



SeerPharmaUK
CONFIDENCE IN COMPLIANCE

Balancing Pharma Compliance and Charitable Efforts



Speaker: Madeleine Ault, SeerPharmaUK

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Welcome to Making Pharmaceuticals 2022

An opportunity to talk about something that touches all of us

- Provision of medicines worldwide
- Balancing compliance and charitable efforts

What do you know about this?

What do I know about this?

Interested in pragmatic compliance – so I decided to do some research on the compliance of charitable donations

Objective - making the most of our influence.



UKRAINE EMERGENCY APPEAL

Update :-

Practical Aid Needed

FOOD

PASTA, RICE, TINNED MEAT, TINNED FISH, TINNED BEANS,
PACKET SOUPS, FLOUR, COOKING OIL, SALT

MEDICAL

DRESSING WOUND PACKS, BANDAGES, GAUZE, GARGEE
PADS, SURGICAL GLOVES, SURGICAL ADHESIVE TAPE,
SALINE STERIL PODS, MASKS, FIRST AID KITS, ANTISEPTIC
CREAMS, PARACETAMOL, IBUPROFEN, HEAT PADS,
PRESSURE DRESSINGS FOR WOUNDS, TUBI GRIP,
TOURNIQUETS.

TOILETRIES

SOAP, TOOTHPASTE, TOOTHBRUSHES, FLANNELS,
SHAMPOO, SANITARY TOWELS, NAPPIES

Donations to Carol at

What do you think about this?

- Paracetamol and Ibuprofen are licensed medicines
- 'Carol' probably does not have a WDA
- No considerations for safe storage or distribution
- Incorrect language for recipients
- Whose hands will this fall into?
- No charity number listed

These situations demand our help, people are in desperate need;

..... but is this the way?

I asked several people; they felt very strongly:

“Are these transported correctly?”

“Where are the big charities?”

“I don’t care about licences so long as the aid gets there”

“We must do whatever we can”

“Are medicines supplied by medically trained staff?”



Easy prepared

Granola bars

Oat bars

Dried fruit

Mixed nuts

Instant soups

Medication/ First Aid:

Anti diarrhoea tablets

Nurofen

Activated charcoal

Bandages

Gauze

Antiseptic spray

Antiseptic wipes

Anything with Iodine

Savlon

Antiseptic cream

Muscle relaxant cream

Antihistamine

Strong painkillers

Medication for children- Calpol etc

Small scissors

Plasters

First aid kits

First aid bags to sort

Babies and Children:

Disposable nappies and wipes

Baby formula: instant and powder

Warm winter wear for babies and children, coats,

hats etc.

Blankets

An extreme example!

- Anti diarrhoea tablets
- Nurofen
- Anything with Iodine (Iodine is a POM, do they mean *Iodine*?)
- Muscle relaxant cream
- Antihistamine
- Medication for children - Calpol
- Strong painkillers!

Can we 'do good' and 'be good'?

- Urgent need and long-term needs

Our conscience demands we help ... and we must do!

Consideration factors:

- Time and urgency
- Responsiveness – getting help where it is needed
- Distance and regional differences
- Scalability and efficiency
- Medicine quality
- Medical oversight – appropriate medicinal products and expertise
- Regulations – at source, in transit, on receipt
- Safety and Security



What does the regulator say?

Gov.uk advice

Unsolicited donations of goods ... can obstruct supply chains and delay more urgent life-saving assistance

Charities with experience of responding to disasters are best placed to reach victims on the ground.

(Source: MHRA advised refer to <https://www.gov.uk/government/news/ukraine-what-you-can-do-to-help> March 2022)

Goods you cannot take out of Great Britain using the simplified process

Include:

Human medicines unless you have a licence to distribute.

(Source: <https://www.gov.uk/guidance/taking-humanitarian-aid-out-of-great-britain-to-support-Ukraine>)

HPRA (RoI) advice

“ the provision of medicines would be more appropriately managed through the existing authorised supply routes.”

“ ... we have worked with a small number of authorised entities within the legal supply chain to assist them in the most efficient way to supply ... while complying with regulatory requirements.”

“ We have ... provided some flexibility with respect to import licences ... and some aspects of safety features requirements.”

(Source: Information response received from HPRA 2nd April 2022)

Guild of Healthcare Pharmacists (UK) advice

Advice to members 2 March 2022:

Why NOT to donate medicines

“Transporting medical supplies from the UK to other countries requires a range of licenses In addition, there must be assurance of environmental control ... they must meet the country’s requirements for labelling, packaging, language and appropriateness.”

“ ... the rule of thumb is to donate cash, not products.”

