A Policy Roadmap for Medicines Manufacturing Leadership

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During the 2019 Parliamentary elections, Medicines for Europe advocated for the EU to support pharmaceutical manufacturing leadership. The COVID-19 pandemic has reinforced this and demonstrated the public health value of a resilient and strong European generic, biosimilar and value added medicines industry. Europe must prioritise health and access to medicines recognising the value of medicines for human health and the need to increase investments in this field. We believe that manufacturing leadership and supply chain resilience rely on smart policymaking based on three key factors:

1. **The competitiveness of our manufacturing and the resilience of our supply chains** are critical for healthcare.

2. Building on the **European manufacturing footprint of over 400 sites and 190000 direct jobs** and investing in technological leadership will deliver a cost-effective solution aligned with public health needs. **The EU should set an ambitious goal to restore Europe** to its former position **as the leading global manufacturing region** for finished product (medicine) and active pharmaceutical ingredients (API) for both the EU and the global market.

3. **Policy reforms** combined with effective implementation at the national level are necessary **to drive investment** to secure existing sites and increase pharmaceutical development, European manufacturing leadership and resilience.

➢ Regulatory oversight for a level playing field

All medicines marketed in the EU must comply with high regulatory, scientific and quality standards and are extensively monitored by industry and regulatory (medicine) agencies. For imported medicines or ingredients, manufacturers conduct a wide array of good practice audits for manufacturing, laboratories and testing (GMP, GCP, GLP) as well as testing procedures for imports to ensure compliance. To enhance this effort and for a level playing field on enforcement, we expect regulatory agencies to devote more resources to GMP inspections in less regulated countries especially for API. Regulatory oversight could be improved by reducing maintenance costs for older medicines (variations), giving a legal role for API producers to submit variations in the regulatory dossier, conducting GMP inspections of foreign API and finished product (medicine) sites and using manufacturing site compliance metrics and risk assessment systems. To encourage more suppliers in the market, a European medicines supply committee could be established to incentivise more competition and manufacturing where supply is too consolidated. Telematics tools should be used to reduce administrative redundancy, increase medicines availability and support in the management of shortages.

➢ Invest in Europe's future healthcare needs

The EU is committed to achieving multiple policy objectives for medicines: make them economically sustainable, reduce their environmental impact, increase manufacturing competitiveness and supply chain resilience and adapt to the digital era. Europe should also become the world leading manufacturing site for pharmaceuticals, from innovative to generic and biosimilar medicines. European funds (Recovery fund, Green deal, EU4health) or state aid criteria (to enable national tax deductions, API and medicines development incentives or other facilities) could kick start development, manufacturing and supply chain investments to achieve these objectives. Concrete initiatives to encourage include: investments in telematics to digitalise regulatory submissions and oversight; newer or greener or more efficient technologies to develop and manufacture API and medicine formulations; securing existing sites, construction or renovation of manufacturing facilities or production lines for competitiveness and new manufacturing processes like flow chemistry for API; information technology deployment across the manufacturing and logistics chain and; environmental studies. Wherever possible, financial support should be combined with market incentives (value added medicines, green or multi-winner procurement market options that consider long-term volume and price certainty) to ensure that these investments are ultimately financed by markets. For pandemic planning, rolling reserves could be financed for a defined list of critical medicines.

➢ A new medicines trade agenda

The EU should continue to be a global proponent of open markets for medicine in trade agreements. Trade agreements should be adapted to include measures for security of supply (reciprocal commitments to avoid export restrictions and cooperation on enforcement of GMP rules), equitable access (enable global development of APIs and generic, biosimilar and value added medicines to lower development costs) and mutual open trade (removing barriers to EU exports – including in procurement).

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➢ Sustainability as a market driver

The European market for prescription medicine is dominated by government (direct or indirect) purchasing based on obtaining the lowest price for most off-patent medicines. This jeopardises the existing strong manufacturing footprint in Europe, disincentivises investments in European manufacturing and in supply chain resilience measures and generates market or manufacturing chain consolidation. The EU can rebalance the market toward investment by legally rewarding resilience and security of supply or other relevant most economically advantageous tender (MEAT) criteria into the implementation Public Procurement and the Transparency Directives. Manufacturing location in Europe of the API and/or medicinal product can be a factor of increased security of supply and resilience, as it shortens the supply chain, allows more effective regulatory oversight and mitigates dependence on third countries, which creates vulnerabilities in situations such as the closure of borders during the COVID-19 outbreak. In addition to supporting European manufacturing, geographic diversification is important to increase resilience supply. There are also other factors such as the number of active manufacturing sites for any individual API, secondary back up options and the ability to scale up production rapidly which requires changes in pharmaceutical regulation. Purchasing policies should be balanced between cost and supply chain reliability including the investment in supply chain resilience, mature quality systems and environmental, health and safety standards. New pricing models for off-patent medicines that reflect increases in costs of goods or regulation are needed for the supply of essential, lower cost medicines. The development of innovative off-patent regulatory pathways for biosimilar medicines, which increased the production of and access to biopharmaceuticals in Europe, could be replicated for other technically complex off-patent medicines (value added medicines) with positive results for healthcare and spin-off benefits for manufacturing. To improve sustainability for healthcare budgets, the EU pharmaceutical strategy should ensure effective competition at loss of exclusivity of originator drugs.

Time\policy	Sustainable Market Drivers	Regulatory Oversight	Invest in health	Open partnerships
Short term: Year 1	EU level: criteria such as Security of supply in (MEAT) Procurement/ Transparency directive implementation and harmonisation of Bolar National level: Implement MEAT and multi-winner criteria in procurement and move away from price only and just in time purchasing models	Amend Variations regulation Ensure level playing field for compliance inspections in non-EU countries and implement risk assessment system Establish European medicines supply committee Map API/medicines manufacturing footprint for strengths and gaps in supply security	EU level: Recognise our industry as critical to the EU economy. Agree funding for rolling national reserves of critical medicines Invest in digitalisation of the medicines regulatory system Incentives for greener production, new technologies, digitalized manufacturing systems	Increase global cooperation on GMP enforcement Define *new medicines trade agenda* based on security, access and mutual openness
Medium term: Year 2	EU & national level: define security of supply criteria for markets EU level: Create value added innovation market for complex medicines	EU & national level: define quality metrics, increase inspectorate resources, implement integrated telematics across EU regulatory network	Create funds and adapt state aid rules for investment in IT development, manufacturing technologies for API and medicines, green technology and resilience	Engage negotiations with key trading partners and WTO/WHO on new medicines trade agenda
Long term Year 3-4	National level: Implement market incentives for complex medicines (value added, biosimilars)	Adapt regulatory system to simplify and improve API oversight		Establish formal trade agreements for accessible, secure and open medicines supplies