



Global Patient Safety Network Webinar Series
Medication Safety: Implementing the Challenge
**Addressing look-alike, sound-alike medicines: role of
regulatory agencies**

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WHO definition of Pharmacovigilance

Pharmacovigilance is the science and activities relating to the...



DETECTION



ASSESSMENT



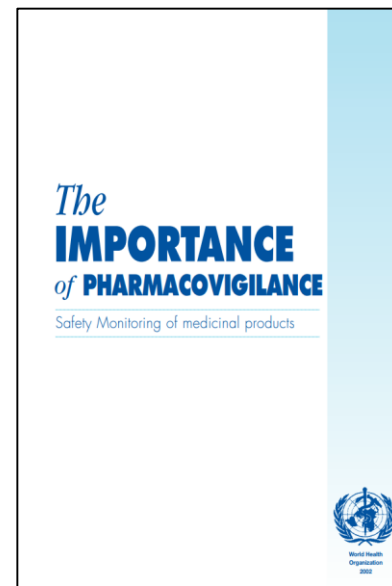
UNDERSTANDING



PREVENTION

...of adverse effects or any other medicine related problem

↳ Medication errors, Lack of effect, Quality problems



Burden of medication errors on public health

- Leading cause of harm in hospitals in developed countries (Bates, 2010).
- Estimates show that in developed countries as many as one in 10 patients is harmed while receiving hospital care due to medication errors (Bates, 2010).
- Look-alike or sound-alike medicinal products are listed one of the sources of medication errors (ASHP 1993).
- Different organizations in different levels are committed to the prevention.
 - Local
 - National
 - Global

Look-alike or sound-alike medicinal products

Medication with similar packaging design

Collection by Chris Langley

I have set-up this Pinterest board to collect images of pharmaceutical packaging with similar design which risks selection error at the point of supply.



Follow

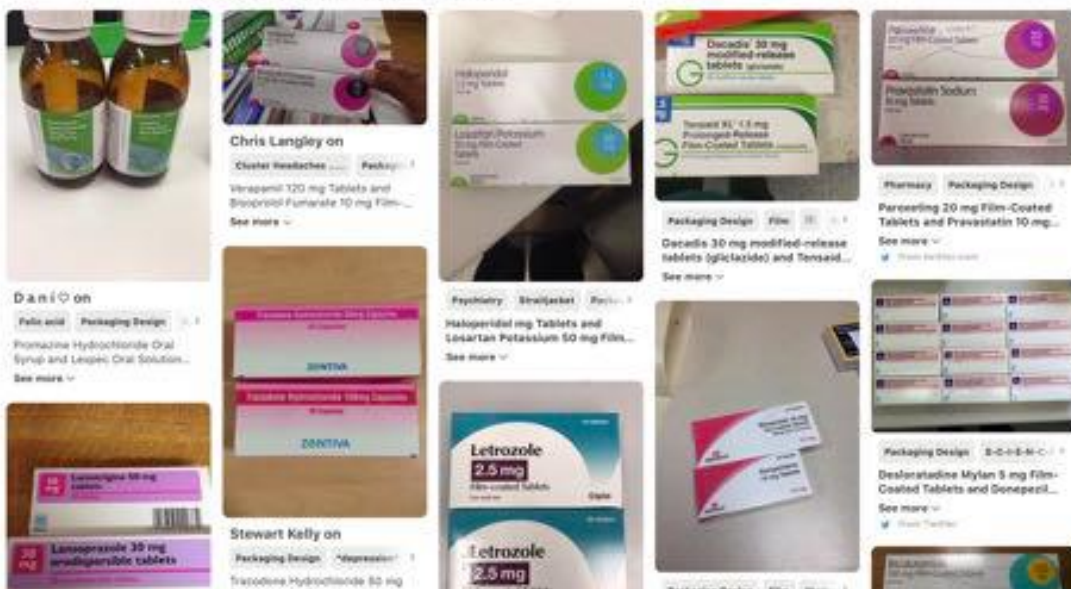


Table 1 – Examples of confused drug name pairs in selected countries

Brand name is shown in *italics*—Nonproprietary name is shown in **bold**

Country	Brand name (Nonproprietary name)	Brand name (Nonproprietary name)
Australia	<i>Avanza</i> (mirtazapine)	<i>Avandia</i> (rosiglitazone)
	<i>Losec</i> (omeprazole)	<i>Lasix</i> (furosemide)
Brazil	<i>Losec</i> (omeprazol)	<i>Lasix</i> (furosemida)
	<i>Quelicin</i> (succinilcolina)	<i>Keflin</i> (cefalotina)
Canada	<i>Celebrex</i> (celecoxib)	<i>Cerebyx</i> (fosphenytoin)
	<i>Losec</i> (omeprazole)	<i>Lasix</i> (furosemide)
France	fluoxétine	<i>Fluvoxamine</i>
	<i>Reminyl</i> (galantamine hydrobromide)	<i>Amarel</i> (glimepiride)
Ireland	<i>Losec</i> (omeprazole)	<i>Lasix</i> (furosemide)
	morphine	hydromorphone
Italy	<i>Diamox</i> (acetazolamide)	<i>Zimox</i> (amoxicillina triidrato)
	<i>Flomax</i> (morniflumato)	<i>Volmax</i> (salbutamol solfato)
Japan	<i>Almarl</i> (arotinolol)	<i>Amaryl</i> (glimepiride)
	<i>Taxotere</i> (docetaxel)	<i>Taxol</i> (paclitaxel)
Spain	<i>Dianben</i> (metformin)	<i>Diovan</i> (valsartan)
	<i>Ecazide</i> (captopril/hydrochlorothiazide)	<i>Eskazine</i> (trifluoperazine)
Sweden	<i>Avastin</i> (bvacizumab)	<i>Avaxim</i> (hepatitis A vaccine)
	<i>Lantus</i> (insulin glargine)	<i>Lanvis</i> (toguanine)

