

Empowering Patients Through Good Aseptic Manufacturing: A Vital Journey Towards Safer Medical Products

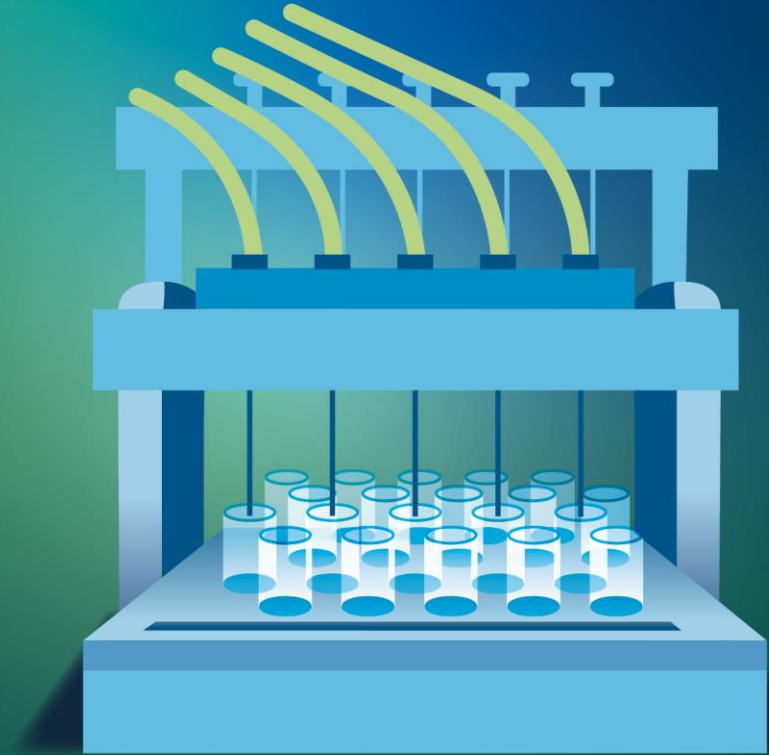
Hussain Jafri

Founding Director, World Patients Alliance
Pakistan



**World
Patients
Alliance**

CONNECTING
PEOPLE
SCIENCE AND
REGULATION®



2024 PDA

GOOD ASEPTIC MANUFACTURING CONFERENCE

15-16 MAY 2024 | STUTTGART | GERMANY



Hussain Jafri

Founding Director, World Patients Alliance

Hussain Jafri is the Executive Director of World Patients' Alliance. He is also the Secretary General of Alzheimer's Pakistan, the national association of Alzheimer's disease and related dementias that Hussain founded in 1999 as a result of his experiences as a care giver for his grandfather with Alzheimer's Disease. He has been very active in the field of patient safety and has remained the Vice Chair of Advisory Group of WHO's Patients for Patients Safety Program (PFPS). Hussain has also founded Pakistan Patient Safety Initiative and has been working towards several patient safety initiatives. The Government of the Punjab has also nominated him the Provincial Focal Person on Patients Safety & Quality and given the responsibility of developing patients safety and quality services in the health sector of the Punjab province.

He has remarkable experience of working as a volunteer in the social sector and has had an opportunity of working with government, national and international non-profit organizations. Hussain is also a member of the Person and Family Centered Advisory Council (PFCAC) of International Society for Quality in Health Care (ISQua). Moreover, he is also a taskforce member of Global Alliance of Partners for Pain Advocacy (GAPPA). He is an experienced speaker and a resource person and has been presenting nationally and internationally on different issues like patient safety, patients centered healthcare, care giving, advocacy, partnership in health, organizational development, etc. Hussain is a PhD from University of Leeds, UK on prevention of genetic disorders. He is currently working as the Director General of Punjab Thalassaemia & Other Genetic Disorders Prevention & Research Institute and has published several publications in international indexed journals.

Presentation Overview

World Patients Alliance

Global Patient Safety Movement

Burden of Medication Harm

Aseptic Manufacturing of Medicines

Conclusion

Who We Are

The World Patients Alliance (WPA) is a nonprofit umbrella organization of patients, patient organizations and stakeholders from around the globe. The WPA provides the platform to **empower and raise the patients' voice** for the provision of and access to safe, quality and affordable healthcare.

WPA works to ensure patients have an **active role** to play in all the stages of healthcare that including planning, provision, monitoring, research and evaluation of health services.

There are no fees for Patient Advocacy Organizations to become members, and our programs and initiatives are at **no-cost** to our Patient Advocacy Organization members.



**World
Patients
Alliance**

World's Largest Patients' Organization Across All Disease Areas



501
Member
Organizations

125
Countries

Europe 138, Americas 119, Africa 125, Asia 104 and Australia 15

WPA's Nine Principles

1. Access to healthcare
2. Patient centered healthcare
3. Financial hardship
4. Empowered patients
5. Patient safety and quality
6. Patient education and information
7. Partnership and collaboration
8. Patient engagement
9. No discrimination

- 
- A photograph of a healthcare setting. In the foreground, a young woman in a white and purple nurse's uniform is smiling broadly while holding a baby wrapped in a yellow blanket. Behind her, another nurse in a similar uniform looks on. The background shows a hospital room with a bed, a green wall, and some papers on a bulletin board. A blue text box is overlaid at the bottom of the image.
- No one should be harmed in health care...

