

IGBA Conference

Geopolitics and the Global Pharmaceutical Supply Chain

15-16 February 2023

Orlando, Florida

patients • quality • value • sustainability • partnership



Table of contents

1. Inflation crisis impact on medicines supply

2. Strengthening manufacturing resilience and reliance

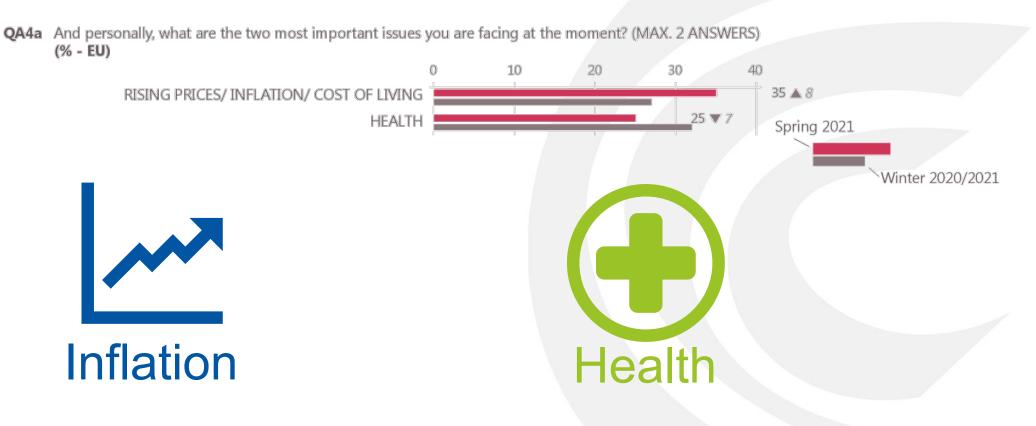
Impact of energy prices, Security of Supply and EU medicines manufacturing





Europe at a crossroads: End of pandemic / war in Ukraine

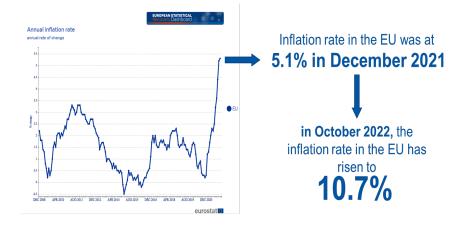
• Europeans have two key concerns (Eurobarometer poll)



medicines for europe **Factors impacting medicine manufacturers** Inflation **Energy prices Raw material prices** Perfect storm **Fuel prices Airfreight prices Shipping prices**



Inflation, Energy costs and Rising costs: The perfect storm



➤ Airfreight prices

Route	Change % Jan 2020 vs Feb 2022	
Frankfurt – North America	171.2%	
Hong Kong -Europe	104.9%	
Hong Kong — N America	208.3%	

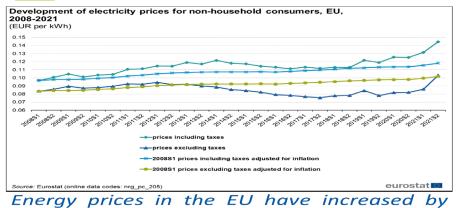
Shipping prices

Country	Change % Jan 2020 vs Dec 2021	
Shanghai to Rotterdam	544%	
Shanghai to US	273%	



Raw Material	Change % Jan 2020 vs Dec 2021	
Crude Oil - Europe	17.5%	
Diesel - Europe	7.6%	
Jet Fuel - Europe	11.5%	
Natural Gas - UK	887%	

