

“Responding to the Pandemic Together” Programme

Episode 25: Medicine Supply Disruptions and Shortages during the Pandemic

Delivered by the FIP Young Pharmacists Group, FIP Industrial Pharmacy Section,
FIP Drug Delivery and Manufacturing SIG

July 22, 2020 16:00 CEST



ADVANCING
PHARMACY
WORLDWIDE

Facilitators

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Welcome to the “Responding to the Pandemic Together” events

FIP’s Special Online Programme on COVID-19

These webinars aim to

- I. Provide relevant information and the pharmacy workforce on Coronavirus SARS-CoV-2/COVID-19
- II. Share and discuss strategies and experiences of Member Organisations – in response to the pandemic
- III. Describe sector or area-specific approaches adopted across pharmaceutical science, practice and education
- IV. Engage frontline workers of pharmaceutical organisations to know about the realities facing them around the world.
- V. Discuss the implications of the pandemic on supply, shortages that have been exacerbated by COVID-19, and the impact on patients
- VI. Consider the impact of this disease on patients across age groups and with concurrent conditions.
- VII. Assess and discuss the evidence behind treatments and the process of developing therapies, vaccines and tests.



To share ideas on webinar topics we should feature, or if you'd like to share your story on dealing with the pandemic please email

lina@fip.org

Important Links & Resources

FIP Covid-19 Information Hub

A comprehensive FIP webpage containing all of our resources and outputs relating to COVID-19, including recordings of previous webinars.

Link: <https://www.fip.org/coronavirus>

FIP Facebook Group: “COVID-19 & pharmacy”

Link:

<https://www.facebook.com/groups/covid19andpharmacy/>



Announcements

FIP Digital Events House Rules

1. This webinar is being recorded and live streamed on Facebook
2. The recording will be **freely available** at www.fip.org/coronavirus and on our YouTube channel
3. You may ask questions by typing them into the Q&A box
4. Your feedback is welcome (webinars@fip.org)

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Learning Objectives

- Describe the differences between supply disruptions, low stocks, and shortages
- List the main medicine and healthcare products affected
- Explain the potential impact of these issues
- Outline different strategies developed to face these problems in different regions and countries

Event Chair/Moderator

Ulf Janzon, MSc

President, Swedish Pharmacists Association
President, FIP Industrial Pharmacy Section

(Sweden)



Speaker 1

Propser Hiag, PhD

- International Pharmaceutical consultant
- Social entrepreneur and advocate for quality drugs access in Africa and WHO Good Manufacturing Practices for drugs conception and promoter of local drugs manufacturing in Africa
- Council Member of FIP
- President of African Pharmaceutical Forum
- President of Cameroon National Pharmaceutical Society (CNOPC)
(Cameroon)



Medicines Supply Disruption and Shortages during the COVID-19 Pandemic in Africa

Main points to be highlighted here

1. Statement on the potential reasons for the disruption and shortages in the Africa region
2. Introduction of actions taken by governments and organizations to face these challenges.

Overview

- COVID-19 pandemic has caused massive disruptions to global supply chains.
- In Africa between 70% and 90% of Drugs are imported
- Significant shortages of other essential medicines can be materialize.
- Rise in substandard and falsified products related to fight against COVID-19.



Some shortages area

- Hydroxychloroquine
- Chloroquine
- Azithromycin
- Dexamethasone
- ARV
- Insulin



Reasons for the disruption and shortages (1)

- Lack of manufacturing capacity
- Shortage of raw materials
- Political instability
- Absence of national contracts on the regional code lists of medicines
- Failure of suppliers to meet demand and the failure to pay suppliers

Reasons for the disruption and shortages (2)

- The buy-out process not structure
- Suppliers not performing
- The inaccuracy of the electronic inventory management system.
- Manufacturing and quality problems
- Production delays



Actions taken by decision makers (1)

- Produce quality-assured, essential pharmaceutical products locally
- Ethiopia and South Africa have developed national strategies and manufacturing roadmaps (to address financial barriers and improve quality)
- South Africa and Egypt are beginning to produce active ingredients locally



Actions taken by decision makers (2)

