VolkswagenStiftung

MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG

MUHAS

UFZ

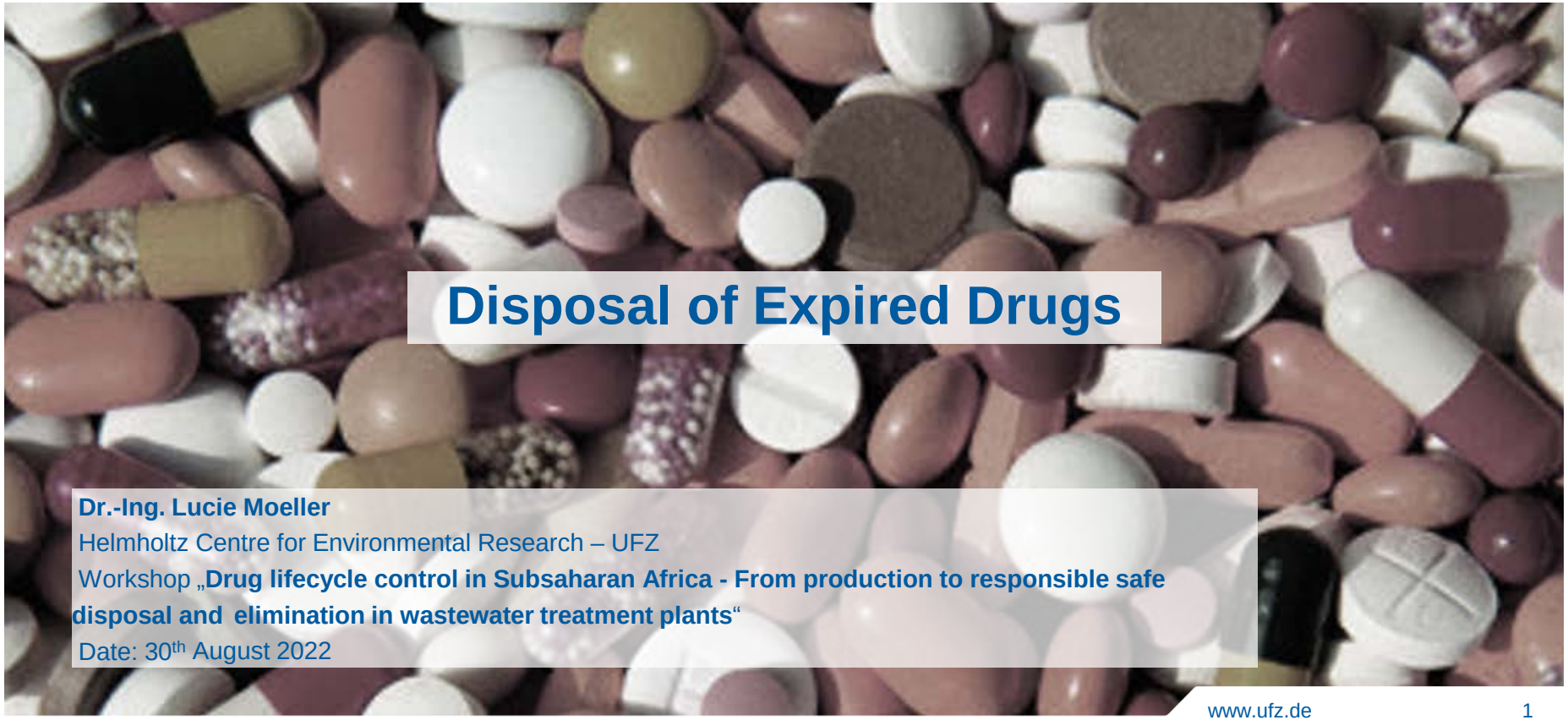
Workshop

Drug lifecycle control in Subsaharan Africa

From production to responsible safe disposal and elimination in wastewater treatment plants

(Med4Africa)

UFZ HELMHOLTZ Centre for Environmental Research



Disposal of Expired Drugs

Dr.-Ing. Lucie Moeller
Helmholtz Centre for Environmental Research – UFZ

Workshop „**Drug lifecycle control in Subsaharan Africa - From production to responsible safe disposal and elimination in wastewater treatment plants**“