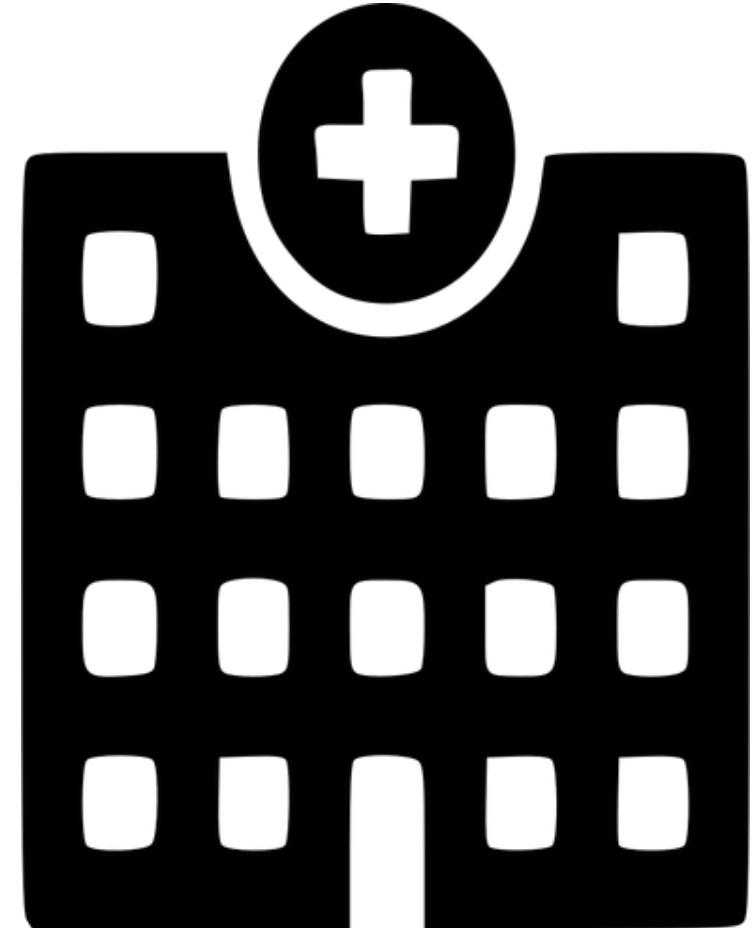
A close-up photograph of a woman with dark hair, smiling warmly while holding a young child. The woman is wearing a purple and white striped tank top. The child has dark hair and is looking towards the camera. The background is softly blurred, showing an orange object on the left and a blue light source in the upper right.

And yet

**globally, at least 5 patients die a minute because
of unsafe health care.**

most of these deaths are avoidable

- 134 million adverse events occur each year in LMICs
- Contributes to 2.6 million deaths annually
- Two thirds of the global burden of adverse events

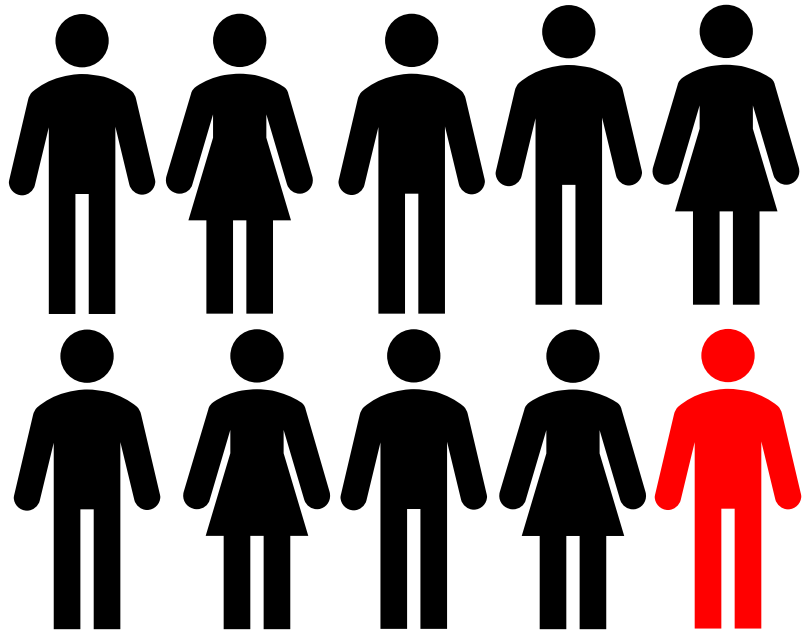


Source:

https://www.who.int/features/factfiles/patient_safety/en/



Adverse events in healthcare are likely to be one of the top 10 leading causes of death and disability worldwide



**One in every 10
patients is harmed
while receiving
hospital care in HICs**

Source:

https://www.who.int/features/factfiles/patient_safety/en/



Medication harm accounts for 50% of the overall preventable harm in medical care.



US\$ 42 billion of global total health expenditure worldwide can be avoided if medication errors are prevented.

Putting Patient Safety on the World's Agenda



World Health Assembly, 2002

'...Urging member states to pay the closest possible attention to...patient safety...'