- In Nigeria, the Central Bank of Nigeria, is working to stimulate the sector by extending lines of credit to local manufacturers
- Afrexim Bank, the UN Economic Commission for Africa (UNECA), and the African Center for Disease Control recently announced emergency interventions to rapidly respond to supply and policy gaps

Actions taken by decision makers (3)

- South Africa, Ongoing monitoring for the future use of computerized inventory management systems is important to reduce medicines shortages, and this is being followed up.
- In Cameroon, the government empower and encourage local production of Hydroxychloroquine.
- UNECA, the Federation of African Pharmaceutical Manufacturers Associations (FAPMA), and the WHO

Actions taken by decision makers (4)

- The African Medicines Agency (AMA), a continental effort to harmonize medicines regulation
- Integration of herbal medicines and Traditional medicines



Conclusion

- Scaling up African pharmaceutical capacity will help to provide sustainable access to quality medical products and increase health security during the COVID-19 pandemic and beyond.
- African countries should improve cooperation and trade within the continent.

Speaker 2

Joan Alexis Sepulveda Mora

Member, Board of Directors of the National
Board of Pharmaceutical Chemists of Colombia

(Colombia)



Colombia: as a case study in the Americas Region

Overview

1. Colombia: as a case study
2. General measures to prevent shortages of supplies and other disinfection elements
3. Measures to prevent the shortage of drugs for symptomatic treatment
4. Measures to prevent the shortage of medicines necessary for treatment in intensive care units
5. General conclusions

Colombia: as a case study

- An upper middle-income economy, member of the OECD since April 28, 2020.
- The health system in Colombia is part of the Colombian Social Security System regulated by the Government of Colombia
- The country has a national regulatory agency (NRA) that approves the marketing of all products that have an impact on public health.



General measures to prevent shortages of supplies and other disinfection elements



- the basic elements for the prevention of virus transmission traditionally in Colombia are classified into several categories according to the regulatory authority: hydroalcoholic solutions for hand disinfection are classified as drugs if they have more than 70% ethanol or as cosmetics if they have a percentage of ethanol between 60 and 69%, meanwhile, facial masks are classified as medical devices.

General measures to prevent shortages of supplies and other disinfection elements

- In general terms, the ANR reduced the conditions so that disinfectant and protection products could be marketed, changing the marketing authorization called sanitary registration or sanitary notification as the case may be and allowing marketing with a temporary permit.



Measures to prevent the shortage of drugs for symptomatic treatment

- Ministry of Health and Social Protection at the moment, a specific treatment for any coronavirus is not recommended, so the treatment of covid-19 is symptomatic.



- Recommendations focus on trying to reduce social interaction as much as possible and, in case of symptoms, isolate yourself voluntarily, request that the test be carried out and maintain treatment at home for as long as possible.
-

Measures to prevent the shortage of drugs for symptomatic treatment



- The primary measure established by the national government is through the NRA to expedite the approval processes for the initiation of clinical studies of new or known chemical entities for the specific indication, at this time studies on Remdesivir, plasma and the clinical study " Solidarity "of the WHO, are being carried out in the country

Measures to prevent the shortage of medicines necessary for treatment in intensive care units

- All the medicines necessary for the treatment of patients with COVID 19 were included in a positive list and will be considered in the same way as the medicines for neglected diseases (better known in Colombia as orphan diseases), which basically simplifies the import procedures of these medications, accelerating their entry into the country



General conclusions

- The national government has taken early measures to prevent the shortage of medicines, however, Colombia, like other countries in the region, does not have the capacity to self-supply, because although it has some capacity to produce a finished product (medicine), it does not produce raw materials or active pharmaceutical ingredients, so the country's ability to meet the need for drugs always depends to a greater or lesser extent on import processes
- Decrease the regulatory requirements for the commercialization of the products necessary to reduce the spread of COVID 19 although it can help to increase the offer of this type of products, it can put users at risk by lowering the quality standards of the products that are market

