Pharmacovigilance in India: Why do we need it ?

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What is Pharmacovigilance?

It is the science & activity relating to detection, assessment, understanding & prevention of adverse effects or any other possible drug - related problems

World Health Organization

Available Data on ADRs....

- ADRs occur in 10 - 20 %of hospital inpatients
- Account for 2 -6% of all hospital admissions
- Are among top 10 causes of death in inpatients
- Overall incidence of ADRs is ~ 6.7 %
- Fatal ADRs - 0.32 %.....

Where does it come from?



European database of suspected adverse drug reaction reports

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Online access to suspected side-effect reports



On this website you can view data on suspected side-effects also known as suspected adverse drug reactions for authorised medicines in the European Economic Area (EEA).

For centrally authorised medicines, access to reports is granted both by the name of the medicine or the name of the active substance. For non-centrally authorised medicines, access is granted based on the name of the active substance only.

Search for a report

Search here for suspected adverse drug reaction reports

PROTECT

imi efpia

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

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Adverse Drug Reactions Database

The **PROTECT ADR database** is a downloadable Excel file listing of all MedDRA PT or LLT adverse drug reactions (ADRs). It is a structured Excel database of all adverse drug reactions (ADRs) listed in section 4.8 of the Summary of Product Characteristics (SPC) of medicinal products authorised in the EU according to the centralised procedure. It is based exclusively on MedDRA terminology. In principle, MedDRA Preferred Terms (PT) are used to map terms of the SPC. When they are used in the SPC to add precision in the description of the ADR, Low Level Terms (LLTs) are also coded. PTs and LLTs are linked to a primary System Organ Class (SOC). The database also includes information on gender, causality, frequency, class warning and source of information for ADRs for which additional information is provided in the SPC. Fields are described in the file Database structure.

The current database has been updated up to 30 June 2013 based on latest available SPC which can be found on the European Commission website. The database includes for each product the date of the SPC which has been used to list ADRs.

The database has been created by EMA and partners in PROTECT Work Package 3 through a stepwise approach using automated mapping of ADR terms listed in section 4.8 of the SPC to the MedDRA terminology, fuzzy text matching (Bergvall et al. Pharmacoepidemiol Drug Saf. 2011;20(S1), S143) and expert review.
It is aimed to routinely update the database at least once a year based on amended SPCs. It can also be amended between routine updates to correct data entries.

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Regulatory Transparency and Openness
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Proactive Disclosure

Drugs and Health Products

Adverse Reaction Database



Canada Vigilance Adverse Reaction Online Database

The Canada Vigilance Adverse Reaction Online Database contains information about suspected adverse reactions (also known as side effects) to health products.

Reports are submitted by:

- consumers and health professionals, who submit reports voluntarily
- manufacturers and distributors (also known as market authorization holders), who are required to submit reports according to the *Food and Drug Regulations*.

Quick Links
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Advisories, Warnings and Recalls
MedEffect Canada RSS Feeds and MedEffect e-Notice
Canadian Adverse Reaction Newsletter
Consultations
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PubMed.gov
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PubMed | adverse drug reactions

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Show additional filters

Clear all

Article types clear
Clinical Trial
✓ **Review**
More ...

Text availability clear
Abstract
✓ **Free full text**
Full text

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Publication dates
5 years
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Species clear
✓ **Humans**
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Display Settings: Summary, 20 per page, Sorted by Recently Added **Send to:**

Results: 1 to 20 of 1855

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Filters activated: Review, Free full text, Humans. Clear all to show 114915 items.

1. Post-marketing safety monitoring of shenqifuzheng injection: a solution made of dangshen (Radix Codonopsis) and huangqi (Radix Astragali Mongolici).
Ai Q, Zhang W, Xie Y, Huang W, Liang H, Cao H.
J Tradit Chin Med. 2014 Aug;34(4):498-503. **Review**.
PMID: 25185371 [PubMed - indexed for MEDLINE] **Free Article**
Related citations

2. Efficacy and safety of puerarin injection in treatment of diabetic peripheral neuropathy: a systematic **review** and meta-analysis of randomized controlled trials.
Wu J, Zhang X, Zhang B.
J Tradit Chin Med. 2014 Aug;34(4):401-10. **Review**.
PMID: 25185357 [PubMed - indexed for MEDLINE] **Free Article**
Related citations

3. Non-cardiovascular **effects** associated with statins.
Desai CS, Martin SS, Blumenthal RS.
BMJ. 2014 Jul 17;349:g3743. doi: 10.1136/bmj.g3743. **Review**.
PMID: 25035309 [PubMed - indexed for MEDLINE] **Free Article**
Related citations

Pharmacogenomics of **drug**-induced hypersensitivity **reactions**: challenges, opportunities and

Quantum of Data from India?