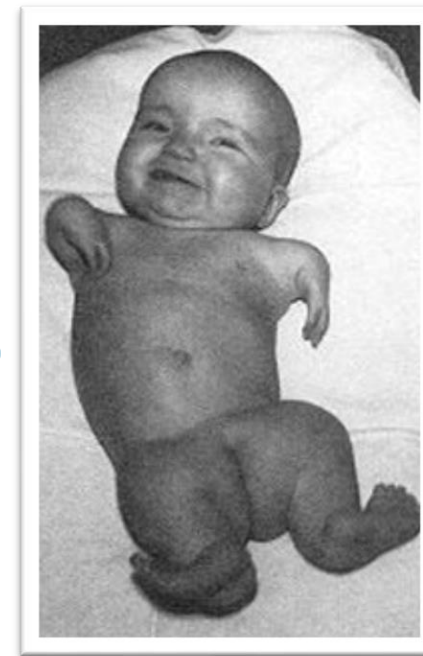
The foundation of the programme

After the thalidomide disaster

World Health Assembly

Resolution 16.36 (1963)

Invite Member States to arrange for a systematic **collection of information on serious adverse drug reactions** observed during the development of a drug and, **in particular, after its release for general use.**



Thalidomide – children born 1957 - 1963

The WHO programme for international drug monitoring (PIDM) was established in 1968.

**WHO
Programme for
International
Drug
Monitoring
(PIDM)
members**



As of March 2021: The WHO PIDM has now a total of 171 Members

144 'Full Members' that share ICSRs* and 27 Associate Members

The WHO global pharmacovigilance database managed and maintained by Uppsala Monitoring Centre (UMC)

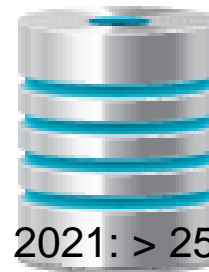
The oldest and largest
ICSR* database

Freely accessible to
National PV Centres

Signal detection

Aggregated data also
accessible to the public
(VigiAccess)

*Individual Case Safety Report



UMC

As of April 2021: > 25 million ICSRs



WHO's normative work

Identification

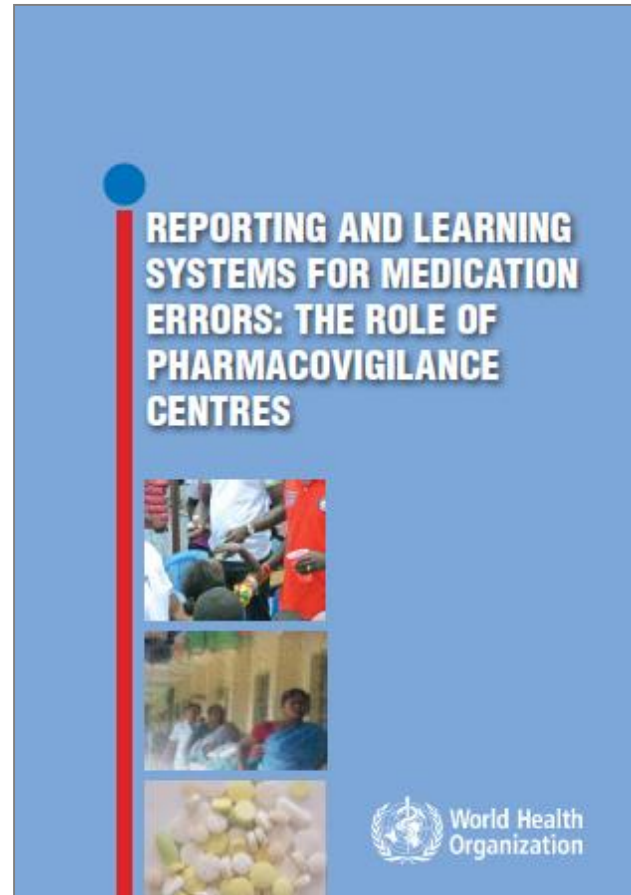
WHO workshop on Identification of Medicinal Products (IDMP) in Geneva, 2019, attended by regulators and industry.

Discussions on PhPIDs (Pharmaceutical Product Identification) as a subset of IDMP (Identification of Medicinal Products).

Traceability



WHO publication regarding Medication Errors



Reporting and learning systems for medication errors: the role of Pharmacovigilance Centres. Geneva: World Health Organization; 2014. All rights reserved.

Conclusion

- Medication errors are also relevance to pharmacovigilance.
- The burden on public health of medication errors remains significant. Look-alike or sound-alike (LASA) medicinal products are listed one of the sources of medication errors.
- The collection of ICSRs serves the importance function to improve the safety profile of medicinal products including detection of medication errors and LASA medicinal products.
- WHO works on normative standards and tools to track and reduce the occurrence of medication errors.

Acknowledgement

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Thank you