Speaker 3

J. Jayaseelan

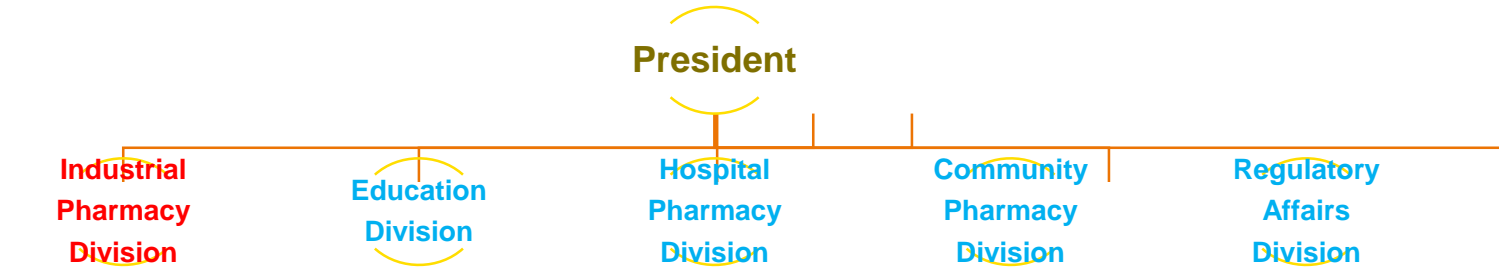
Chairman, Indian Pharmaceutical Association –
Industrial Pharmacy Division

(India)



Medicines Supply Disruption and Shortages during the COVID-19 Pandemic in South-East Asia (India)

Indian Pharmaceutical Association



J. Jayaseelan

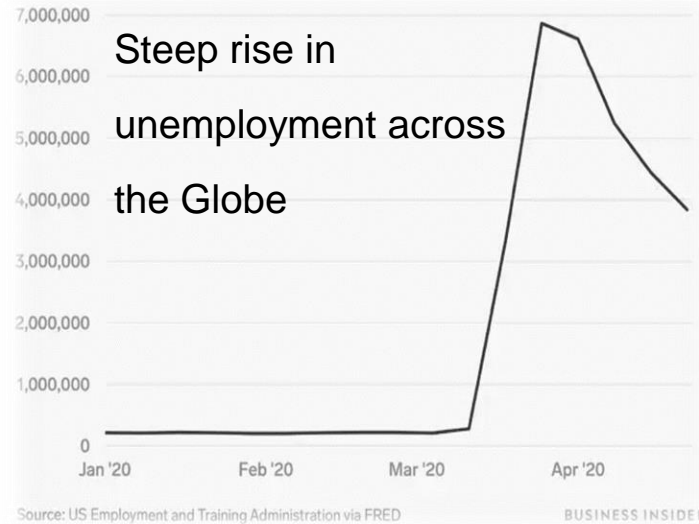
Chairman

The **Indian Pharmaceutical Association (IPA)** founded in 1939, is the oldest premier **association** of **pharmaceutical** professionals in **India**, with a **member** base of over 13,000, spread across the length and breadth of the nation. IPA operates in **India** through 20 state branches and more than 46 local branches.

Global Impact – Covid 19



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Effects on Health Care Systems



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- Prioritization and increase of hospital space
- New protocol emerged for treatment
- Sudden importance for Siddha and Ayurveda
- More focus on prevention and immunity boosting
- Rapid Regulatory Changes



Effects on Health Care Systems



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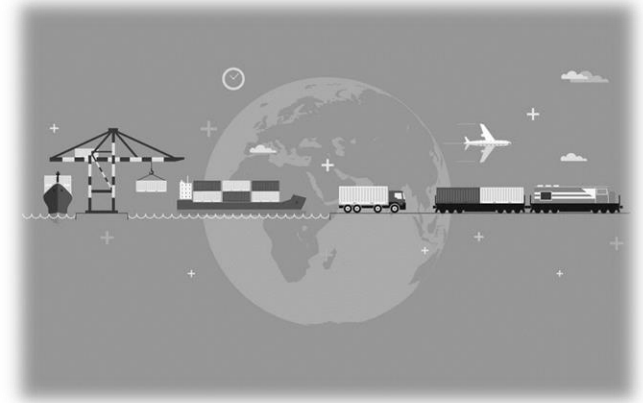
- Invention of new medicines and vaccines
- Preparedness for pandemic / next wave
- Budget restrictions on insurance / Government / Individual
- Emerging of Virtual management of healthcare
- Doctor Patient communication collapsed and emergence of tele medicine.





