Spontaneous reporting of problems related to medicines

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METHODS USED TO STUDY PROBLEMS RELATED TO MEDICINES

Experimental

- animal experiments
- clinical trials

Observational

- epidemiological methods
  - Spontaneous reporting
    - case reports (ICSR)
    - case series
  - Open cohort studies
    - Targeted spontaneous reporting
    - Prescription Event Monitoring (active)
    - Intensive hospital monitoring
  - Controlled cohort studies
  - Case - control studies
  - Record-linkage

Meta-analysis

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Spontaneous ADR reporting

Principle

1. The alert patient/health professional connects an undesirable medical event with drug exposure

A SUSPICION is created

2. Reports suspicion to pharmacovigilance centre

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SPONTANEOUS REPORTING

- Advantages
  - large population
  - all medicines
  - can cover all facilities where care is provided
  - long perspective (life-cycle approach)
  - patient analyses possible
  - inexpensive

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SPONTANEOUS REPORTING

- Inherent limitations
  - underreporting

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Reporting varies with:

- seriousness and severity of reaction
- time from market introduction
- promotional claims
- promotion of reporting system
- publicity of specific association
- etc.

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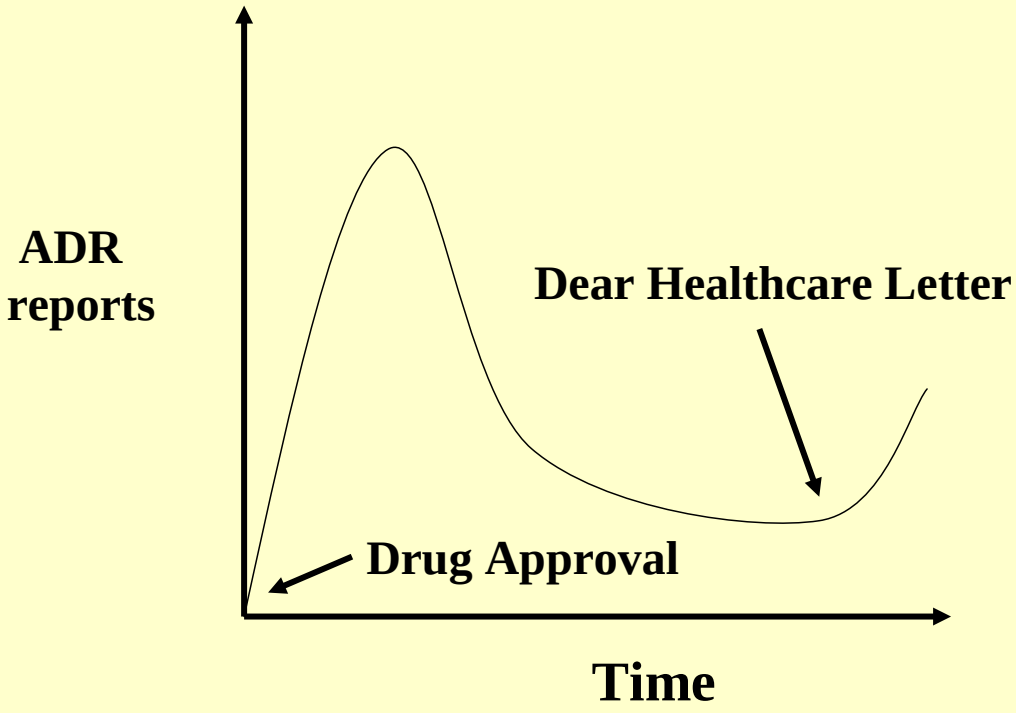
“Weber effect” in postmarketing



- Weber JCP. Advanced Inflammatory Res 1984; 6:1-7

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SPONTANEOUS REPORTING

- Inherent limitations
  - underreporting
    - difficult to detect
      - delayed reactions
      - reactions with high background incidence (Type C)
    - important details often missing
    - number of exposed unknown
    - bias

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What to report?

Early phase – creation of a reporting culture

- Simple message :
  - Report as soon as you suspect that drug therapy has resulted in a negative, unintended effect.
    - i.e all suspected reactions
    - *If considered unrealistic*: everything that concerns you e.g. unexpectedly serious or severe
- Speed is essential

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What to report?

Alternative approach

- Serious reactions (definitions available)
- Unexpected reaction (not in product info)
- Unusually severe reactions
- New medicines (everything)

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What to report?