2004: WHO Patient Safety Programme

Aims to coordinate, disseminate and accelerate improvements in patient safety worldwide.



Patients for Patient Safety (PFPS)

Engaging for patient safety remains a key priority

Patients for Patient Safety
Partnerships for Safer Health Care



- ❖ Aims to incorporate the patients voice in all levels of healthcare
- ❖ Offers a platform to patients to provide their input on patient safety issues
- ❖ Empowers and facilitates patients and their families to advocate for change collaboratively
- ❖ Encourage partnership, empowerment and inspire action of patient safety worldwide

Global Patient Safety Action Plan (2021 – 2030)

Framework for Action - The 7x5 Matrix

1		Policies to eliminate avoidable harm in health care	1.1 Patient safety policy, strategy and implementation framework	1.2 Resource mobilization and allocation	1.3 Protective legislative measures	1.4 Safety standards, regulation and accreditation	1.5 World Patient Safety Day and Global Patient Safety Challenges
2		High-reliability systems	2.1 Transparency, openness and No blame culture	2.2 Good governance for the health care system	2.3 Leadership capacity for clinical and managerial functions	2.4 Human factors/ ergonomics for health systems resilience	2.5 Patient safety in emergencies and settings of extreme adversity
3		Safety of clinical processes	3.1 Safety of risk-prone clinical procedures	3.2 Global Patient Safety Challenge: Medication Without Harm	3.3 Infection prevention and control & antimicrobial resistance	3.4 Safety of medical devices, medicines, blood and vaccines	3.5 Patient safety in primary care and transitions of care
4		Patient and family engagement	4.1 Co-development of policies and programmes with patients	4.2 Learning from patient experience for safety improvement	4.3 Patient advocates and patient safety champions	4.4 Patient safety incident disclosure to victims	4.5 Information and education to patients and families
5		Health worker education, skills and safety	5.1 Patient safety in professional education and training	5.2 Centres of excellence for patient safety education and training	5.3 Patient safety competencies as regulatory requirements	5.4 Linking patient safety with appraisal system of health workers	5.5 Safe working environment for health workers
6		Information, research and risk management	6.1 Patient safety incident reporting and learning systems	6.2 Patient safety information systems	6.3 Patient safety surveillance systems	6.4 Patient safety research programmes	6.5 Digital technology for patient safety
7		Synergy, partnership and solidarity	7.1 Stakeholders engagement	7.2 Common understanding and shared commitment	7.3 Patient safety networks and collaboration	7.4 Cross geographical and multisectoral initiatives for patient safety	7.5 Alignment with technical programmes and initiatives



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Strategic Objective 4

Patient and family engagement

Engage and empower patients and families to help and support the journey to safer health care



Schools Awareness Campaign (Uganda)



Awareness Football Match (Israel)



Conference, (Poland)



Street Theater (Ghana)

World Patient Safety Day 17 September

WPA is proud to have organized the most activities globally for World Patient Safety Day in 2021,2022 & 2023

Around **1,600** events organized globally in the last three years



World Patient Safety Day 2023

Engaging Patients for Patient Safety



Global Celebration



400 Events



Member Organizations
In Collaboration with WPA

Reach

- ✓ 500,000 in-person
- ✓ 100,000 online
- ✓ 10,000,000 social media impressions



A



Aseptic Manufacturing

Historical Instances of Contamination

- **Heparin Contamination (2008, US):**

Issue: Contaminated heparin, a blood thinner, led to numerous severe allergic reactions and deaths.

Consequence: A heightened awareness of the potential life-threatening consequences of contaminated medications.

- **Meningitis Outbreak (2012, US):**

Issue: Contaminated steroid injections caused a widespread outbreak of fungal meningitis.

Consequence: Increased patient anxiety and a loss of trust in medications.

- **Salmonella Contamination (2020, Various Countries):**

Issue: Contaminated batches of a common diabetes medication led to a recall.

Consequence: Patients faced uncertainty about the safety of their medications, resulting in anxiety and potential disruptions to their treatment plans.

Notable cases: Pharmaceutical recalls or safety issues

Valsartan Contamination (2018, Global):

- **Issue:** Contamination of the angiotensin II receptor blocker (ARB) valsartan with N-nitrosodimethylamine (NDMA), a probable human carcinogen.
- **Consequence:** Widespread recalls and concerns about the long-term effects on patients who had been taking the contaminated medication.

Thalidomide (1950s-1960s, Global):

- **Issue:** Prescribed to pregnant women for morning sickness, thalidomide caused severe birth defects in thousands of infants.
- **Consequence:** A global tragedy that led to increased scrutiny of drug approval processes and the establishment of more rigorous regulatory frameworks.

Tylenol Recall (1982, US):

- **Issue:** Tampering with Tylenol capsules resulted in seven deaths due to cyanide poisoning.
- **Consequence:** Immediate nationwide recall, change in packaging practices, and the introduction of tamper-evident packaging in the industry.

Vioxx (2004, Global):

- **Issue:** Vioxx, a painkiller, was withdrawn from the market due to an increased risk of heart attacks and strokes.
- **Consequence:** Resulted in thousands of lawsuits and a shift in focus towards drug safety and post-market surveillance.

