Pharmacovigilance in Kurdistan, Iraq

Erbil, February 3rd 2011

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Two main kinds of adverse effects

Type A	Type B
Known pharmacological effects, common, dose-dependent, low morbidity, low mortality.	Unknown pharmacological effects, rare, dose-independent, high morbidity, high mortality.
Exemples: • dryness of mouth (ach) • drowsiness (sleep pills) • bleeding (warfarinum) • tachycardia (adrenergic) • orthostatism (hypotensives) • drug interactions (common)	Exemples: • exfoliativ dermatitis • liver reactions • asthma attacks • anapylactic schock • hematologic effects • maligancy, cancer

% chance to find adverse effects. Rule of 3.

	Risk of suffering the adverse effect		
	1/1.000 eye damage- practolol	1/10.000 Anaphylaxis – penicillin	1/100.000 Aplastic anemia- Chloramphenicol
10.000 patients using the drug	99%	63%	10%
95% chans to detect one (1) case with an ideal reporting system, requires….	3.000 patients	30.000 patients	300.000 Patients

Illegal medicines

- Illegal medicines is a rapidly growing market
- 10% of all medicines (worldwide) are counterfeit!
- 30% - 40% of medicines in some countries are fake: Useless, dangerous or inferior.
- 50% of all counterfeit medicines come from internet

Problems with illegal drugs and devices

- Reduced amount of active pharmaceutical ingredient (API)
- Wrong API. Potentially life threatening.
- No active ingredient
- They may be potentially life threatening
- They are easily accessible (internet!)
- No checks of QC or QA
- You may have received just anything
- Very limited legal possibilities for compensation

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Which medicines may be dangerous?

- High value medicines
- High demand medicines
- High turnover medicines

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Examples of counterfeit drug brand names

Drug name	Used for…
Reductil	Weight reduction
Viagra, Cialis	Male impotence
Plavix	Myocardial infarction, stroke
Casodex	Prostate cancer
Lipitor	Hypercholesterolemia
Seretide	Asthma, Chronic brochitis
Sensodyne	Tooth Paste

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Strategies for safer use of D&D

- Inspections. Traceability is needed in the chain:

  Manufacturer – Distribution – Storage – Release

- Collaboration.

  Customs – Police – Trading systems

- Reporting Systems for adverse effects:

Doctors – Hospitals – Regulatory Authorities - WHO

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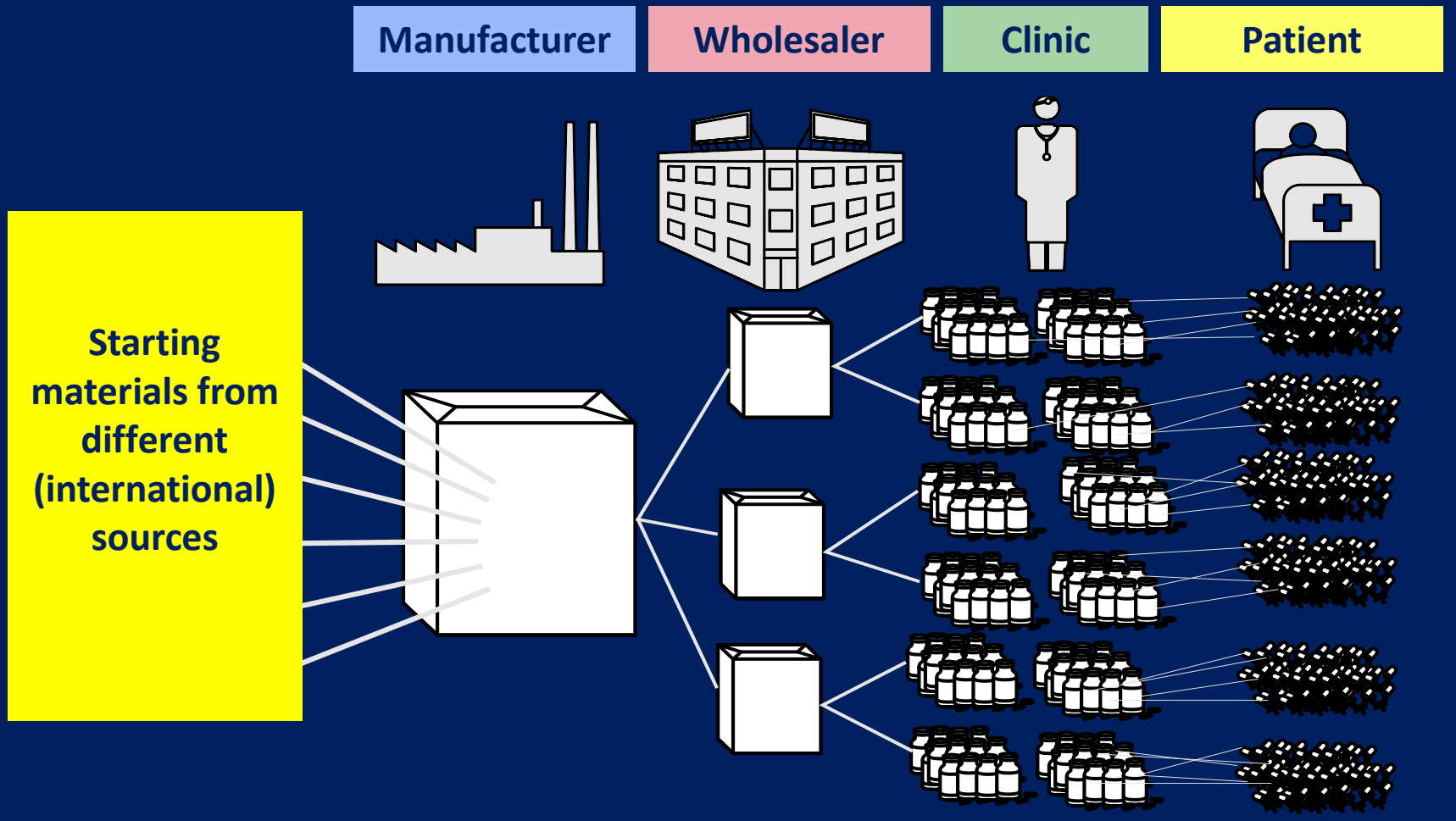
The necessity of traceability of drugs



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Why is Drug Monitoring so essential? (1)

- Safety for the patients has an increasing priority
- Drugs are increasingly potent and potentially dangerous
- Counterfeit drugs is an increasing global problem
- Drug Authorities have the right to know all about drug effects, since they regulate the drugs. Drug central

- Physicians have the right to know all about the drugs they prescribe
- Interactions between drugs is an increasing problem
- Lawyers have an increasing focus on maltreatment issues and have the legal right to obtain all drug safety information

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Why is Drug Monitoring so essential? (2)

- There is no existing system for reporting adverse drug reactions
- There is no system at the Drug Directorate for receiving reports.
- Minimal or no collaboration with other countries
- Minimal exposure to international bodies, which can help in pharmacovigilance system implementation
- There is no effective PV information-exchange system between physicians and the Drug Directorate
- Pharmaceutical manufacturers in Iraq produce mainly generic drugs, so they depend on information from others.

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Reporting systems to be implemented

- Doctor´s reporting serious adverse reactions to Regional PV Centers (RPVC)
- Reports/Alerts from Drug Directorate (DD) to medical community
- Analysis at RPVC/DD. ”Signal Detection”
- Reports from Drug Directorate to WHO Collaboration Centre (a world wide system).

Pharmacovigilance Reporting
The importance of the terminology

Which is the proper term?

- Cardiac Infarction
- Myocardial infarction
- Infarctus cordis
- Heart infarction

We need a common terminology: MedDRA!

