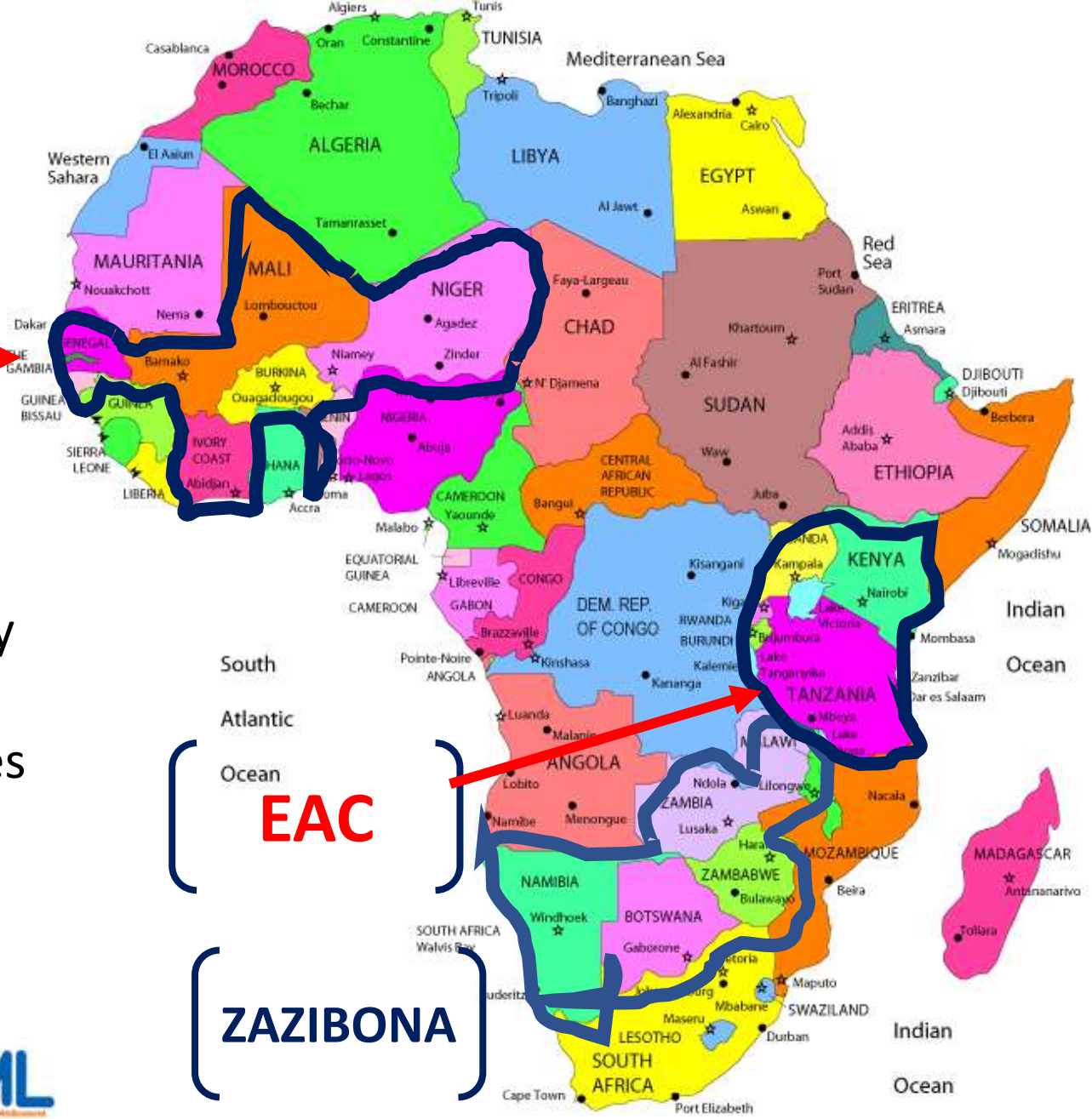
	Armenia, Azerbaijan, Georgia Kyrgyzstan, Moldova Tajikistan, Turkmenistan Mongolia	Belarus, Kazakhstan, Uzbekistan	Russia	Ukraine
Mutual recognition (MR) & WHO Collaborative procedure*	**Armenia, Azerbaijan Georgia (US & EU – MR acceptable) Kyrgyzstan**	**Belarus Kazakhstan Uzbekistan**	**-**	**Ukraine (US & EU – MR acceptable)**
Plant inspection	Not required	Required	Required	Required / Disk audit based on PIC's approval
Labelling	English and French	Russian & Local language	Russian with QP details	Ukrainian
Documents Mfg. lic, GMP, COPP, FSC MFR, PDR, DMF, RM, PM, FP Spec STP &, COAs, PV, AMV. BE required Stability data [3 batch] [Zone II or Zone IV]	Samples: Total 300 + W/S	Additionally, Product lic and FSC (Apostilled) FP samples – quantity required Ref. / working std, HPLC column for 3-time analysis,	Additionally, Product lic and FSC (Apostilled). FP samples - quantity required Ref. / working std, HPLC column for 3-time analysis	Additionally, Product lic and FSC (Apostilled). FP samples - quantity required Ref. / working std, HPLC column for 3-time analysis.

