



**Kurdistan Regional Government – Iraq
Ministry of Health**

**The International Congress on Reform and
Development of the Health Care System in
Kurdistan Region - Iraq**



SAFE MEDICINE PROCUREMENT

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Feb., 2011

Threat overview

- ▶ Growing evidence of a **crisis** enveloping the international drug supply network
- ▶ Size and scale of the problem hard to define due to lack of hard evidence
- ▶ Under threat from people wishing to introduce **sub-standard, out-of-assay, out-of-date, unlicensed or counterfeit products** INTO the network, or remove high quality material FROM it.
- ▶ Overwhelmed by drugs acquired illegally or **illegally imported** from overseas
- ▶ Many imports are of **dubious** safety, efficacy and provenance
- ▶ Many traders are targeting population at greatest risk
- ▶ Trade affecting developed and developing countries
- ▶ Latest WHO counterfeit statistics:
 - US, Europe, UK (<1%)
 - Russia (10%), CIS (20%), PRC (8%), Indonesia (25%), India (10-20%). Nigeria (16%), Kenya (30%), Lebanon (35%) and Cambodia (13%)

At risk countries

- ▶ Weak regulatory & enforcement regimes due to lack of legislative power or resources
- ▶ Scarcity or erratic supply of basic medicines
- ▶ Unregulated market & distribution systems
- ▶ Where drug prices are high and there is a lack of affordable medicines
- ▶ Where significant price differential exist - encourages arbitrage opportunities
- ▶ Lack of GMP compliance and poor storage and distribution conditions
- ▶ Lack of respect of trademark or other agreements
- ▶ Endemic corruption and fraud
- ▶ Denial of the problem
- ▶ Lack of legal remedies and sanctions

At risk countries (continued)

- ▶ Lack of market surveillance
 - unable to identify what is on the market
 - unable to identify where it is being sold
 - unable to determine the scale of spatial distribution of the problem
- ▶ Multiple distribution points
- ▶ Markets habits allowing repacking from original containers or labeling
- ▶ Implementation of poor product security measures
- ▶ Lack of national tracking programmes (Note: technology driven solution not always the best solution)
- ▶ Weak administration and trade rules:
 - opaque procurement system including the use of intermediaries
 - lack of vetting and due diligence of consignors and consignees and their supporting paperwork
 - open or porous borders and ineffective supervision of free ports

Focal point risk issues

- ▶ The World Bank says:
 - "transparent and institutionally strong pharmaceutical systems can contribute towards improving access of the populations to pharmaceuticals. But, the pharmaceutical supply and distribution systems in developing countries often are not fully transparent and/or have weak institutions that can lead to corrupt practices."
 - "knowledge of the respective strengths and weaknesses of the core decision points, and subsequently the specific activities which fall under each decision point in the pharmaceutical system is of utmost importance for any type of pharmaceutical system lending. Without this knowledge the likelihood of making poor investments is simply too great."
- ▶ perActum says:
 - "Accidents rarely happen by chance - more often they occur as a result of a set of compounding events."

CONTRACTS TENDERS & PROCUREMENT ISSUES - RISKS

- ▶ Over supply in return for commissions.
- ▶ Expenditure on good that cannot be verified.
- ▶ Bribery to win contracts.
- ▶ Triangulation fraud.
- ▶ Purchases involving opaque intermediaries.
- ▶ Award of contracts to parties unable to service contract obligations.
- ▶ Patronage of certain suppliers, leading to a market distortion/corruption.
- ▶ Risk of over ordering of some goods for legitimate or for illegitimate reasons.
- ▶ Not receiving a competitive price from a supplier who is making a high a margin.
- ▶ Kickbacks for public servants where major donor programmes are concerned.

QUALITY CONTROL ISSUES - RISKS

- ▶ Inability to assure the quality of goods being purchased, with possibility that sub-standard, out-of-assay or counterfeit goods are being delivered.
- ▶ Purchase of low quality medicines not conforming to agreed national standards, or as not defined in the tender document.
- ▶ QC determination not being carried out impartially or accurately, risking the safety of the population.

DRUG SELECTION ISSUES - RISKS

- ▶ Purchase of drugs that are not nationally or regionally approved.
- ▶ Drugs purchased not purchased on a basis of need - encouraging re-sale activities while damaging the reach of the drug procurement budget.
- ▶ Country becomes dustbin of failed sales in other countries.
- ▶ Purchase of drugs that that seek to pass themselves off using non-standard nomenclature.
- ▶ Use of out of date or un-referenced approved drug data.
- ▶ Attempts by people to introduce medicines onto the market using cover of international development aid/donations.
- ▶ Rules concerning drug substitutions and branded vs. generic drugs needs to be clear and understood by all enforcement teams and regulators otherwise it will be impossible to identify illegal sales at a local level.
- ▶ Without checks on warehouses and physical stock it is difficult to interdict illicit purchases of goods already in the supply chain.

