Session 3

FUTURE-PROOF GLOBAL MANUFACTURING AND RESILIENT SUPPLY CHAINS

ANNUAL
Medicines for Europe & International Generic and Biosimilar Medicines Association
CONFERENCE

Divani Apollon Hotel
ATHENS

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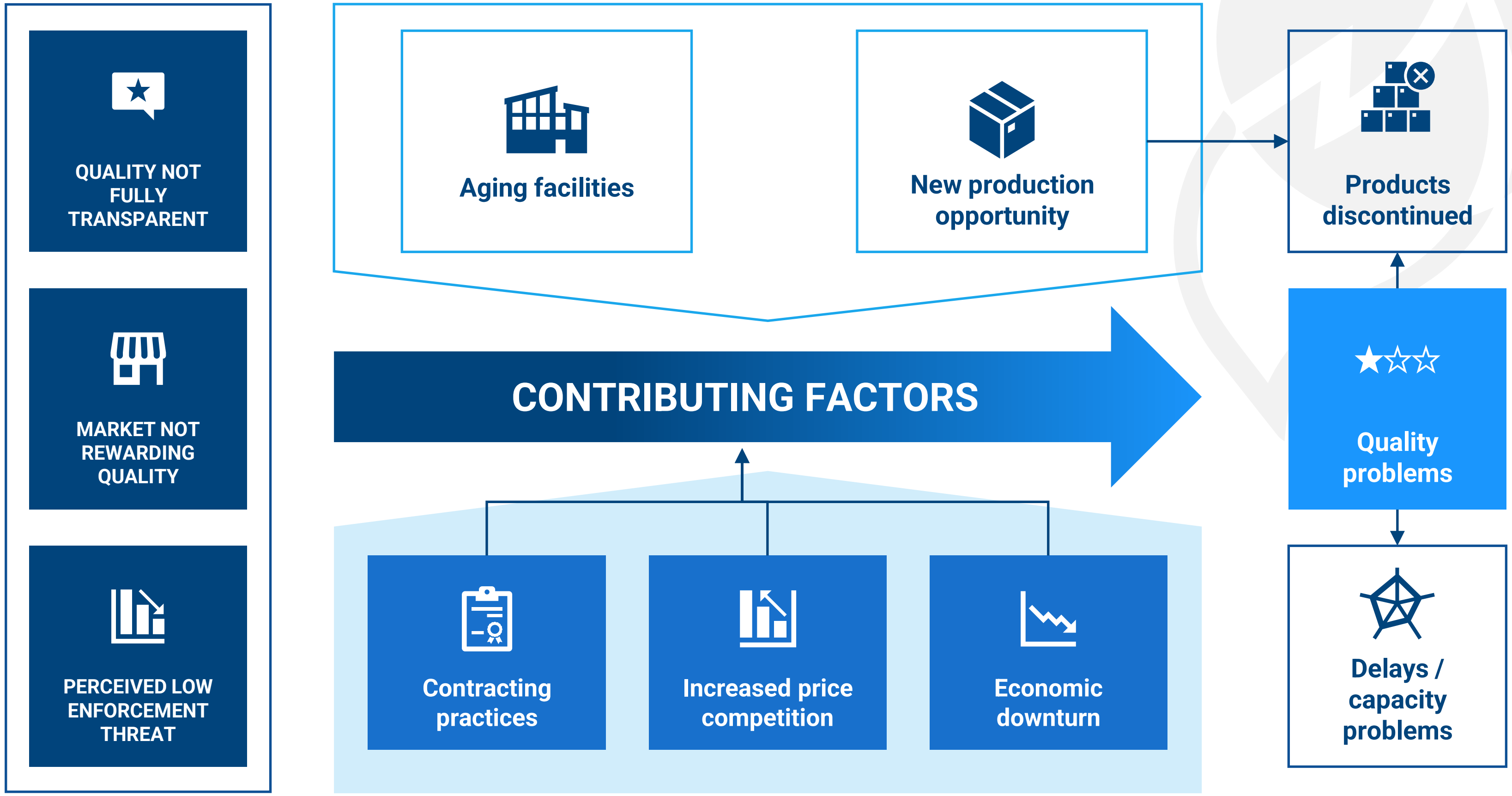
FACTS ABOUT PHARMA SUPPLY CHAIN