Energy prices

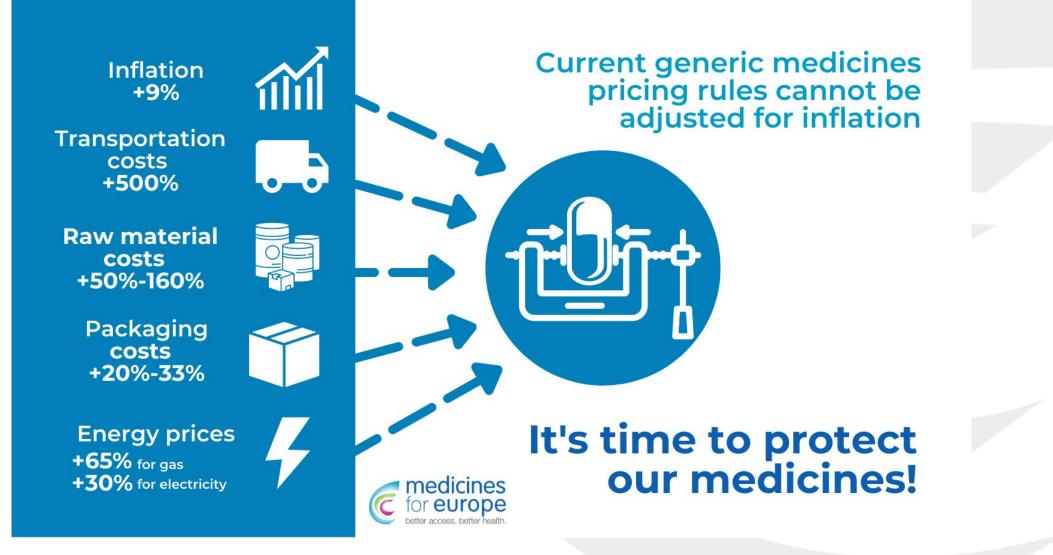


65% for gas and 30% for electricity

Raw **Therapeutic area** Price Change % Material Q1 2020 vs Q1 2022¹ 6-APA¹ Antibiotic used to treat infections 160 % such as inflammatory diseases and sever infections such as pneumonia and sepsis Ampicillin¹ Antibiotic used to treat respiratory 50% infections and meningitis, also to prevent some infections in newborns DCDA Diabetes: to control blood sugar 180% levels DMA Diabetes: to control blood sugar 90% levels



Inflation





Price and reimbursement rules paired with pricedriven tendering are key barriers to cope with raising costs





In the news...



Europe's generic drugmakers say they may cut output due to energy bills



Verband für Generika-Hersteller schlägt wegen hoher Stromkosten Alarm

Zdravotnický Evropští výrobci generických léků varují: deník zdravě je vědět Omezíme produkci, drtí nás ceny energií

LesEchos

Médicaments : les fabricants européens de génériques brandissent le risque d'arrêt de production **a**



quotidiano <mark>sanità</mark> .it	Scienza e Farmaci		
Home Cronache Governo e Parlament			
Health Media Company SCRIVEREMO IL TUO FUTURO			
novavax	Scopri la nostra innovativa tecnologia del vaccino ®Nevava, Inc (2021). COM-IT-COV-2100005 12/21		
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Farmaci generici. *Medicines for Europe*: "Senza agevolazioni sull'energia forniture a rischio"

Sono tre le richieste delle aziende europee dei generici e dei biosimilari ai ministri Ue dell'energia in vista dell'incontro del 30 ottobre a Bruxelles contenute in una lettera aperta della presidente di Medicines for Europe, Elisabeth Stampa



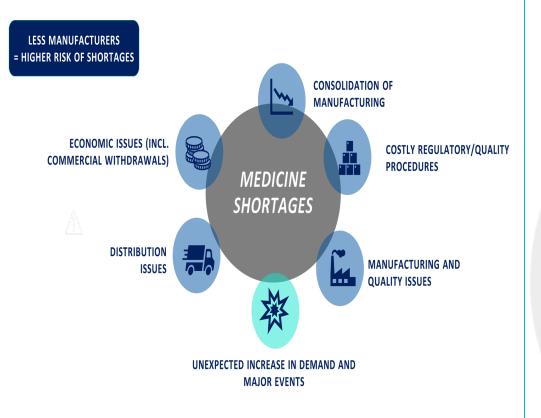
8str - Individuare con chinetzza i settori industriali cittici che potranno enclicare degli interventi di fascancio dei prezz per la fontutta di energia la richiesta di notuco dei consumi interativo dei piani azionali di ali crinista di notuco dei consumi interativo dei piani azionali di di cuizzato di cui di di cui di di cui di di cui di di cui di di cui di di cui di

Sono le tre richieste che il presidente di *Mediones for Europe*, frassociazione chi rappresenta la aziende europee de generico e del biosimiare. Elitabeth Stampa, ha avanzato in una lettera aperta al ministi europei dell'Energia e al Cormissa europei responsabili sulfitzance e sui costi energicci in visa dell'inconto del ministi dell'Energia dell'UE-27 in programma 130 settembre a Bruxelles per cercare di raggiungere un accordo sulle recenti misure di emergenza proposi de dial Cormissione europea per far fronte al prezzi etati dell'energia.