Date: 30th August 2022

source: umweltbundesamt.de

Circular Economy

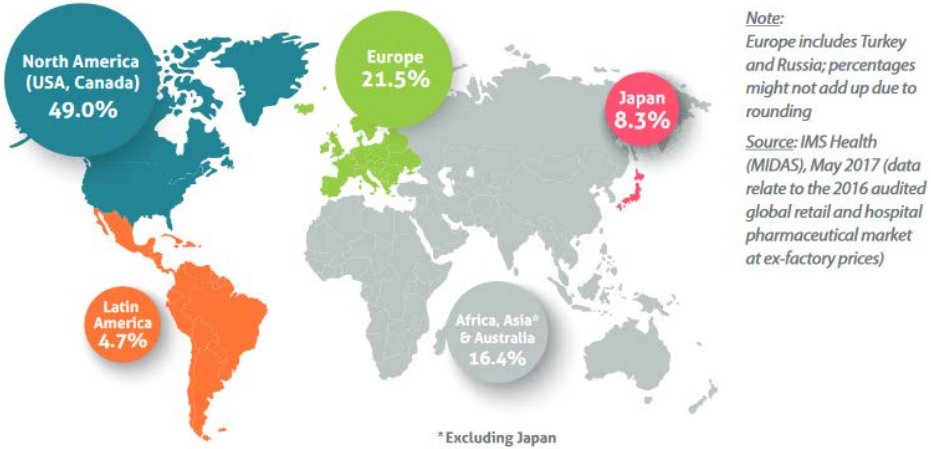
source: iurban.in.th

Pharmaceutical sales

PHARMACEUTICAL SALES

The world pharmaceutical market was worth an estimated € 763,101 million ($ 844,676 million) at ex-factory prices in 2016. The North American market (USA & Canada) remained the world's largest market with a 49.0% share, well ahead of Europe and Japan.

BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET – 2016 SALES



Note:
Europe includes Turkey and Russia; percentages might not add up due to rounding

Source: IMS Health (MIDAS), May 2017 (data relate to the 2016 audited global retail and hospital pharmaceutical market at ex-factory prices)

source: efpia.eu

ALNAHAS ET AL., 2020:

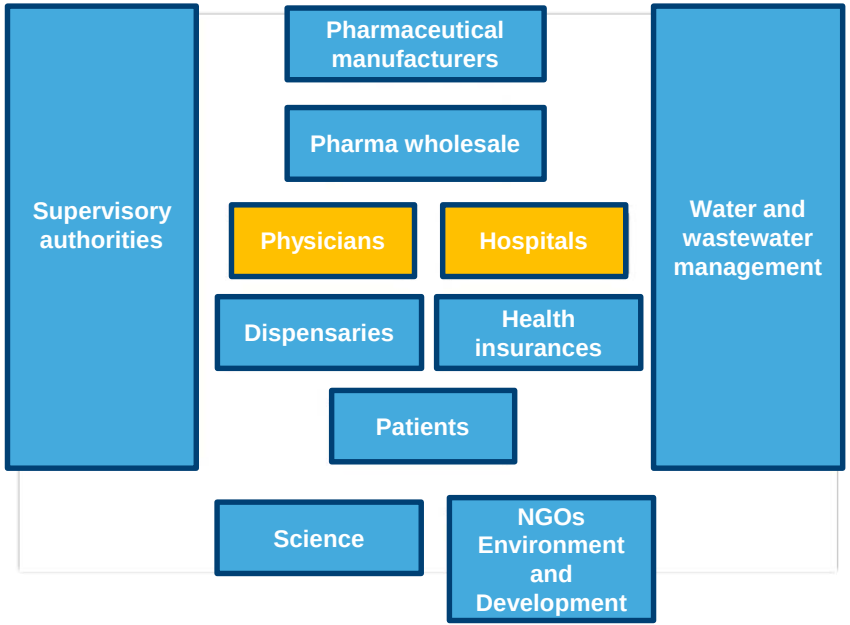
Variant Market Research:
universal OTC market is expected to grow **from USD 125 bn in 2016 to USD 273 bn by 2024**

German Federal Ministry for the Environment (2014): worldwide production of synthetic chemicals by pharmaceutic companies: **100,000 tons per year**

GUIRGUIS, 2010:
The economic value of pharmaceutical waste per patient and year in Australia: USD 1,280