Multistate Outbreak of Fungal Meningitis and Other Infections

In September 2012, the Centers for Disease Control and Prevention (CDC), in collaboration with state and local health departments and the Food and Drug Administration (FDA), began investigating a multistate outbreak of fungal meningitis and other infections among patients who received contaminated preservative-free MPA steroid injections from the New England Compounding Center in Framingham, Massachusetts. (US)

source: [Centers for Disease Control and Prevention](#)

At-A-Glance

- [Infection: Fungal](#)
- [Facility Type: Inpatient and Outpatient](#)
- [Case Count: 753](#)
- [States: 20](#)
- [Deaths: 64](#)

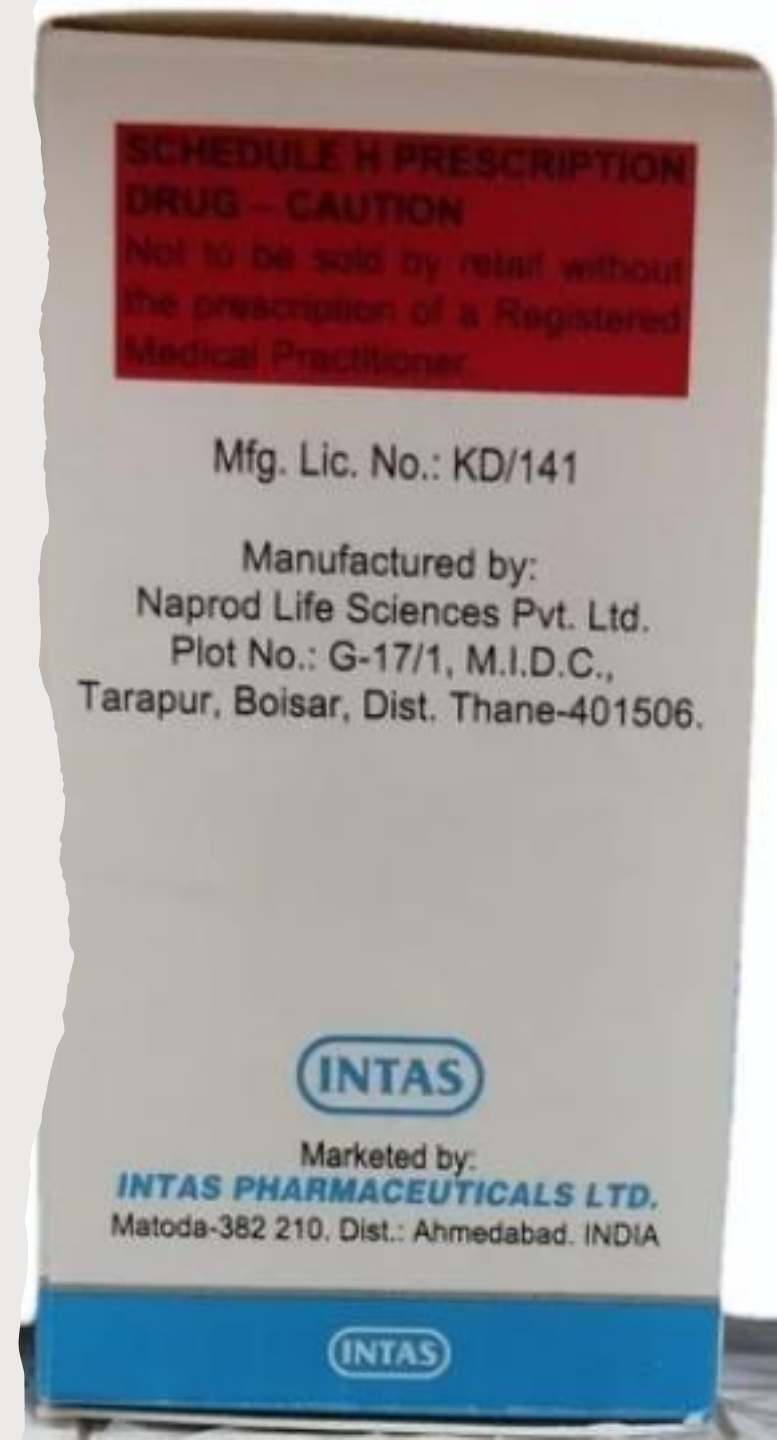


How Sick Kids Got Contaminated Cancer Drugs

- Hospitals around the world use drugs from a small but crucial Indian supplier. In Colombia, four children died and more than a hundred fell ill.
- Source: [Bloomberg](#)

Methotrexate Manufacturing

- Methotrexate is a drug used to treat leukemia and other cancers, commonly prescribed and usually tolerated.
- This medicine is manufactured by Naprod Life Sciences in an industrial town north of Mumbai, India.
- Requires strict control to maintain sterility and prevent contamination.



Colombian Outbreak

- In 2019, clinics in Colombia reported patients developing high fevers, altered states of consciousness, and other symptoms after receiving Naprod's methotrexate.
- Testing revealed the presence of *Pseudomonas aeruginosa* in the contaminated drug batches.
- More than 100 patients suffered reactions, and four children died as a result of the contaminated medicine.