AFRICA OVERVIEW

- Expected to surpass 2 bn within 5 years
- 17% of world's population
- Pharmaceutical market ~ US$ 30 Billions
- Generic market- $13 Bn
- 2.14% of the world's market
- **Exports FY23: USD 3.65 bn | Apr-Sep FY24: USD 1.9bn**
- < 1% of worldwide clinical trials (excluding Israel which is a developed CT market)
- Predicted to increase exponentially in next decade.

Opportunity Cluster Markets

UEMOA



UEMOA is Economic and Monetary Community of West Africa.

The UEMOA is a trade agreement of 8 countries in Western Africa.

All member states comprise a total population of 130.85 million people.

Member countries are:

Benin,Burkina Faso,Guinea Bissau,Ivory Coast,Mali,Niger,Senegal,Togo

Opportunity window
30 Shortlisted countries

Standard Surveillance

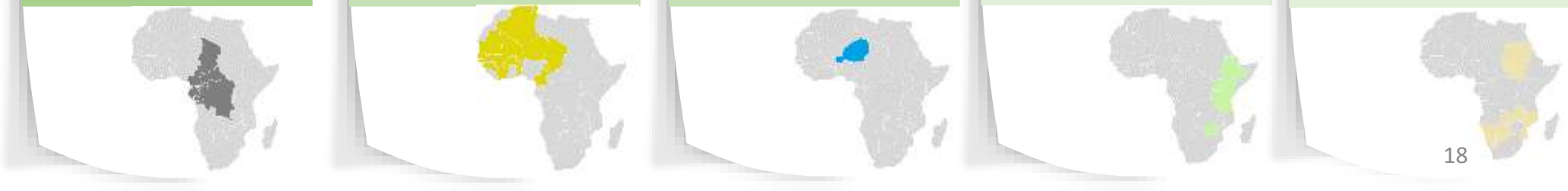
High Surveillance

23 countries

7 countries

Africa Region – Regulatory Requirements

	Cameroon, Congo, DRC, Gabon, Chad	French Africa	Nigeria	Zimbabwe, Ghana, Uganda Kenya, Ethiopia, Tanzania	Zambia, Malawi, Namibia, Botswana, Mozambique, Rwanda, Sudan, Sierra Leone
Dossier Format	**Country Specific**	**CTD**	**Country Specific**	**CTD**	**Country specific Botswana - CTD**
Plant inspection	Not required	No inspection done, but Plant approval is to be submitted	No inspection required. But Power of Attorney required	Inspection required and Ethiopia Legalization required	Inspection Required for Malawi
Labelling	English and French	English and French	English with distribution data	English	English Mozambique: Portuguese
Documents MFR, RM, PM, FP Spec STP, CoAs, Stability Data 3 M, labels	Additionally, BE or CDP Samples 300 + W/S	Additionally, BE or CDP, PDR, DMF, PV, AMV, Samples 700 + W/S	Additionally, BE or CDP, PDR, DMF, PV, AMV, Samples: 100	Additionally, BE, PDR, DMF, PV, AMV, Samples: 15- 50	Additionally, BE, PDR, DMF, PV, AMV, Samples: 15 each



ASIA PACIFIC MARKET

- 60% of world's population
- The ASEAN region comprises 10 countries: Malaysia, Indonesia, Thailand, Philippines Singapore, Brunei, Vietnam, Laos, Cambodia, and Myanmar. All 10 countries are seeking economic development to improve competitiveness by eliminating trade barriers
- Epidemiology and Unmet Medical Need

ASEAN Harmonization

Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

ASIA Pacific Market – Regulatory Requirements

	Singapore	Malaysia	Philippines	Indonesia	Thailand
Dossier Format	**GDA and NDA Application**	**ACTD**	**ACTD**	**Country Specific**	**GDA and NDA Application**
Plant inspection	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site
Labelling	English	English	English	English	English
Documents	COPP and Country Specific Requiremnt	ACTD Structure	ACTD Structure	ACTD Structure	ACTD Structure

ROW markets
(Site Inspection is not mandatory)
Selected SE Asian markets
West African Markets,LATAM Markets

ROW markets
(Site Inspection is mandatory)
Selected East African Markets
Selected LATAM markets

Cambodia,Myanmar,Srilanka
IVC,Cameroon,Benin,Senegal,Nig
er,Mali,Burkina Faso,Congo Braza