LEGISLATIVE ISSUES - RISKS

- ▶ Poorly formulated and rarely updated legislation makes it hard to control and enforce a modern, sustainable and safe medicines procurement regime.
- ▶ Are there conflicts of interest between those who regulate and those who enforce?
- ▶ Poorly crafted and confused or out-dated legislation allows illicit players in the market to operate for longer without being detected.
- ▶ Ineffective legislation is not a disincentive to abuse the system where considerable money can be earned.
- ▶ Without intelligence coming from the ground, it will be harder to enforce national legislations.

MARKETS & STRUCTURES ISSUES - RISKS (1)

- ▶ Invasive bureaucratic interventions/corruption or conflicts of interest/vested interests.
- ▶ Corruption in free trade/port clearance zones.
- ▶ Substitution or flushing of goods onto the market.
- ▶ Lack of knowledge of informal market makes enforcement of national or regional legislation that much harder
- ▶ Without supply chain choke points into which is invested time, effort and training, imports are able to enter and be distributed around the country/region with relative impunity.
- ▶ Training and education needs to be continuous, or the capability to defend boundaries from attack and infiltration will be badly affected.
- ▶ Illicit goods being placed on the market where there is a lack of scrutiny of the mechanics and speed of doing so.

MARKETS & STRUCTURES ISSUES - RISKS (2)

- ▶ Lack of quality of information & documentary processes causes market and geographical distortions.
- ▶ If drugs can enter the country via differing and confusing administrative regimes, it is hard for local enforcement teams to control inbound flows and stop channels being used to import substandard or dangerous goods.
- ▶ Poor market awareness allows effective political or financial controls to be eroded through a lack of evidence to counter any claims being made.
- ▶ Without any mapping of the market it will be hard to see changes to the way it operates or see how legislation or policy changes are affecting market behaviour.

REGULATION & ENFORCEMENT ISSUES - RISKS (1)

- ▶ Poor training and education makes the challenge of enforcement that much harder.
- ▶ Reliance on non-existent or poor quality drug and RPOS registration data makes enforcement almost impossible.
- ▶ Without a centralised databases/control of data it impossible to promulgate registrations efficiently (e.g. line extensions, new RPOS registrations) or know that a drug found on the market is unlicensed and dangerous.
- ▶ Lack of capacity to distribute changes to registered information to local staff allows illegal importers and traders to operate with ease.
- ▶ Inability to flush out scrip forgeries erodes drug supply volumes and supports illegal secondary market activities.
- ▶ Without track and trace and without vetting or pre-qualification, the candidate pool of potential abusers of the system is very much bigger.
- ▶ Lack of audit capability makes enforcement of regulations almost impossible.

REGULATION & ENFORCEMENT ISSUES - RISKS (2)

- ▶ Failing to establish an audit trail leaves the drug supply chain vulnerable to attack.
- ▶ Without actively searching for substandard goods the likelihood of interdicting and disrupting illicit supply chains will be marginal.
- ▶ Poor scrutiny of the RPOS network will allow past offenders to build up their illegal business streams with relative impunity.

THE OPPORTUNITY

- ▶ Establishing effective procurement protocols and transparency :
 - enhances price stability
 - demystifies the procurement process
 - minimises risk to the supply chain
 - makes it easier for health care providers to manage stressed budgets and maintain quality standards by enabling purchasers to source and trust competing brands or generic alternatives
- ▶ Other structural requirements:
 - Public awareness and education
 - Strengthened regulatory authority and QC laboratory capacity
 - Regional cooperation and inter agency collaboration
 - Enforcement of legislation and imposition of harsher penalties
 - Establish disclosure and reporting channels within the market
 - Audit and monitoring - establish better market surveillance and inspection regimes
 - Establish clear agreement and transparent referencing of what constitutes an unlicensed, out-of-assay, counterfeit or out-of-date medicine

THE RISK OF A MISSED OPPORTUNITY

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THE RISK OF A MISSED OPPORTUNITY

- ▶ Poor scrutiny of the RPOS network will allow past offenders to build up their illegal business streams with relative impunity.
- ▶ As long as a disconnect between theoretical and actual holdings of drugs is allowed to happen, RPOS have the ability to flush out poor quality medicines into the marketplace in large volumes.
- ▶ Returns and drug recycling rules must be enforced, otherwise expired or poorly handled drugs will soon get lost in the market for an economic gain to someone
- ▶ Without nationally or regionally adopted checklists, local interpretation of rules will not deliver a consistent enforcement regime across the region or country.

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