PMID: 24210066 [PubMed - indexed for MEDLINE] **Free Article**
Related citations

35. Immune response in severe infection: could life-saving drugs be potentially harmful?
Surbatovic M, Jevdjic J, Veljovic M, Popovic N, Djordjevic D, Radakovic S.
ScientificWorldJournal. 2013 Sep 30;2013:961852. doi: 10.1155/2013/961852. eCollection 2013. **Review**.
PMID: 24198733 [PubMed - indexed for MEDLINE] **Free PMC Article**
Related citations

36. Patch testing in cutaneous adverse drug reactions: methodology, interpretation, and clinical relevance.
Mahajan VK, Handa S.
Indian J Dermatol Venereol Leprol. 2013 Nov-Dec;79(6):836-41. doi: 10.4103/0378-6323.120751. **Review**. No abstract available.
PMID: 24177628 [PubMed - indexed for MEDLINE] **Free Article**
Related citations

Indian data..

- 0.7% - 3.4% admissions due to ADRs
- 3.7% hospitalized patients had an ADR
- 1.3% were fatal

(South India, Ramesh *et al.*, Arulmani *et al.*)

- Incidence of ADRs 8%
- Serious ADRs 6.7%.

(rural South India Ahmad *et al.*)

- 10% ambulatory elderly patients had ADRs

(Chandigarh, Mandavi et al)

India records 5.2 million medical injuries a year'

TNN | Sep 21, 2013, 05.55AM IST

A landmark report by an Indian doctor from Harvard School of Public Health has concluded that more than 43 million people are injured worldwide each year due to unsafe medical care.

..... approximately 3 million years of healthy life are lost in India each year due to these injuries.

"Unfortunately, our data from India is among the poorest - there have been very few studies done on this topic and so we are making estimations based on a global average for low and middle income countries, with only a few data inputs from India itself"!!!!

Why do we need data from India?



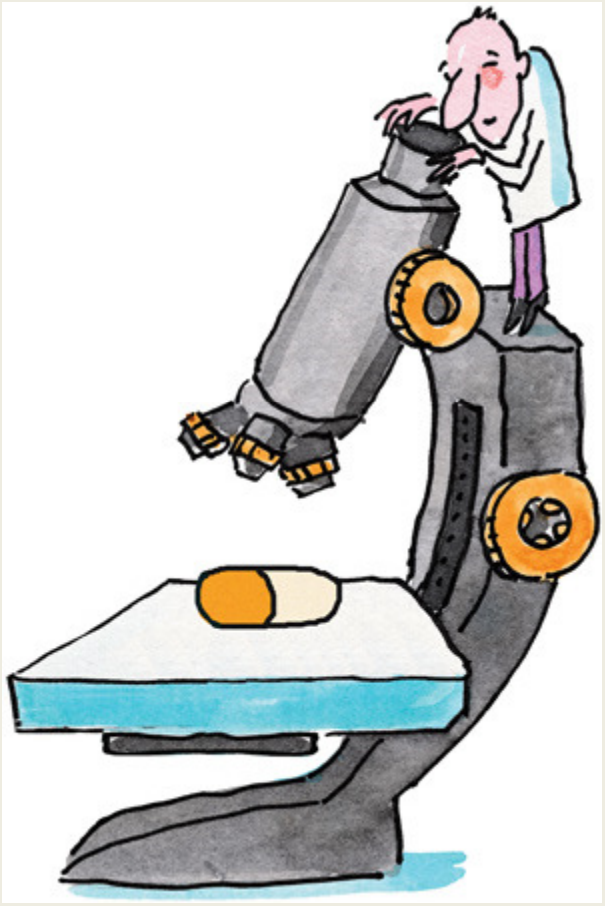
International Differences in ADRs

- Disease prevalence
- Indication for and use of medicines
- Genetic
- Social-Cultural
- Healthcare systems
- Health professional practices
- Pharmaceutical formulations

International Differences

Some Examples-

- Metamizole
- Phenylpropanolamine
- Nimesulide




Incredible India

Multiple systems of healthcare



OTC availability of “prescription only ” drugs



Come March 1, the directorate of Food and Drug Administration will enforce restrictions on the sale of 46 drugs, under the new schedule H1 notification.