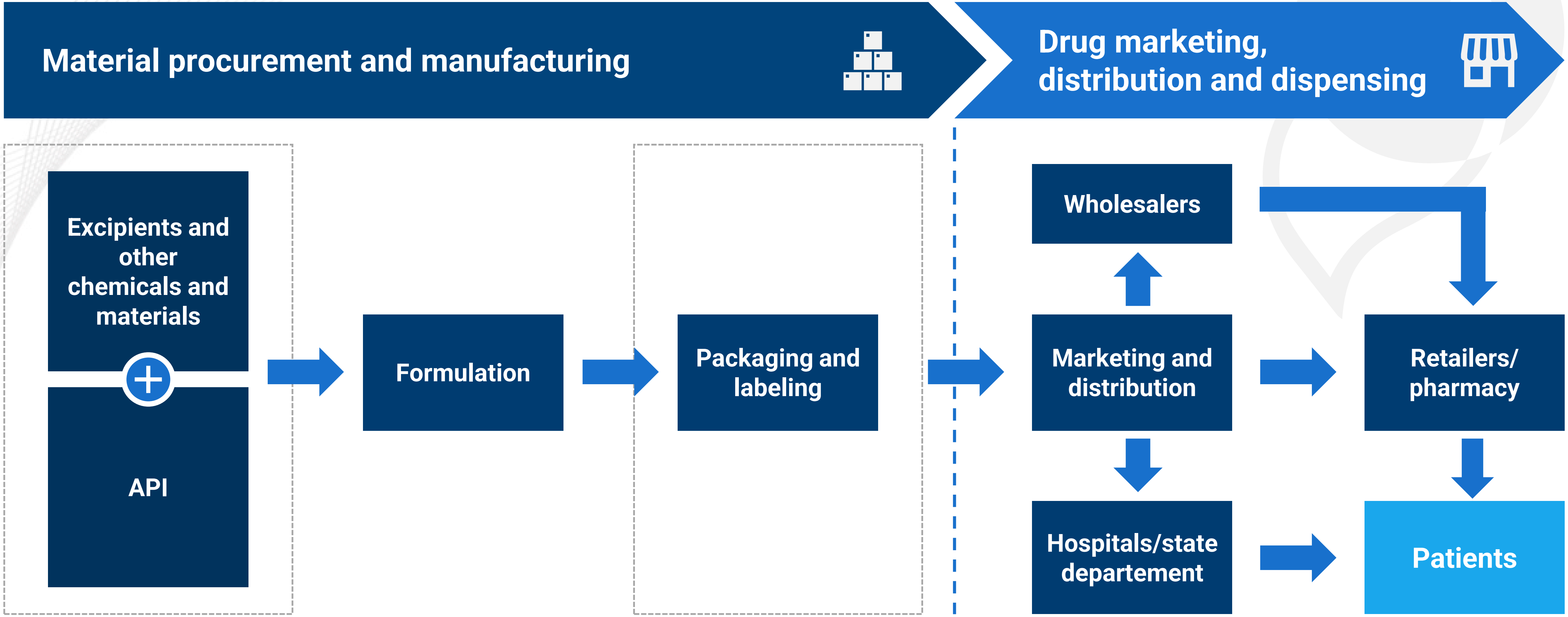
CONCERNS ON SHORTAGES & QUALITY ISSUES ARE NOT NEW

Economic Drivers of Manufacturing Quality Problems (The White House, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth, Jun.2021)



Source: Reproduced from Woodcock, Wosinska, Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages, Nature Publishing, 93(2): Feb 2013

WHO IS WHO IN THE (PHARMA) SUPPLY CHAIN?