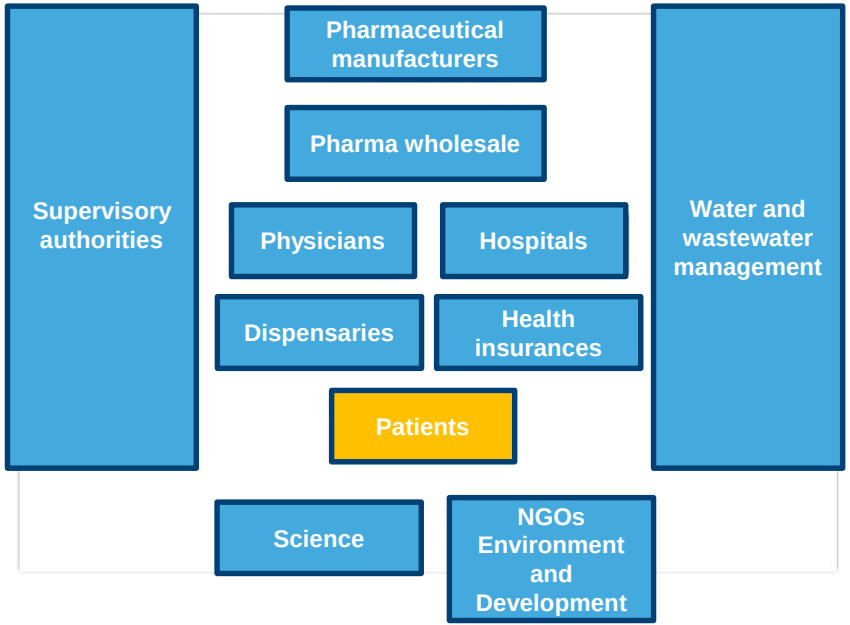
Pharmaceutical waste - Actors

Actors in the health sector / institutions in the water and wastewater sector (GERMAN FEDERAL ENVIRONMENTAL AGENCY)

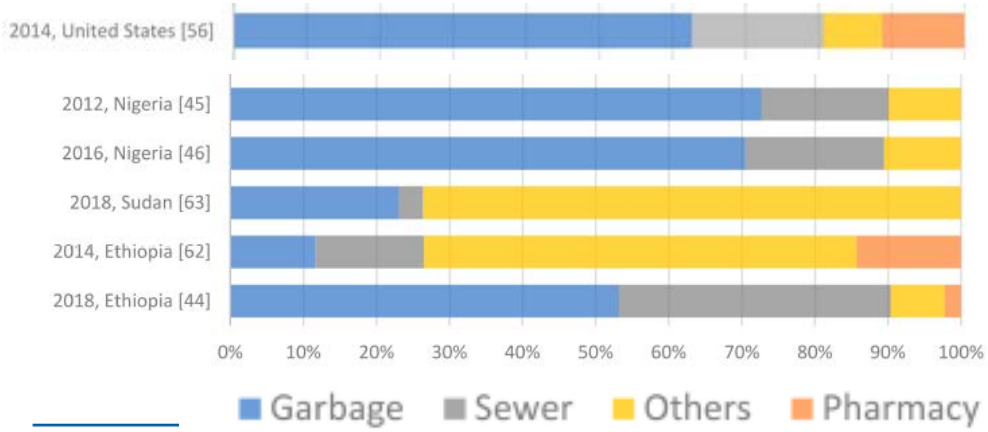


Pharmaceutical waste - Actors

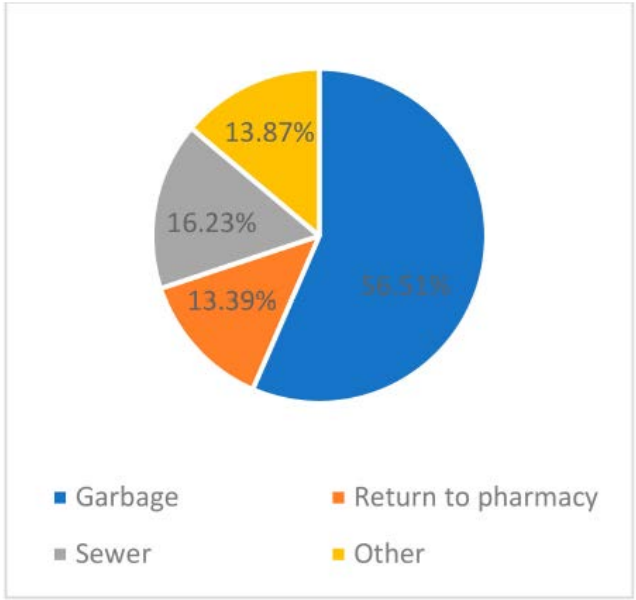
Actors in the health sector / institutions in the water and wastewater sector (GERMAN FEDERAL ENVIRONMENTAL AGENCY)



Pharmaceutical waste - Actors



How is unused medication disposed of by patients?