Generic drug sector appeals for EU relief on gas and power supplies



Reforming pricing policies to manage cost inflation



Medicines for Europe actions to mitigate the impact of inflation

Creativ Ceutical

New pricing models for generic medicines to ensure long-term healthy competitiveness in Europe

Reference: 21-MFE01GNR

Version 1.0

Date: 24.06.2022

New pricing models for generic medicines to ensure long-term healthy competitiveness (link)

Toolbox of new pricing models for generic medicines to be generic implemented at national level

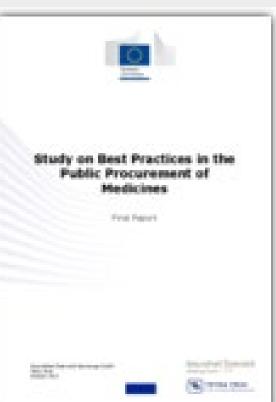
Automatic indexation: the manufacturer would be able to adjust the price of medicines according to the inflation rate, protecting the economic viability of medicines against fluctuations in costs of medicines according to the inflation rate.





Focus: Commission Study on Procurement

- Multiple winners and other criteria than price contribute to more sustainable procurement
- Price only key award criterion for procurement of medicines (75%)
- MEAT criteria about willingness to pay = challenging
- Criteria used so far: security of supply, environment and added therapeutic value
- Procurement of biosimilars needs support biosimilar uptake including hesitancy and behaviour to impede market entry and uptake of competitor products





Reducing shortage risks: Example Amoxicillin shortage

Demand driven shortage:

- 2020-21: amoxicillin/clav demand fell in EU --> *reduction of production capacity*
- 2022: amoxicillin/clav demand increased in EU (+35-50%; pediatric +300-500%) --> increase of production capacity – too late for pediatric!

How to improve demand prediction/supply chain planning?

- Centers for disease control dialogue w/ manufacturers --> 1 year planning required!
- Risk sharing on building up reserves: Who will pay for over-supply?
- How to avoid hoarding? Improve data on consumption --> serialisation data = consumption data

Supply chain consolidation

- Antibiotic production consolidated due to large volume/low price policies
- Consolidated supply chains = limited ability to react
- Adapt market policies to encourage investment in diversification

Lessons for LMICs:

- Consider demand planning with antibiotic manufacturers
- Markets: are antibiotics "essential/critical" or "commodities"?

Strengthening Manufacturing Resilience





Manufacturing competitiveness Oral solid dosage forms

- Mostly generic/older medicines: tablets/capsules
- Market policies drive price reduction (DE avg €0.06/DDD) → consolidation/globalisation
- Large volume/scale production → risk for low volume (oncology 85% consolidated in EU!)
- Non-sterile multi-purpose plants (cardiovasculars)
- Dedicated mono-manufacturing for high potent medicines (Beta lactam antibiotics and oncology)
- Substantial API and FdF manufacturing capacity in EU, *but growth is in Asia*.
- Dependency concern: export controls; erratic local policies; war
- Which molecule classes matter?



How to expand solids API/medicines manufacturing in EU?