(Source: <https://www.ghp.org.uk/2022/03>)



The Guild advise donations to:

Medecins Sans Frontiers

International Health Partners

Malta advice

Verbal advice given:

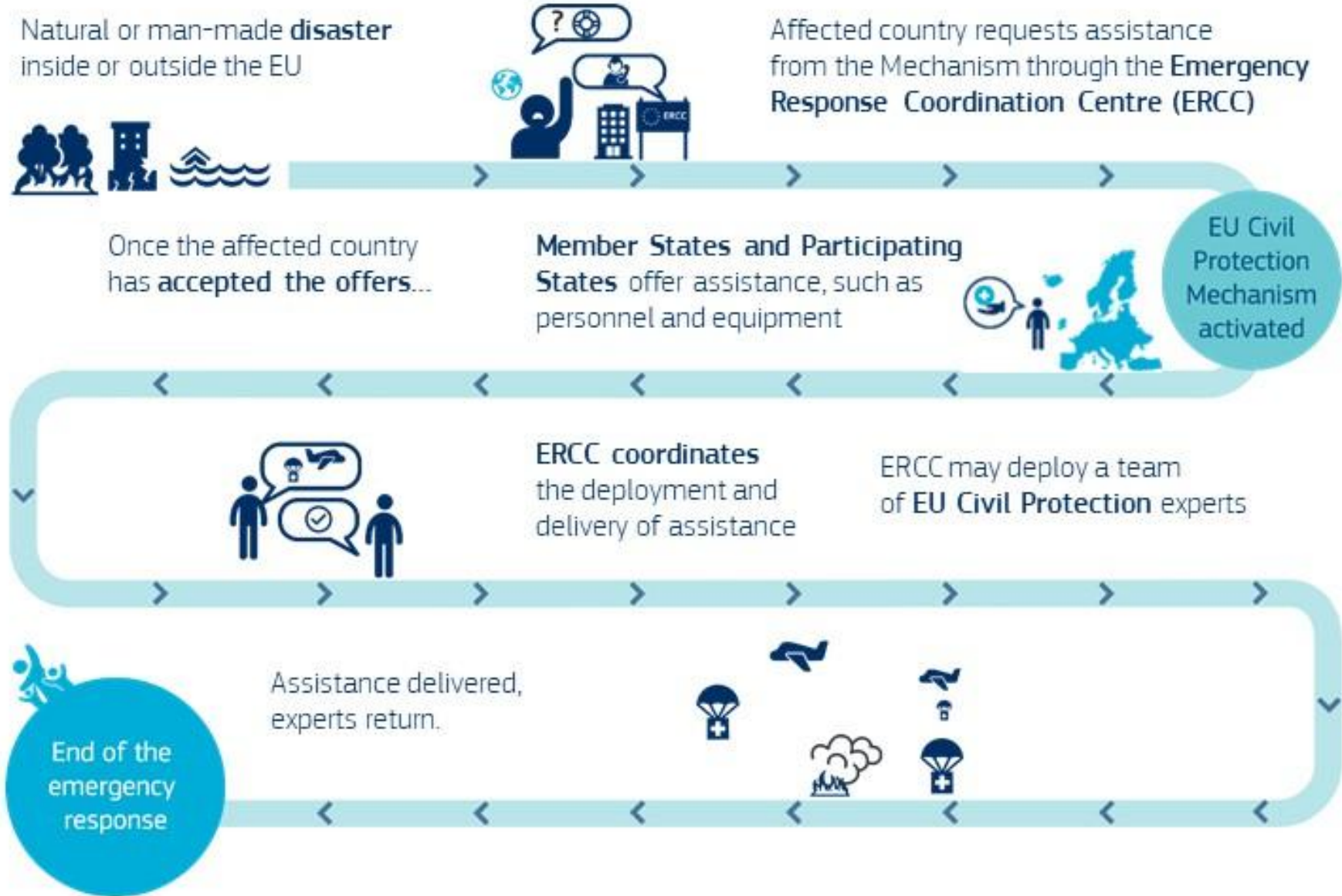
“All supplies of medicines and medical devices are expected to be in compliance.

Some flexibilities in licensing have been made in limited circumstances.”

(Source: anecdotal evidence in direct conversation with the regulator, March 2022)



How does the **EU Civil Protection Mechanism** work?



(Source: https://ec.europa.eu/echo/what/civil-protection/eu-civil-protection-mechanism_en)

World Health Organization

The World Health Organisation (WHO) encourages the donation of money to enable charities to purchase essential priority medicines and to support the healthcare workforce.

Funding:

Assessed contributions (AC)

Voluntary contributions (VC)

(Source: <https://www.who.int/emergencies/situations/ukraine-emergency/medical-supply-donations>)



World Health Organization

WHO have a **World Patient Safety Day** with a different focus each year. **‘Medication Safety’** - the theme for World Patient Safety Day 2022

(World Patient Safety Day <https://www.who.int/campaigns/world-patient-safety-day/2021>)

“2 billion people globally still lack access to medicines. Ensuring access to the right medicine for the right patient in the right place at the right time is a complex feat that requires a multifaceted approach.”