Opportunity

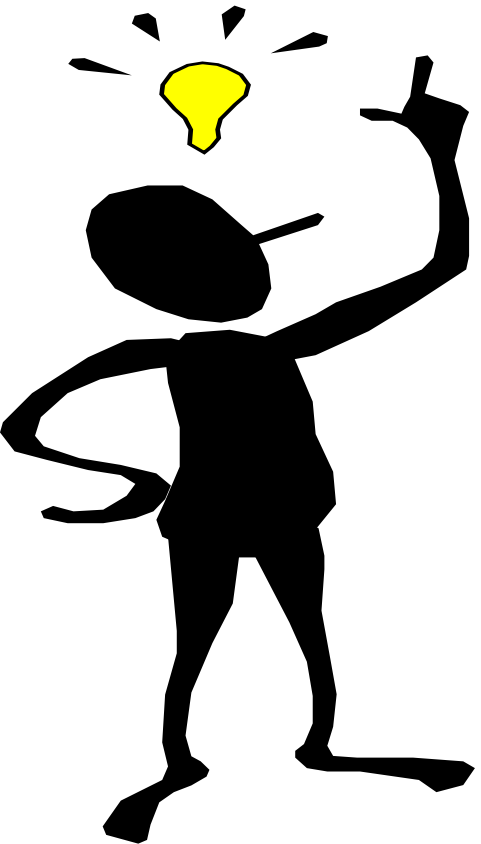
Kenya Uganda Zambia Tanzania
Ethiopia
Peru ,Chile (with CRO)

Out sourced products on Loan License from APPROVED Sites

ROW markets
Tender participation (COVID Budget)


Opportunity
Don't follow the Leaders
Lead your own way…
Go…….. Market Minus

Opportunity



- Select the market with lesser regulatory challenges.

  Four Countries

- Select 10 products :(avoid injection)

  *Antibiotic(adult & child) *Cough remedy *Anti Allergic,

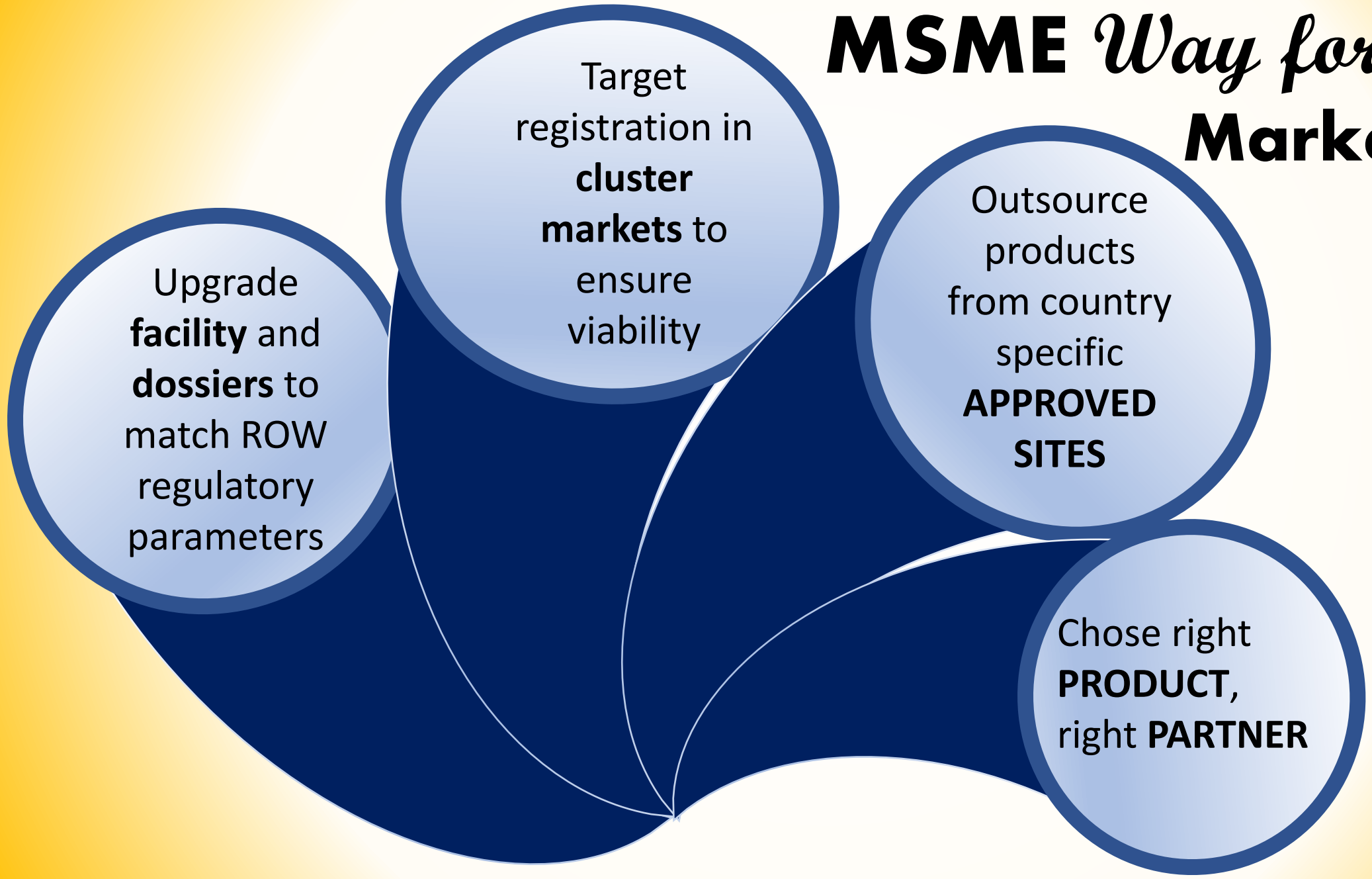
  * Pain,Inflammation (NSID)(adult & child) * Anti Anemic
  * Protien nutrition (adult & child) * Speciality