ALNAHAS ET AL., 2020

Pharmaceutical waste - Actors

What is being returned?

Australia (BERGEN ET AL., 2013)

686 RUM bins with 24,000 individual items containing > 700 diferent active ingredients

- 85.4 % scheduled drugs
- 80 % prescription medicines subsided by the Pharmaceutical Benefits Scheme
- 44 % still within their expiry date

- **annual costs to taxplayers**: **$2.05 million**
  - the highest costs:
    - tiotropium,
    - fluticasone-salmeterol combinations,
    - paracetamol (due to the large quantities dispensed and discarded)

Pharmaceutical waste - Actors

Why is medicine being returned / disposed of?

Ethiopia (ATIFANU ET AL., 2017)

- Change of prescription
- Adverse effects of the drug
- Unclear instruction
- Resolution of condition/clinical symptoms
- Expiry date

“89.1 % of medicines purchased by consumers are never used”

Australia (BRUSHIN ET AL., 2005)

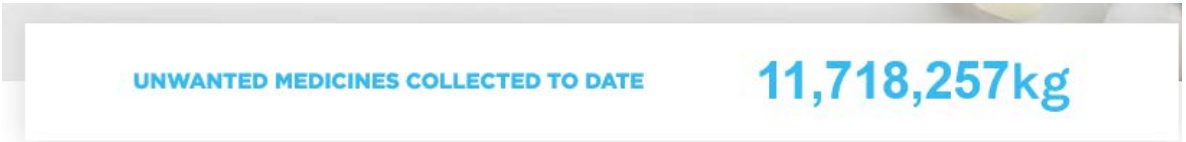
- Concerns about safety and efficacy
- Death of a family member
- Change in therapy (e.g. cardiovascular medicines)
- Perceptions about the unwanted effects and need for the medicines (e.g. anti-infective drugs)

Approaches to reduce amount of pharmaceuticals released to the environment (GAUTAM ET AL., 2018)

- To **reduce generation of pharmaceutical waste**
  - first priority
  - can be achieved through good inventory management
- To **increase efficiency of sewage treatment plants**
  - fourth purification stage (ozonation, activated carbon)
- Use of **Green and Sustainable Pharmacy** (e.g. KÜMMERER & HEMPEL 2010)
  - design of pharmaceutical products and processes → adoption of a new eco-compatible ways to synthesize drugs
- Developing better **Drug Disposal Programs**

Drug disposal programs

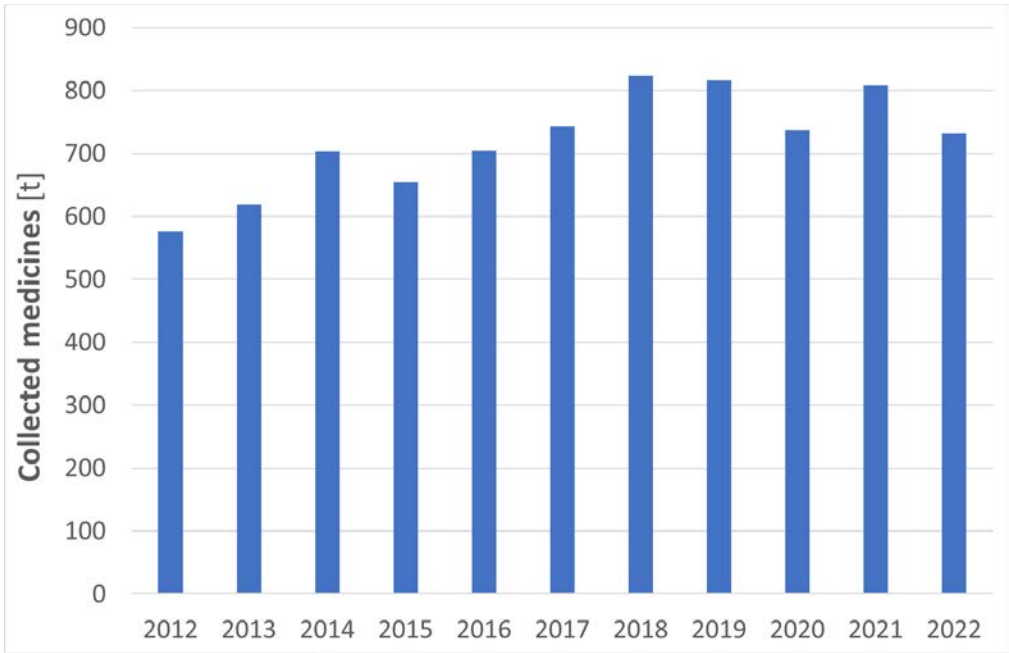
Australia: National Return and Disposal of Unwanted Medicines (NatRUM) program