Quality Control Failures

- European inspectors found severe violations of manufacturing guidelines at Naprod's sister company, Mac-Chem Products India Pvt Ltd.
- Former employees reported being pressured to hurry through sterility tests to expedite production.
- Employees who reported unsafe practices were ignored or pushed out by management.

Naprod's Role in Drug Supply Chain

- Naprod provides low-cost generic cancer medicines to hospitals worldwide, especially in developing countries.
- None of Naprod's products are approved for sale in the US, where regulations are stricter.

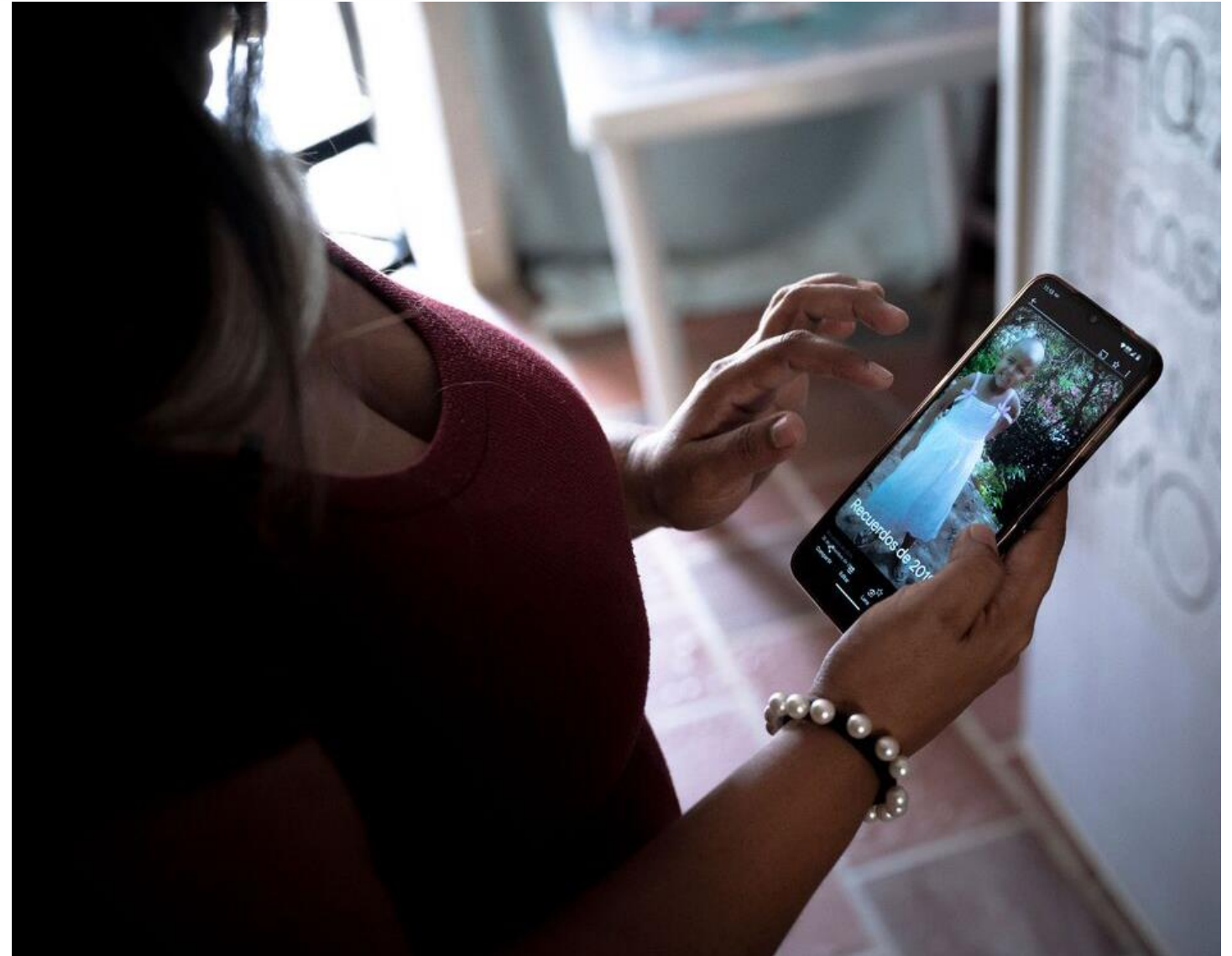
The Naprod Life Sciences plant, three hours north of Mumbai



Impact on Patients and Families

- Valery Fernandez, Cristhian Vivas, Alan Martinez, and Jesus Salazar suffered severe symptoms after receiving contaminated methotrexate.
- Valery and Cristhian died as a result of the contamination, leaving grieving families behind.

Valery's mom showing her picture



Regulatory Response and Future Challenges

- Colombian authorities were slow to recall the contaminated batches, and Naprod faced minimal consequences for its actions.
- Lack of oversight in the global pharmaceutical supply chain poses risks to patient safety, highlighting the need for stricter regulations and quality control measures.