FACTS

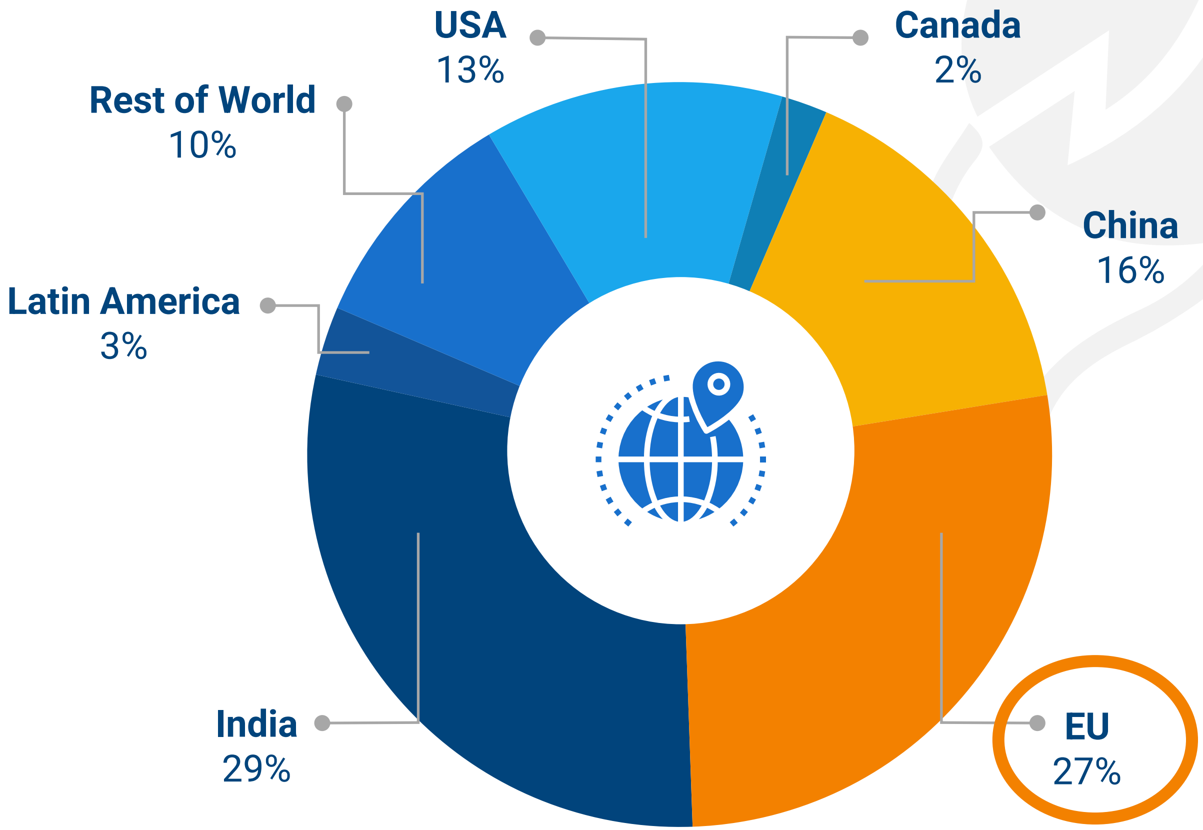
The supply chain for pharmaceuticals is fragmented, complex and spread among different geographies

Interesting considerations:

- **Europe:** 1/3 of CEPs (Certificate of the EU Pharmacopeia) are for products manufactured in Europe and **2/3 from Asian** manufacturers (Progenerika Wirkstoffstudie, 2020)
- **USA**: 52% of FDA registered FDF sites and 73% of FDA registered API sites are **located outside US** (The White House, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth, Jun.2021)
- **China**: Europe relies on 70% of API and KSM&intermediates coming from China (IQVIA, EU Fine Chemical Commercial KPI, Dec.2020)
- **Some chemical processes** for Key Starting Materials (KSM) **cannot be done in Europe** due to EHS regulations -> currently purchased beyond EU & shift of pollution
- **Tenders "price-only" criteria:** very low prices (i.e. in ES a pack of chewing-gum more expensive than 20 x 400 mg paracetamol tabs)
- **Production costs** in "high-volume/low-margin" products in Asia **are 20-40% lower**
- **Different level of Intellectual Property enforcement** in Asia has led to disadvantages for EU manufacturers