(Source: 17 September 2019 <https://www.savethechildren.org.uk/blogs/2019/functioning-regulatory-systems-the-cure-for-lack-of-access-to-medicines-in-low-and-middle-income-countries>)

The UK Disasters Emergency Committee

- Brings together 15 leading UK aid charities to raise funds.
- Co-ordinates the UK public's response to overseas disasters.
- Rapid Response Network to launch high-profile appeals.
- Immediate impact, getting help to people who need it, fast.

(Source: <https://www.dec.org.uk>)

DEC MEMBER CHARITIES



act:onaid



The bad old days



Low to zero compliance:

- Poor expiry dates
- Inappropriate storage
- Controlled drugs
- Mixing medicines
- Not matched to patient need
- Interruptions in supply

But ... high community involvement.

Save The Children International – some headline points



(Source: Photo credit: Hanna Adcock/Save the Children)

Save the Children hold UK WDA(H) 49244 - Ensuring safe and reliable medicine supplies

In partnership with GSK promoting the concept of Universal Health Coverage:

- creating child-friendly medicines at not-for-profit prices. E.g. a heat stable chlorhexidine gel, designed for hot and humid environments distributed under the trade name Umbipro™ – at a not-for-profit price

Immunising entire communities and raising awareness about the importance of vaccines

Working with NGOs to train local people to administer drugs (examples in Africa and South America).

Save The Children International – an example from Nigeria

A medicines formulary:

- Based on national prescribing guidelines ... is available to all medical staff
- This supports the supply chain teams in predicting what medication is most likely to be required and ordered on a regular basis
- This ensures Save the Children medical teams are always using the most effective medicines available
- The medication prescribed is evidence based.

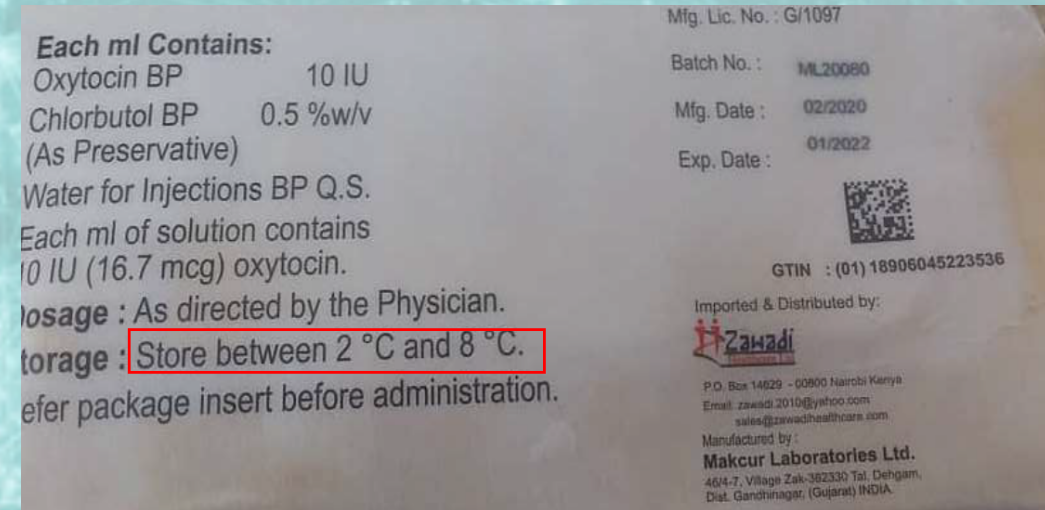


(Source: <https://www.savethechildren.org.uk/blogs/2022/safe-medicine-saves-lives--habibah-s-malnutrition-and-tb-recover>)

Save The Children International – an example from Somalia

“Our Country Office in Somalia needed Oxytocin and decided to purchase through a partner charity organisation. Unfortunately the organisation was not qualified as a medical supplier, and the medicines were shipped via airline from Kenya to Mogadishu.

A passive cold chain box was used. There was no validation to support the cold chain box used, the product was poorly packed and warm to the touch. The whole shipment was rejected and marked for destruction. A GDP incident was raised to follow-up on training.”



(Source: direct communication)

Pharmaceutical supply chains are complex, fraught with inefficiencies leading to shortages and poor-quality medicines. Infrastructure is often lacking

Pharmaceutical companies engage local stakeholders to strengthen supply practices and transfer knowledge to local manufacturers

The report assessed 68 supply chain initiatives in respect of:

- Partnerships with local third-part actors
- Addressing local needs and/or gaps
- Clear, measurable goals, objectives, outcomes and integration within the system
- Support to local distributors on GDP, sustainable practices and cold chain supply.