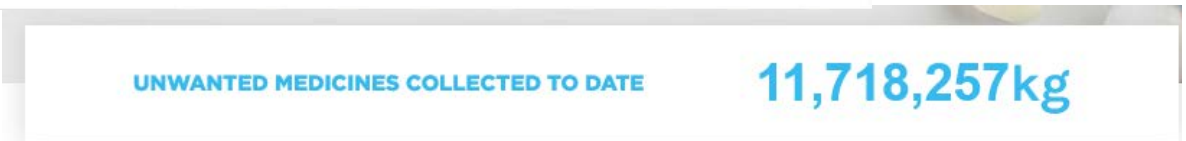


Bergen et al., 2015, https://returnmed.com.au/

Drug disposal programs

Australia: National Return and Disposal of Unwanted Medicines (NatRUM) program





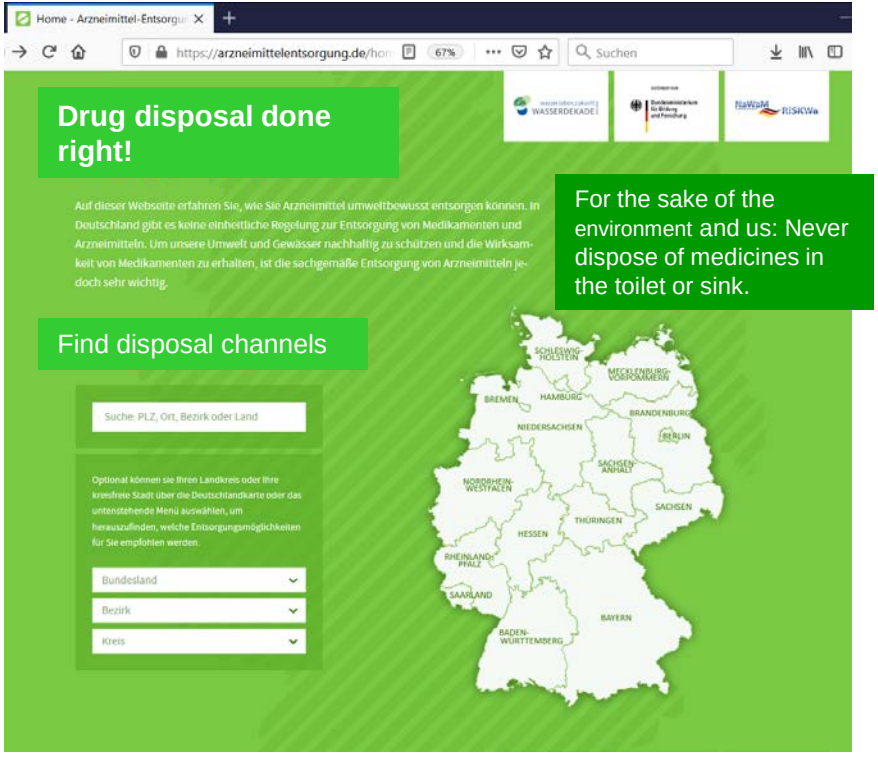
Bergen et al., 2015, https://returnmed.com.au/