Cristhian when he was 15



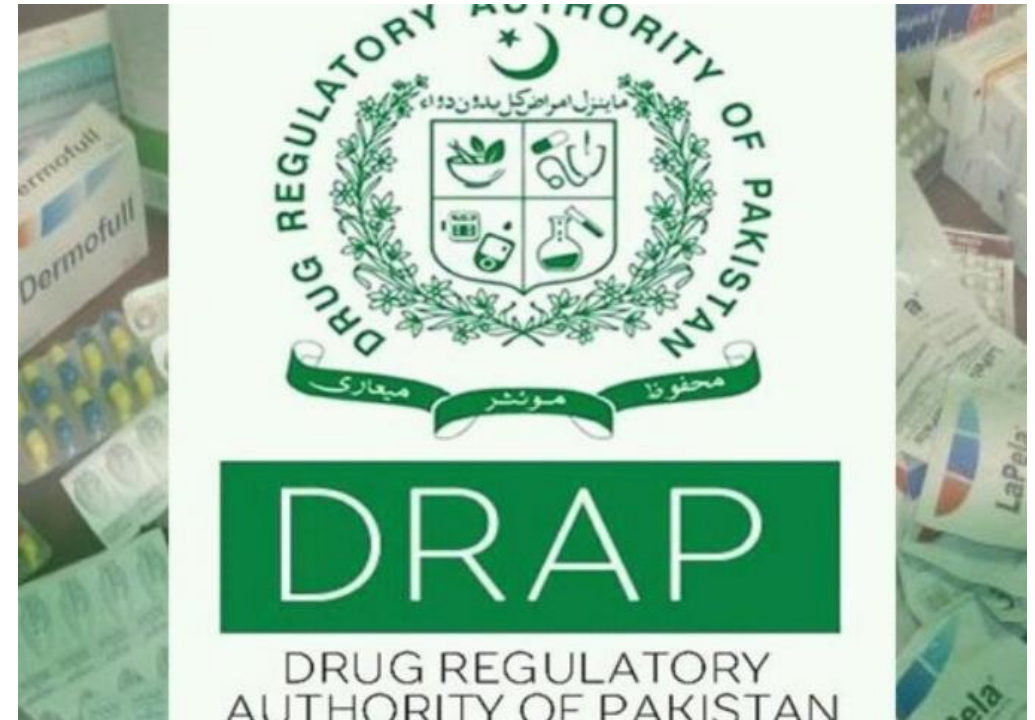


Housefly in Injection Vial

- Video showing a Housefly (*Musca domestica*) in an injection ampoule goes viral on the media in Pakistan
- Date: November 27, 2023
(<https://www.thenews.com.pk/print/1132937-video-of-fly-in-injection-viral-on-social-media>)

Response and Actions Taken

- DRAP recalled the drug as a precautionary measure to prevent public health hazards.
- Legal action was taken against parties involved in negligence, including manufacturers, suppliers, distributors, and medical stores.
- Company challenged the drug court's decision in the Provincial Quality Control Board (PQCB), currently under review.
- Plan to refer the matter to the Regional Police Officer for criminal investigation into motives behind video resurgence.



Community's Confidence Shattered

- Medicines available in the market
- Medicine manufacturers
- Regulatory agency



Reasons for Non-Aseptic Manufacturing of Parenteral Drugs

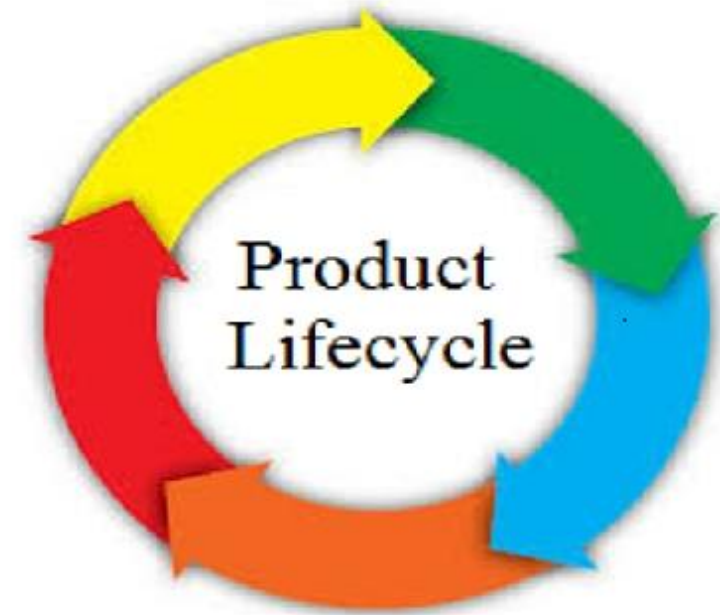
- Lack of required infrastructure, equipment and resources
- Incorrect aseptic techniques
- Poor training and lack of experience
- Cost - compromise in manufacturing practices
- Poor regulatory framework
- Stakeholders not engaged

Other Issues

- Varying levels of quality of medicines in all world regions
- Manufacturing of medicines by a company in different countries, remote site factory and through sister concerns or other manufacturers
- Deliberate compromises made on quality of medicines
- Role of companies and drug manufacturer associations
- Lessons learnt or same practices are continued

Manufacturer's Responsibility

- Supply chain
- **Manufacturing**
- Packaging
- Storage
- Distribution
- Administration



Understanding Patient Fears

- Patients experience anxiety when considering the possibility of receiving contaminated medications
- The fear is rooted in the potential consequences of contaminated drugs on patient health
- Leads to poor compliance treatment

!!!???