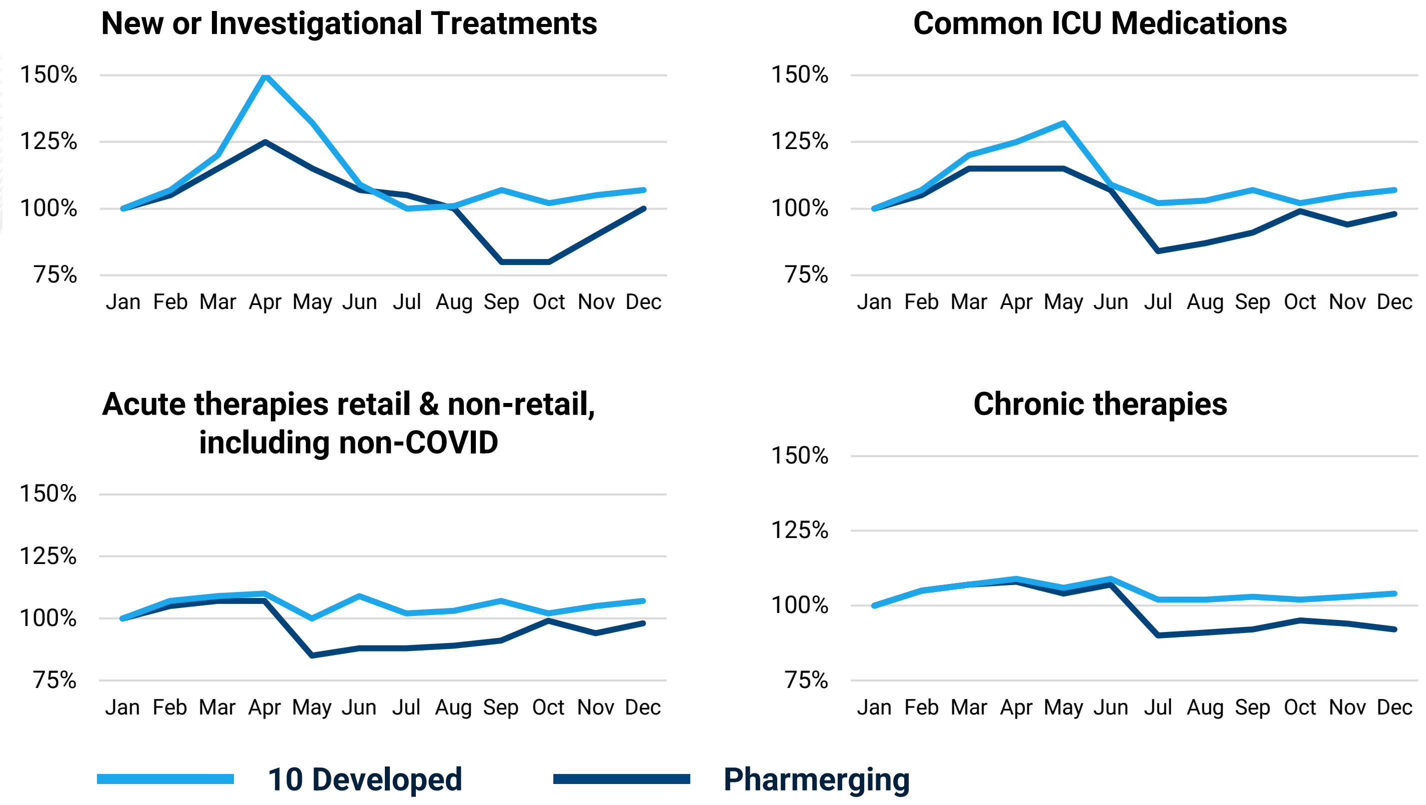
US: PERCENTAGE OF API MANUFACTURING FACILITIES FOR GENERIC DRUGS

(Approved Under ANDAs) by Country or Region, Mar.2021



COVID-RELATED FACTS

Monthly Percent Change in Medicine Use in 2020 Compared to Expected (IQVIA, Global Medicines Spending & Usage Trends, Outlook to 2025, Apr.2021)