Drug disposal programs
Germany

https://arzneimittelentsorgung.de/

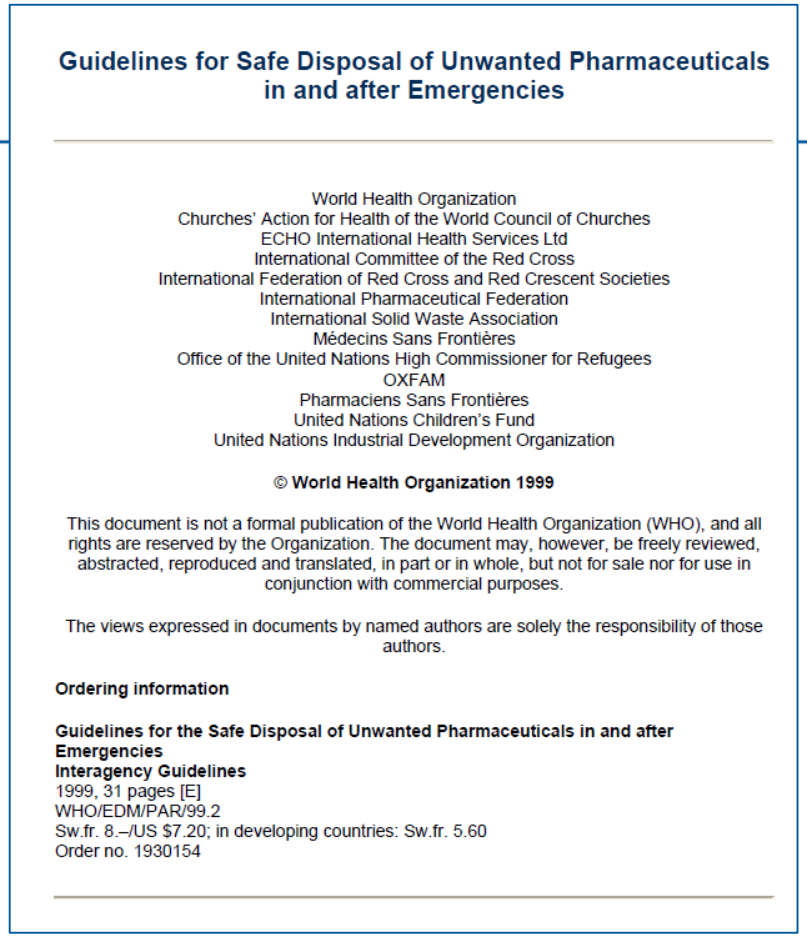
Disposal routes in Leipzig

Disposal via hazardous waste vehicles	**Responsibe institution:** City cleaning of Leipzig
Disposal via pharmacies on a voluntary basis	Can be handed in at a stationary pollutant collection point; Drop-off possible free of charge at a number of Leipzig pharmacies
Disposal via recycling centres	



Disposal methods

- Return to donor or manufacturer
- Incineration
- Immobilization
- Landfill
- Sewer and Fast-flowing watercourse
- Burning in open containers
- Chemical decomposition



Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies

World Health Organization
Churches' Action for Health of the World Council of Churches
ECHO International Health Services Ltd
International Committee of the Red Cross
International Federation of Red Cross and Red Crescent Societies
International Pharmaceutical Federation
International Solid Waste Association
Médecins Sans Frontières
Office of the United Nations High Commissioner for Refugees
OXFAM
Pharmaciens Sans Frontières
United Nations Children's Fund
United Nations Industrial Development Organization

Ordering information

Guidelines for the Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies
Interagency Guidelines
1999, 31 pages [E]
WHO/EDM/PAR/99.2
Sw.fr. 8.–/US $7.20; in developing countries: Sw.fr. 5.60
Order no. 1930154

Disposal methods (WHO, 2018, TRIVEDI ET AL., 2018)

❖ **Return to donor or manufacturer** (transfrontier transfer for disposal)

- types of pharmaceuticals: all bulk waste pharmaceuticals, particularly antineoplastics
- usually not practical – transfrontier procedures may be time consuming
- Conventions:
  - The **Basel Convention** (Control of Transboundary Movements of Hazardous Wastes and Their Disposal) from 1989
  - The **Bamako Convention** (based on the import into Africa and the control of transboundary movement and management of hazardous wastes within Africa) from 1991
  - The **Stockholm Convention (POP Convention)** (protection of human health and environment against persistent organic pollutants) from 2006

BASEL CONVENTION

BAMAKO CONVENTION
Against Illegal Dumping of Hazardous Wastes

Disposal methods (WHO, 2018, TRIVEDI ET AL., 2018)

❖ Incineration

- **pollution control systems** (srubbers etc.) on incinerators are essential to avoid release of dioxins and other chemicals
- **reduction of waste volume** by 85%-95%

→ **High temperature incineration** with temperatures greatly in excess of 1,200 °C

- types of pharmaceuticals: solids, semisolids, powders, antineoplastics, controlled substances
- drawback: high invest and operating costs

→ **Medium temperature incineration** with two-chamber incinerator with minimum temperature of 850 °C

- cement kiln incineration
- types of pharmaceuticals: solids, semisolids, powders, controlled substances (antineoplastics best incinerated at high temperature)
- used only in absence of high temperature incinerators

picture: www.rotarykilnfactory.com

Disposal methods (WHO, 2018)

❖ Immobilization

→ Waste encapsulation

- immobilizing of pharmaceuticals in a **solid block within a plastic or steel drum** (filled to 75 % capacity with solid and semi-solid pharmaceuticals, filled to full capacity by pouring in a medium: cement, cement/lime mixture, plastic foam, bituminous sand) → the sealed drums should be **placed at the base of a landfill** and covered with fresh municipal solid waste
- types of pharmaceuticals: solids, semisolids, powders, liquids, antineoplastics, controlled substances