Patients' Trust

- Good Aseptic Manufacturing is not just about sterile environments
- It's about trust and assurance in the manufacturing process
- Patients need to be ensured about the quality of medicines
- Partnership between patient organizations and the industry



Safety First

- Ensure Sterile manufacturing environments
- Aseptic manufacturing ensures safety, efficacy, and consistent dosages
- Rigorous quality standards play an important role in protecting patients from harm
- Ensuring therapeutic benefits for patients



Examples

Clean Room Standards:

Pharmaceutical companies investing in state-of-the-art clean room facilities to ensure the highest level of sterility during drug manufacturing.

Regulatory Compliance:

Compliance with guidelines from regulatory bodies like the FDA or European Medicines Agency (EMA) to meet or exceed safety standards.

Recalls Due to Contamination:

Recall cases due to contamination highlight the tangible consequences of not maintaining sterile manufacturing environments.

Strong Relationship between: Patient adherence and the perceived safety and effectiveness of medications

- Patient adherence improves with trust in healthcare system
- Confidence in aseptic manufacturing processes improves perceived safety
- Patient Education & Communication lead to enhanced understanding and confidence thus ensuring better health outcomes



Examples enhancing Patient trust:

FDA Inspections and Patient Trust:

- **Example:** Positive inspection reports and adherence to regulatory standards contribute to building patient trust. Companies like Genentech, Novartis, and Johnson & Johnson have, at times, received positive feedback from regulatory authorities.

Patient Surveys:

- **Example:** Positive feedback from patients who are informed about and trust the manufacturing processes of their medications.

Company Transparency Initiatives:

- **Example:** Companies like Pfizer, Moderna, and AstraZeneca providing detailed insights into their vaccine manufacturing processes, fostering trust in their products.

Empowering Patients

- Trust is a cornerstone in any effective healthcare system
- Two-ways street: trust in system & reciprocation by ensuring highest quality of standards and efficacy
- Stringent aseptic conditions contribute to building and maintaining patient trust in the industry's commitment and positive health outcomes



Empowering Patients

Trust & confidence in the good quality of medicines is essential for empowering patients:

- Trust
- Peace of Mind
- Informed Decisions
- Adherence to Treatment Plans
- Advocacy and Engagement



Global Health Impact

- Beyond individual patients: Good Aseptic Manufacturing's impact on global health
- Ensuring well-being on a broader scale



Global Health Impact

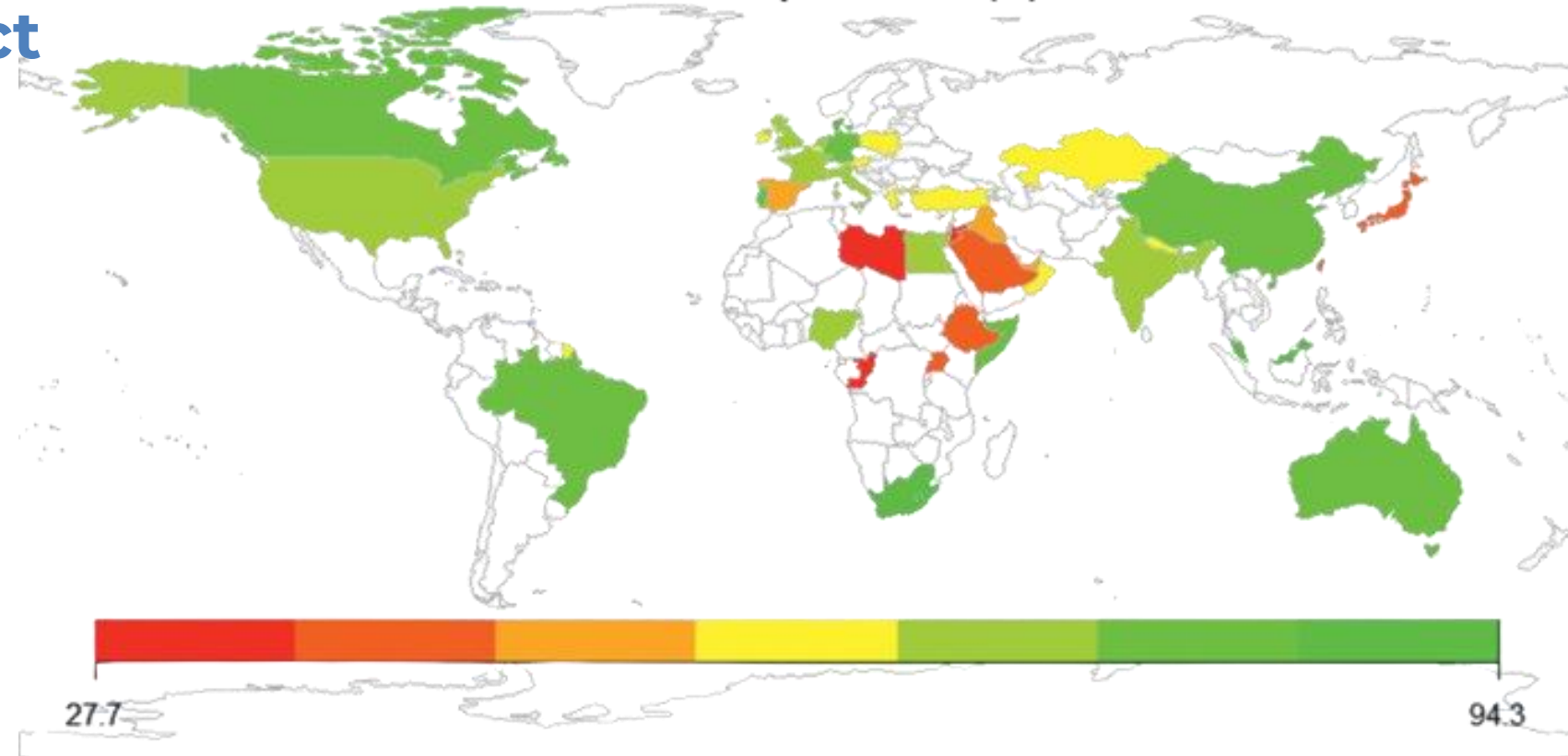
Preventing Disease Outbreaks:

Healthcare System Resilience:

Access to Quality Medications:

Reducing Economic Burdens:

COVID-19
Vaccine Acceptance Rate (%)



Attitudes, acceptance and hesitancy among the general population worldwide to receive the COVID-19 vaccines and their contributing factors: A systematic review

RESEARCH PAPER [VOLUME 40](#) 101113, OCTOBER 2021 | THE LANCET

Positive Patient Outcomes: Aseptic Manufacturing

Vaccine Efficacy

Insulin Therapy for Diabetes

Biologics and Monoclonal
Antibodies

Anti-Infective Medications

Sterile Injectables

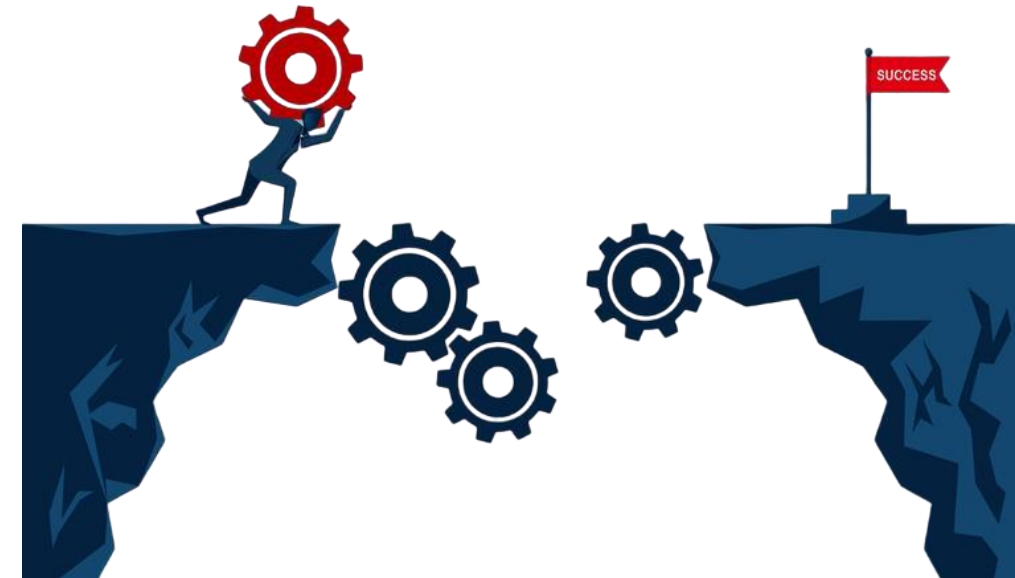
Biologic Therapies for
Rheumatoid Arthritis

Cell and Gene Therapies

Cancer Chemotherapy

Bridging the Gap

- Pharmaceutical manufacturers and patients is crucial for fostering a collaborative and patient-centric healthcare ecosystem.
- Understanding the patient perspective is key
- Strengthens the relationship between pharmaceutical manufacturers and patients leading to improved health outcomes.





Learning from Patient Experiences & Stories

- Importance of aseptic manufacturing in preventing health hazards associated with contaminated drugs.
- Need for public awareness, education and engagement in using properly manufactured and quality-assured medicines.
- Emphasis on regulatory oversight and prompt action to address issues of drug contamination for public safety.

Conclusion

- Humanize the significance of Good Aseptic Manufacturing from a patient's viewpoint
- Not just a product but lifeline
- Patient empowerment & engagement
- Partnership of all stakeholders especially between industry and patients
- Working collectively for safer, more reliable medications and better health outcomes worldwide



Call to Action

- Emphasizing the collective responsibility for ensuring safer pharmaceuticals
- Encouraging collaboration between stakeholders, especially between industry and patients



SAVE THE DATE



**World
Patients
Alliance**

Cape Town

19 - 20 October, 2024



**World
Patients
Alliance**

**2ND WORLD
PATIENTS CONFERENCE**

The Role of the Patient in a Changing World



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Thank You!



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