A list of **46 antibiotics, anti-TB medicines and psychotropic drugs** have been included in the notification, passed in August 2013 to prevent pharmacies from selling them over the counter.

..... **so every pill is accounted for**. We will monitor this through regular inspections of pharmacies."

Booming Pharma Industry

India's pharmaceutical sector will touch US$ 45 billion by 2020

- McKinsey & Company
(Global management and consulting firm)

IBEF
INDIA BRAND EQUITY FOUNDATION
www.ibef.org



Financial Express-04-Oct-2014

The over the counter (**OTC**) **drug** market in **India** is expected to grow to USD 6.6 billion by 2016....

"India is the 6th largest pharmaceutical market globally in terms of size," and is "expected to rank amongst the top 3 in terms of incremental growth by 2020".

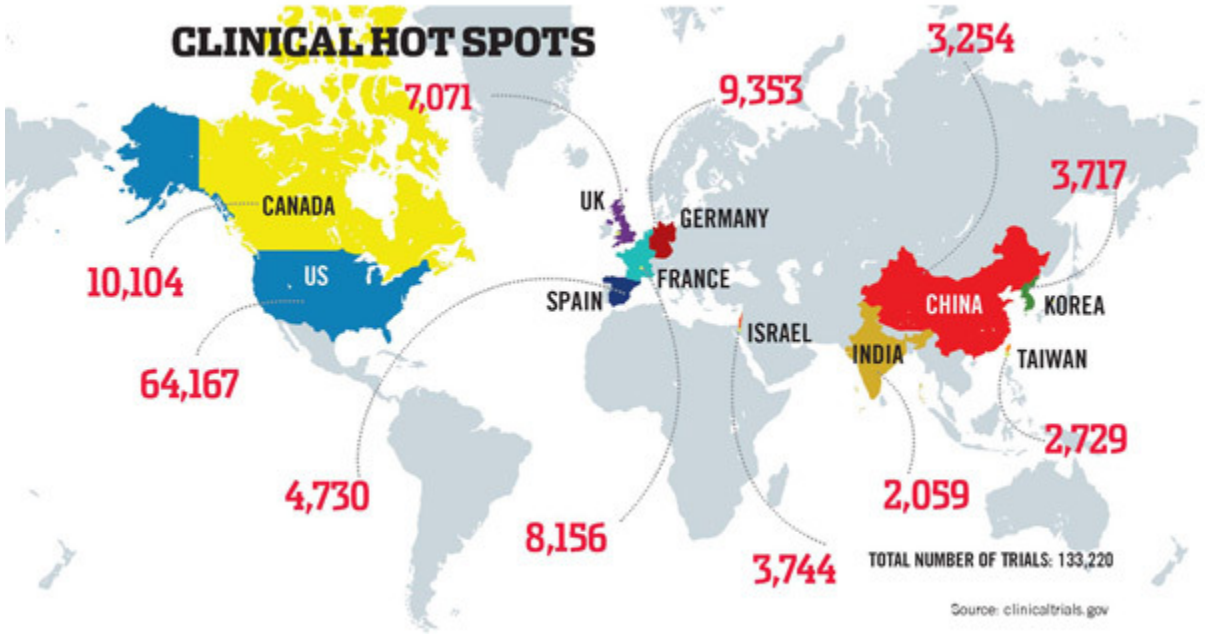
Biosimilars

Medical Devices

- Biosimilars cannot be considered as replicas of the innovators' molecules due to their complex structure and high molecular weight

- Medical devices use increasing too

India - Global Clinical trial hub



- Simultaneous global introduction of new medicines







Zelnorm® (tegaserod)

- Marketed by Novartis
- 5-HT4 agonist withdrawn from market in spring 2007 due to cardio-toxicity
- $560 M sales in 2006, worldwide



This means is that we no longer have the luxury of learning from others' experience



ADR management a burden on healthcare budget





Doctors appeal to Indian Govt to increase GDP for healthcare to 3 per cent



Thank You