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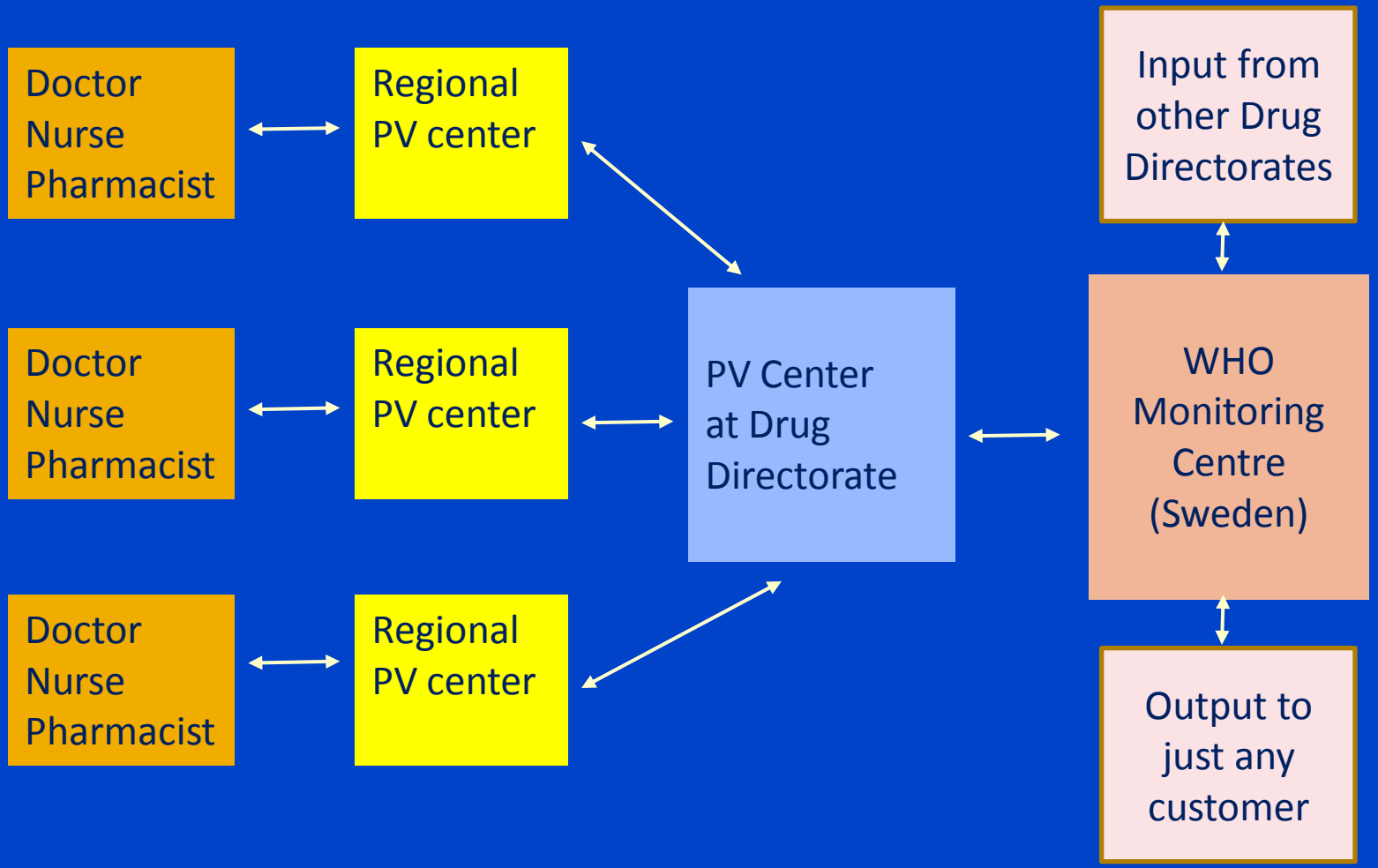
Flow of adverse event (”side effect”) reports



Pharmacovigilance in KRG - Iraq
Detailed Plan

A detailed plan for building a pharmacovigilance system has been submitted to relevant authorities

Thank You !