→ Inertization

- **unpacked pharmaceuticals** are **ground and mixed with water, cement and lime** to form a homogenous paste → transport in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste
- types of pharmaceuticals: solids, semisolids, powders, antineoplastics, controlled substances
- advantage: inexpensive, without sophisticated equipment

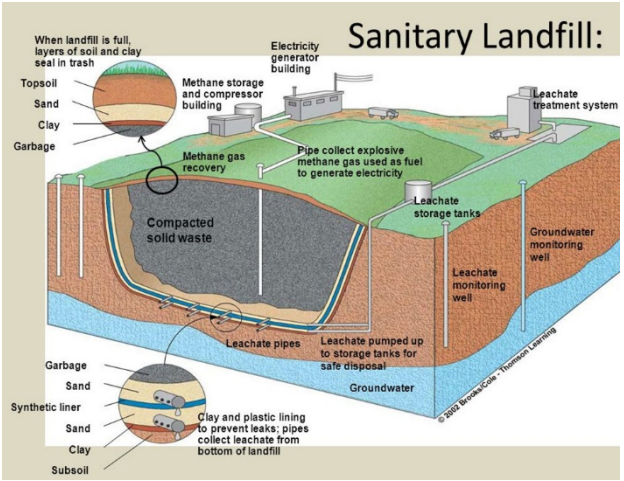
picture: www.slideshare.com

Disposal methods (WHO, 2018)

❖ Landfill

→ **Highly engineered sanitary landfill** (consisting of an evacuated pit isolated from watercourses and above the water table)

- types of pharmaceuticals: limited quantities of untreated solids, semisolids, powders (preferable after immobilization)



picture: www.exnora.org

Disposal methods (WHO, 2018)

❖ Landfill

→ **Highly engineered sanitary landfill** (consisting of an evacuated pit isolated from watercourses and above the water table)

- types of pharmaceuticals: limited quantities of untreated solids, semisolids, powders (preferable after immobilization)

→ **Engineered landfill** (features to protect loss of chemicals into aquifer)

- types of pharmaceuticals: waste solids, semisolids, powders (after immobilization)

→ **Open uncontrolled non-engineered dump**

- as a last resort (!)
- types of pharmaceuticals: untreated solids, semisolids, powders (preferable after immobilization)
- if not immobilized: untreated waste must be covered immediately with municipal waste to prevent scavenging
- not for untreated controlled substances (e.g. cytotoxics)

picture: www.brainly.com

Disposal methods (WHO, 2018)

- **Sewer and Fast-flowing watercourse**
  - types of pharmaceuticals: diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants
  - antineoplastics and undiluted disinfectants and antiseptics not recommended
- **Burning in open containers**
  - as last resort (!) as toxic pollutants may be released into the air
  - types of pharmaceuticals: packaging, paper, cardboard
  - not acceptable for PVC plastics or pharmaceuticals

- **Chemical decomposition**

  in accordance with the manufacturer's recommendations (followed by landfill)
  - need of special chemical expertise and materials
  - antineoplastic drugs in amounts < 50 kg

Picture: panow.com

Expiration date = end of drug‘s life? (ALNAHAS ET AL., 2020)

„A waste of pharmaceuticals is, to some extent, a waste of ethics.“

UN report „Dying from Lack of Medicines“:
more than 1.5 million people died in Africa in 2015 due to preventable or treatable diseases with affordable, yet locally unavailable medicines… but **less than 2% of drugs consumed in Africa are produced on the continent**, meaning that many sick patients do not have access to locally produced drugs and may not afford to buy the imported ones.

Expiration date = end of drug‘s life? (ALNAHAS ET AL., 2020)

Shelf life extension program (SLEP) in the USA (DIVEN ET AL., 2015)

= federal program aiming to save government resources by extending the shelf-life of medications in military stockpiles