(Source: <https://accesstomedicinefoundation.org>)

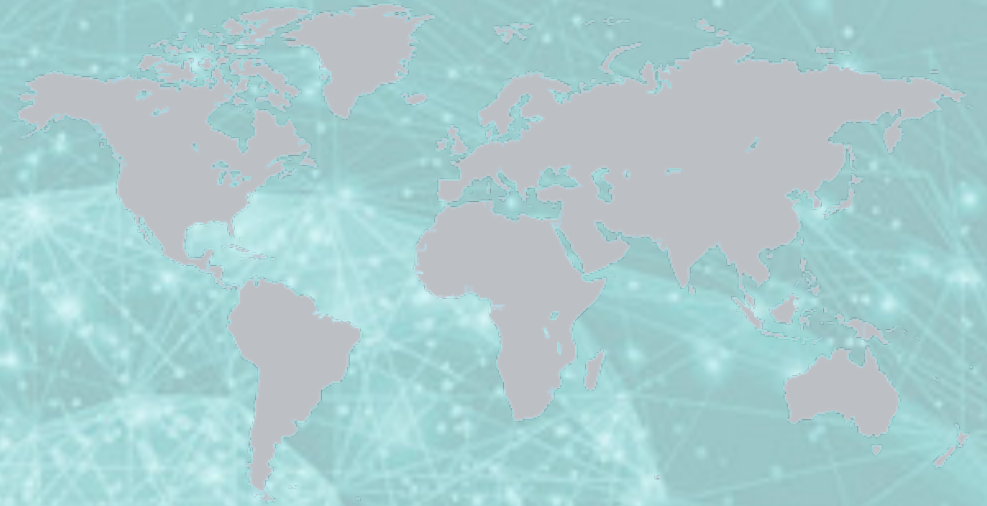
“We are the largest coordinator of donated medical products in Europe, with a strong network of product donors, known as our Healthcare partners. Most of these partners are pharmaceutical companies and medical supplies companies.”

Needs-led:

- Disaster response
- Health programmes
- Essential health Packs
- Web-based Donations Platform – from June 2019.

(Source: ihp.org.uk)

IHP - £24.6m worth of medicines in
2021



Supporting 31 countries:

Including: DR Congo, Yemen, Palestine, Lebanon, Ukraine, North Macedonia, Myanmar, China, Bangladesh, Venezuela, Nicaragua, Guatemala, Honduras, Syria, Sierra Leone, Ethiopia, Malawi.

IHP – Partner Companies

A rigorous process to accept partners.

30+ Companies, majority UK & EU

“We are very proud to have been able to contribute to IHP’s great work in reaching the needy in almost unreachable parts of the world.”
- **BD, healthcare partner**

“IHP has become the number one partner that we go to when an emergency strikes and we need to get supplies to the field quickly. It has the ability to move more rapidly than any other organisation that we work with and consistently exceed expectations.” - **NGO partner**

(Source: <https://www.ihpuk.org>).



IHP - Achieving Compliance

- IHP have UK WDA(H) 42642 - Inspections had good outcomes – ‘other’ deficiencies
- *“Never compromise compliance, must invest in compliance all the time and mirror that diligence overseas”*
- Committed to vigorous and accountable GDP
- Fully compliant with medicine supply chain legislation including EU FMD
- Harsh decisions are made as to which products are accepted – promises must be fulfilled such as: Full provision of information, CoA, expiry dates
- Ensure corporate partners have the same expectations as IHP
- A system in place to report adverse medical events
- Only accept medical donations in accordance with guidelines
- A signatory to the WHO Guidelines for Medicine Donation
- Belong to PQMD (Partnership for Quality Medical Donations).



(Source: verbal and <https://www.ihpuk.org/programme-quality-standards>)

Problem:

Product delayed at Djibouti for 3 months

Compliance:

Freight company used that can guarantee temperature control and security.

Temperature trackers are used

Note:

More donations of freight service needed.

IHP would really like to use GPS trackers.
Is there a company who can donate these?



UK to
Djibouti to
Yemen

Summary



Donations from pharmaceutical companies play an important role in health around the world

Charities are working hard to achieve compliance because everyone deserves medicine of the same high quality

Compliance IS achievable

Pharma CAN balance compliance with charitable efforts

Share experiences or comments please?

[IHP Donate](#) [Save the Children Donate](#)

[IHP Contact us](#)



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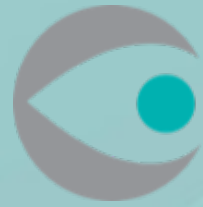


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Contact us at:

PO Box 3408, Littlehampton, BN16 9JX, United Kingdom

T: + 44 (0)1903 730 622 (Office)

E-mail: enquiries@seerpharma.co.uk

Web: www.seerpharma.co.uk

Also at: Australia - Singapore

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