Global Supply Chain Affected

- Impact on India / China
- Transportation, import and Logistics cost increased to new height.
- Thin Margins.
- Customers not accepting any Cost Increase.
- Major Supply chain disrupted
- Affected Clinical Trial Landscape



Indian Pharma Industry – The Pharmacy of the World



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3rd Largest Producer of Medicines by Volume in the World
Largest Exporter of Medicine

Every
2ND
Vaccine

Export to **200** Countries



Recognized as global leader in supply of generic

10% volume



Share of world's total pharma output

Covid-19



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- China is leader in API
- India imports almost 68 per cent of its API consumption by value from China
- Highly reliant on China for fermentation-based APIs (antibiotics) and many key starting materials
- China has the advantage of cost competitiveness through value-chain integrated clusters, low-cost utilities, high capacity utilization and economies of scale



Medicine Disruption



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Manufacturing

MARKETING

STAND
STILL



DISTRIBUTION

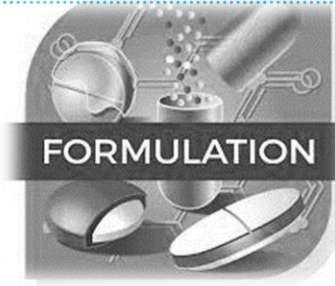


Dispensing

Manufacturing



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- Lockdown issues
- Supporting industries closure
- Logistics breakdown

- Doctors, Nurses, Hospitals, Clinics closed during lockdown



Distribution



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**Export –
Restrictions on Export / Import**

Dispensing - Shortages

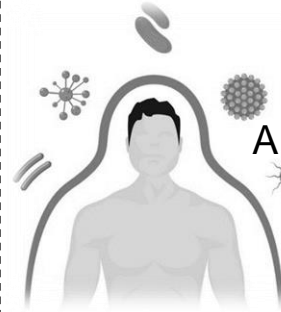


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CHRONIC THERAPY MEDICINES

ACUTE THERAPY MEDICINES



Immunity Boosters
A New Segment evolved

Challenges Ahead



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- Continues Lockdown created lot of back log.
- Normal processes wont work
- Access and affordability are the Key.
- Controlling Transport and logistic cost
- New ways of working are essential.
 - *Flexibility in R&D , Regulatory, Marketing ,etc..*
 - *Digital adaption and remote working.*

Speaker 4

Joao Ferreira

Scientific Officer,
European Medicines Agency (EMA)

(The Netherlands)



Securing availability of medicines across the EU

European response to medicine shortages during the COVID-19 pandemic

Background: How does the EU manage shortages?



- ❑ Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Network**. In the EU, most medicine shortages are dealt with at national level by national competent authorities.
- ❑ In December 2016, a joint **HMA/EMA Task Force on the Availability of Authorised Medicines** for Human and Veterinary Use was established in order to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability.
- ❑ In April 2019, the task force established a **EU single point of contact (SPOC) network** to improve information sharing between EU Member States, EMA and the European Commission (EC) on shortages of critical human and veterinary medicines.

Main shortage root causes in the context of the COVID-19 pandemic

- Temporary lockdowns of manufacturing sites
- Travel restrictions impacting exports
- Export bans
- Increased demand for medicines used to treat COVID-19 patients
- Stockpiling by hospitals, by individual citizens or at Member State level.

Responding to the COVID-19 pandemic



EU Executive Steering Group on shortages of medicines caused by major events

- Strategic leadership and EU coordinated actions
- Prevent and mitigate supply disruptions

i-SPOC reporting system between industry and EU regulatory authorities

- Fast-track shortage monitoring system
- Data collection on supply disruptions (and their causes) in relation to COVID-19 medicines (ICU setting)

EU Single point of contact (SPOC) network

- Gathered information on COVID-19 medicines (ICU setting) on shortages
- Collected demand data from EU MSs for 14 APIs under export restrictions (India)

Any questions?

Further information

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Question Time

*Please use the chat
board to log your
questions & comments.*

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“One FIP” means
trust, solidarity and action!



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Thank you for participating!

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