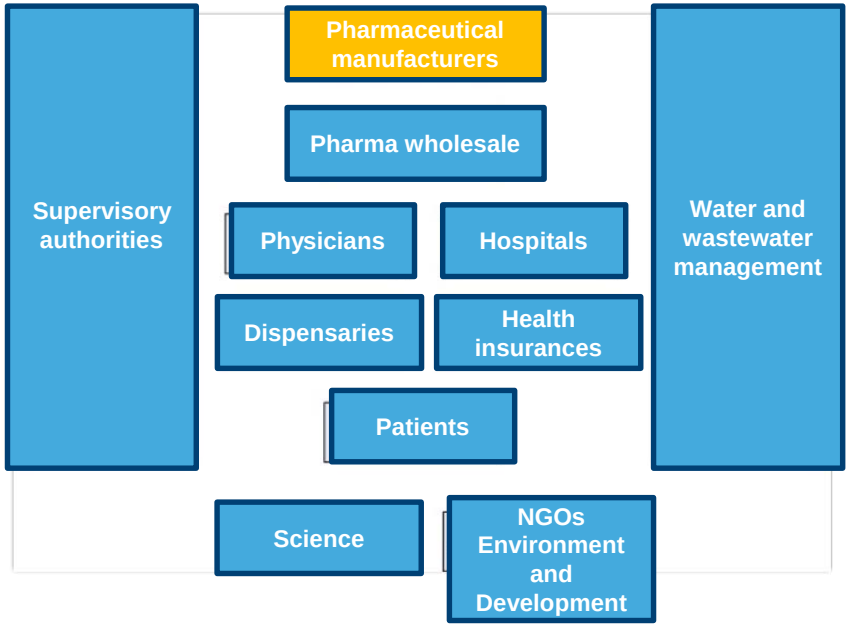
- established 1986 by U.S. Department of Defence and the USFDA
- approx. 90 % of 3,000 tested batches of medications (122 different drug products) were valid for use after the expiration date (average extension period was 5.5 years)

Bayer® Aspirin

- expiration date: up to 3 years after manufacture
- ROY ET AL. (2012): Aspirin remains valid up to 5 years

Pharmaceutical waste - Actors

Actors in the health sector / institutions in the water and wastewater sector (GERMAN FEDERAL ENVIRONMENTAL AGENCY)



Expiration date = end of drug‘s life? (ALNAHAS ET AL., 2020)

Pharmaceutical manufacturers

→ considering the **balance between production and consumption**

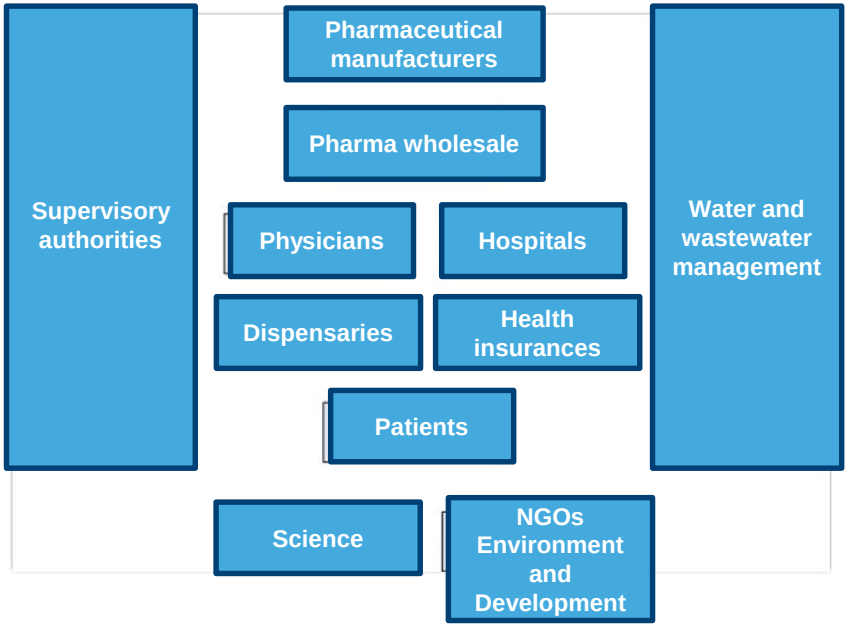
→ **extension of the expiration date** of a drug utilizing **innovative stability tests**

→ **raising public awareness regarding the appropriate disposal practices**
(e.g. mention the instruction of proper disposal practices on the package)

picture: www.huffingtonpost.ca

Approaches to reduce amount of pharmaceuticals released to the environment

Actors in the health sector / institutions in the water and wastewater sector (GERMAN FEDERAL ENVIRONMENTAL AGENCY)



Circular Economy

source: iurban.in.th

Thank you!

Dr.-Ing. Lucie Moeller

Helmholtz Centre for Environmental Research – UFZ

Workshop „**Drug lifecycle control in Subsaharan Africa - From production to responsible safe disposal and elimination in wastewater treatment plants**“

Date: 30th August 2022

source: umweltbundesamt.de