Manufacturing competitiveness Aseptic/sterile products

- Mostly generic and older off-patent medicines
- Medium production volumes
- Mostly sterile injectable liquids based on small (chemical) molecules.
- Large scale sterile production available in EU, but limited surge capacity in EU or globally
- Policy concerns
 - Covid ICU demand surge required shifting lines to meet demand
 - Vaccine fill & finish could require stopping injectable production (supply risks for critical medicines)
 - Surge capacity uneconomic & difficult reg. compliance



What is the additional capacity needed in sterile manufacturing? Who will pay for it?

medicines for europe *better access* **Cetomplex drug systems (large molecules/biologics)**

- Mixture of on and off-patent medicines requiring innovation in manufacturing techniques
- Low volume, large molecule biologics or vaccines or very complex chemical forms in sterile injectable forms
- Europe globally competitive but manufacturing not adapted to scale
- EU market doesn't encourage volume development of this technology → slow scale up
- Policy concern: ability to rapidly adapt to changing needs (vaccines, biologics, etc.)



Can we incentivise complex drug system production on a higher volume scale?



What policies could support investments in capacity?

Market policies

- Generic purchasing policies should *drive diversification and manufacturing investment*
- Smart policies for *emergency (rolling) medicine reserves*
- Encourage a volume complex drug market (VAMs, expansion of biosimilar use, vaccination policies)

Incentives for manufacturing

- For technology investments in *manufacturing innovation* (green chemistry/automation)
- Enable tax incentives for manufacturing
- Encourage *vertical integration* of supply chains? (*link API and KSM location*)

Regulatory policies

- Improve data on *demand planning* i.e., infectious diseases
- *Digitalise the regulatory system* to reduce burden on volume medicines
- Facilitate *resilience measures*: dual sourcing, API variations/changes, digital regulatory info, reduced time for documentation review, modified stability studies, etc.

Off patent industry new investments in EU manufacturing



New investments in the EU







(Expansion)

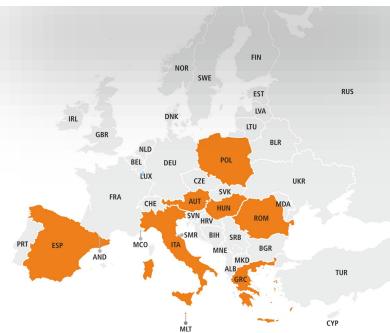


BIOLOGICALP	
API PLANTS	
VAM PLANTS	
FDF PLANTS	PRI

PLANTS



APIPLANTS



New investments in the EU



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(Expansion)	





FDF PLANTS

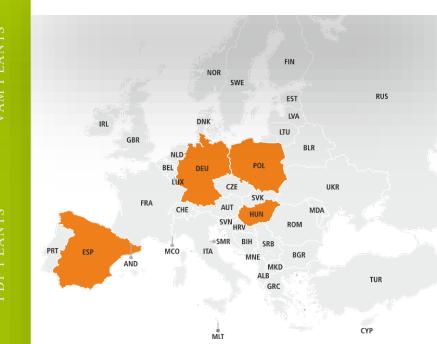


New investments in the EU



BIOLOGICAL PLANTS

BIOLOGICAL PLANTS

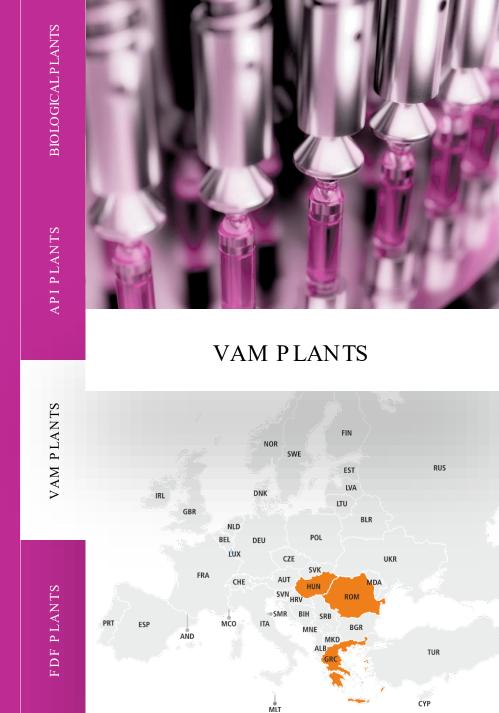


New investments in the EU





ZENTIVA O HUNGARY **O** ROMANI (Expansion)



SPEECHMAKING SPEECHMAKING Mat support does manufacturing get from governments? ACTION