During COVID - lockdown times:

- Public opinion realized products like **paracetamol** were **no longer produced in Europe**
- There was a **shortage of some essential drugs: sedatives, neurom.blockers, analgesics…**
- (Temporary) closing of borders (India, temporary closing of Swiss/IT borders…) -> **delays of APIs & some finished products**
- Initial lockdown in China (main supplier of KSM and intermediates):
  - **scarcity KSM&intermediates**
  - **delays in production**
  - **increase in prices**

HOW DID API INDUSTRY OVERCOME COVID-CHALLENGE

- **Employees in production and labs coming to work** every single day of hard lockdowns
- Having **long-term relationships with suppliers** as the key starting materials (KSM) and intermediates need to be:
  - Compliant to specifications
  - Tested and validated before used in commercial batches
  - Included in regulatory files
- Having **more than one approved & validated supplier** of KSM & intermediates
- **Increasing stocks** of KSM & intermediates -> higher working capital and increased COGS
- **Negotiating with European & National Regulators** some exceptions to the Guidelines

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POLICIES AFFECTING PHARMA SUPPLY CHAIN

SOME INITIATIVES HAPPENING IN EUROPE POST-COVID PANDEMIC OUTBREAK

*The GREEN DEAL was issued in Dec.2019, aiming for EU to become climate-neutral in 2050

Pharmaceutical Strategy -> Structured Dialogue with industry and stakeholders -> 4 main streams of conclusions

Launch of **European Health Emergency preparedness and Response Authority (HERA)** for development, production & distribution of medicines, vaccines & others in health emergencies

Update of New Industrial Strategy -> considers active pharmaceutical ingredients one of the vulnerable supply chain

UPDATED VERSION OF THE NEW INDUSTRIAL STRATEGY

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STRENGTHEN SINGLE MARKET RESILIENCE

DEAL WITH DEPENDENCIES

ACCELERATE THE TWIN TRANSITION

WHAT THE COMMISSION WILL DO, AMONG OTHERS

- Engage with Member States, industry, and social partners, to address **the security of medicines supply and the pharmaceutical strategy.**
- Identify measures to **reinforce the EU position in global value chains**, also by strengthening and diversifying external trade, creating new opportunities also for low- and middle-income countries.
- Review **strategic dependencies** – i.e., on raw materials, batteries, active pharmaceutical ingredients, hydrogen, semiconductors, and cloud and edge technologies- **and monitoring of associated risks** (starting in 2021).

EUROPEAN CHEMICALS STRATEGY

THE EU'S CHEMICALS STRATEGY AIMS TO

1. **Better protect citizens and the environment**
2. **Boost innovation for safe and sustainable chemicals**

ACTIONS

- Banning the most harmful chemicals in consumer products - **allowing their use only where essential**
- Account for the cocktail effect of chemicals when assessing risks from chemicals
- Phasing out the use of per- and polyfluoroalkyl substances (PFAS) in the EU, **unless their use is essential**
- Boosting the investment and innovative capacity for production and use of chemicals that are safe and sustainable by design, and throughout their life cycle
- Promoting the EU's resilience of supply and **sustainability of critical chemicals**
- Establishing a simpler "one substance one assessment" process for the risk and hazard assessment of chemicals
- Playing a leading role globally by championing and promoting high standards and not exporting chemicals banned in the EU

THE BENEFITS OF THE EUROPEAN GREEN DEAL

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The European Green Deal will improve the well-being and health of citizens and future generations by providing:

- Fresh air, clean water, healthy soil and biodiversity
- Renovated, energy efficient buildings
- Healthy and affordable food
- More public transport
- Cleaner energy and cutting-edge clean technological innovation
- Longer lasting products that can be repaired, recycled and re-used
- Future-proof jobs and skills training for the transition
- **GLOBALLY COMPETITIVE AND RESILIENT INDUSTRY**

?