- **Select the right marketing Agent**
- Appoint a capable Regulatory assistant
- Same 10 products should be registered (to match the batch size and language of packing material and to facilitate transfer of excess stock)
- Submit 40 **dossiers** at a time and be ready to launch in FOUR markets

Opportunity

- Upgradation to WHO GMP facility
- Ensure COPP ,FSC
- Ensure CTD compliant data & Dossier
- Trigger site Inspection

MSME *Way forward :* Market Minus



MARKET ACCESS INITIATIVE SCHEME (MAI)

Financial Assistance from Govt to PHARMEXCIL Members

50% Reimbursement of expenditure incurred on statutory compliances in the buyer country

a) Registration cost

b) Plant inspection cost

c) BA BE Studies

d) Patent Filing Charges etc

e) Quality Certifications for Natural Products

f) Implementation of Barcoding

g) Conduct of clinical Trials & Data validation

Max Rs. 2 Cr / Yr

Claim within 90 days

https://pharmexcil.com/relevent-members-forms

MAI SCHEME-2021

Eligibility Criteria

- **Member of Pharmexcil**
  Selecting the appropriate category of RCMC. (LSM/SSM/ME)

- **Filing in 90 days timeline**
  Select the correct country, financial year of claim, category.

- **Reimbursement under the Scheme will be limited to the exporters having f.o.b value of exports up to Rs. 100 Crore during the preceding financial year**.

- Reference dates for calculating the eligibility period

Reference Date Registration / Renewal

Reference Dates for Retention

REIMBURSEMENT OF AIRFARE FOR PARTICIPATION IN APPROVED INTERNATIONAL EVENTS

Maximum of Rs. 90,000 & (Rs. 1,50,000/- for Africa and American continents)

- **Permissible only to the regular director/ partner/proprietor or a regular officer of the company on senior managerial position.**
- **Claim forms to be submitted within 45 days of return to India.**
- **Eligible for members with exports < Rs 50 Cr FOB in the preceding financial year**
- **Members having Nil exports/start-up/new exporters : Exporter has been active in the domestic market and has at least annual turnover of Rs. 50.00 lakh in the preceding financial year**

REIMBURSEMENT FOR PARTICIPATION IN APPROVED INTERNATIONAL EVENTS DURING A YEAR

- **A maximum of three participations in a particular trade fair/exhibition would only be eligible for MAI assistance,**
- **In the case of exporters belonging to SC/ ST/ women and the exporters having F.O.B. Value of exports of or less than Rs.50 crore in a year, 5 participations in a particular event is allowed.**

Pharmexcil Membership

Registration Cum Membership Certificate (RCMC)

Category	Membership Fee (INR)	Entrance Fee (INR)	GST (18%) (INR)	Total (INR)
Large Scale Manufacturer	36,000/-	18,000 /-	9,720 /-	63,720/-
Small Scale Manufacturer	10,000/-	5,000/-	2,700/-	17,700/-
Merchant Exporter	12,000/-	6,000/-	3,240/-	21,240/-

Note : Renewal Fee Every Financial Year (Membership Fee + GST)

The membership fee of Rs.1000/- for the exporters with ZERO turnover w.e.f 15/8/2019

pharmexcil

PHARMACEUTICALS EXPORT
PROMOTION COUNCIL OF INDIA

iPHEX Latam

3rd–14th FEBRUARY 2024

Pharma Business Delegation to

Colombia

Gautemala

Chile

SCAN QR CODE
FOR REGISTRATION

www.pharmexcil.com

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Any Questions?

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