How to make API industry resilient and competitive and green at the same time?

Does EU-API industry compete in the same level playing field as players located outside the EU?

IN OTHER PARTS OF THE WORLD SIMILAR INITIATIVES AIMING FOR RESILIENCE/RE-SHORING:

US

100 Days Reviews under Executive Order 14017 (Building Resilient Supply Chains, Revitalizing American Manufacturing, and fostering Broad-Based Growth)

INDIA

2020 setting up **production linked incentive scheme** for promotion of domestic manufacturing of critical Key Starting Materials (KSMs), drug intermediates and APIs under which they will be eligible for financial incentives

INDIA

2021 PLI scheme: Roll-Out of Manufacgturing Incentives in India's **Pharmaceuticals Sector: Approved Beneficiaries and New PLI Scheme Criteria**

FUTURE TRENDS

FUTURE TRENDS IN API PHARMA INDUSTRY

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Demographics in 2025:
11% > 65 years WW
21% > 65 years in Europe

DEMAND WILL INCREASE

EFFECT ON DEMAND?
Telehealth increase

INCREASED EFFICIENCY IN THE WHOLE SUPPLY CHAIN
AI & Robotics

PRODUCTION OF VACCINES & ANTIBIOTICS NEEDED

COVID & INFECTIONS will still exist

EFFECT ON EMPLOYMENT?

About **3000 manufacturing plants in Europe** (Proprietary, Gx, CMOs, Vaccines,…) -> about 10% API sites

POTENTIAL MEASURES TO KEEP EU MANUFACTURING COMPETITIVE AND ATTRACTIVE

EUROPEAN COMPANIES ARE STRUGGLING TO BE COMPETITIVE, INNOVATIVE AND STRONG

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Currently many initiatives ongoing:

- Resilient supply chain in Healthcare
- Industrially strong Europe
- Clean sky and adoption of green technologies
- Innovation & new technologies

Significant efforts devoted to discuss policies and initiatives: no clear guidelines yet

The EU is formed by 26 different countries: not always aligned amongst themselves

The right timing is NOW. Outside-EU competition will also become sustainable…in 10-15 years and at a better cost

1. Clear guidelines

2. Transparency

3. Incentives

POTENTIAL MEASURES (AMONG OTHERS)

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Cooperation *among* European Authorities

Reasonable EHS constraints in Europe (Green Deal and Chemical Sustainability Strategy) for pharma industry

Direct **incentives** for **innovation, new manufacturing techniques** and attraction & retention of **talent**

Harmonized and more **flexible regulations** for products produced within EU

In tenders **consider factors beyond price:** location of manuf. Sites, compliance track record, use of cleaner & safer technologies, level of innovation…)

Incentivize **cooperation** among **small/medium European enterprises:** combine technologies & expertise for new technologies, innovation,…

CONSIDER IF OTHER RESHORING INITIATIVES BE A THREAT FOR THE EUROPEAN PRODUCERS?

FOR THE API INDUSTRY

- Provide a **level playing field** compared to Asian manufacturers (EHS, IP,…)
- **Align & clarify requests** at Regulatory, Industrial and Environmental level
- Propose **long term incentives for strategic investments**
- Promote **new** process & analytic **technologies**

Producing in Europe <u>will be more costly</u> than in other parts of the world, but it may:

- Be **only a fraction** of not having needed APIs or medicines **available**
- Enhance **innovation** and technology
- Create employment & attract **talent**
- Attract **investment**
- **Return the core of pharma industry to Europe**

PROVIDE DIFFERENTIATION

Thank you!