- Adverse reactions
  - Type A
  - Type B
- Unexpected lack of effect
  - substandard or counterfeiting
  - resistance
  - interaction
- Product quality problem
- Dependence and abuse
- Medication errors
- Poisoning (?)

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What to report?

- Allopathic medicines
  - Prescription
  - OTC
- Traditional medicines
- Biologicals including vaccines and blood products

(what about devices, cosmetics, veterinary medicines etc?)

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Who should report?

- Physicians
- Traditional therapists
- Nurses
- Pharmacists
- Dentists
- Public Health Programme managers
- Manufacturers
- Patients/care takers
  - Particularly for self medication

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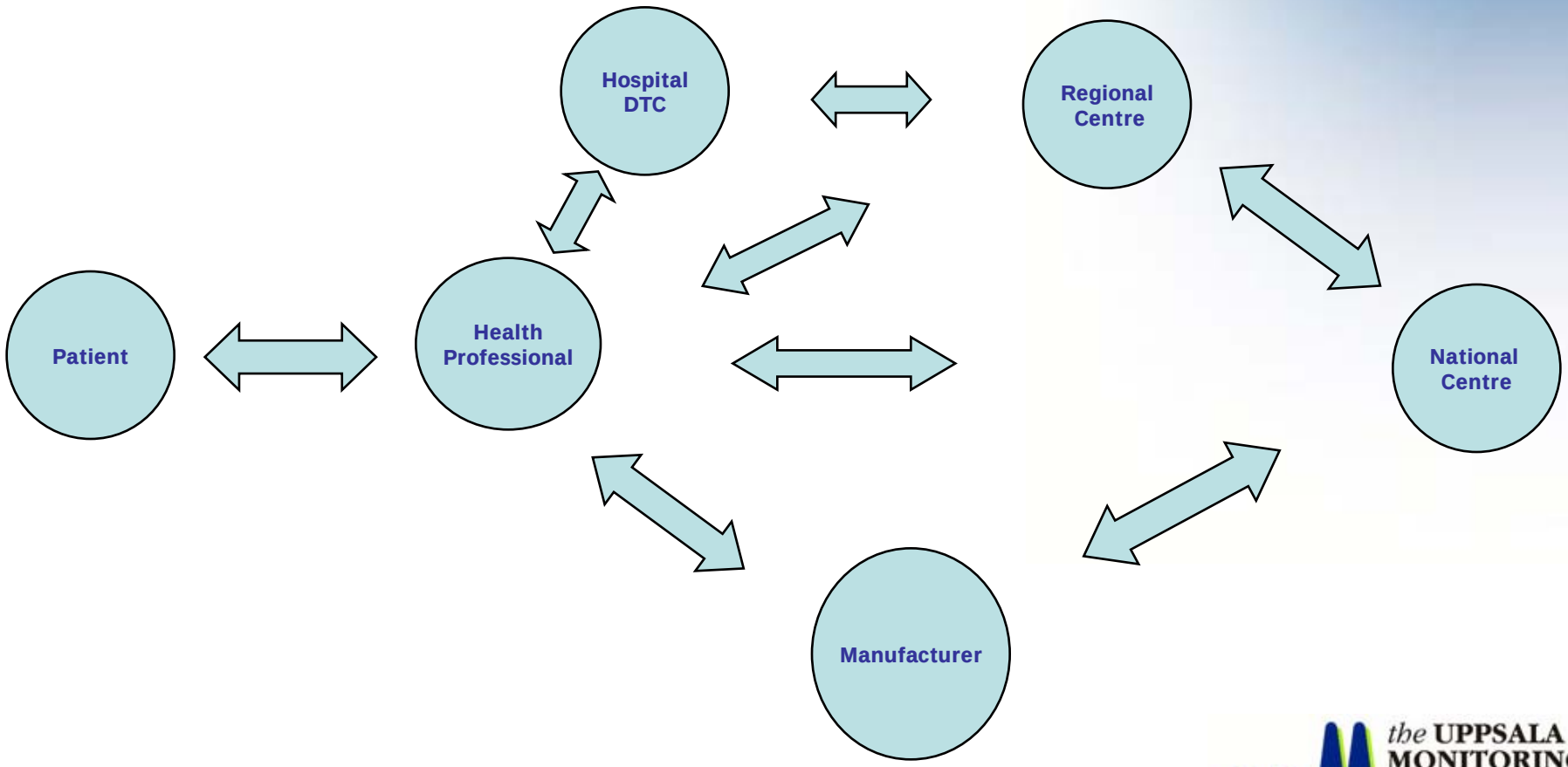
Where to report?



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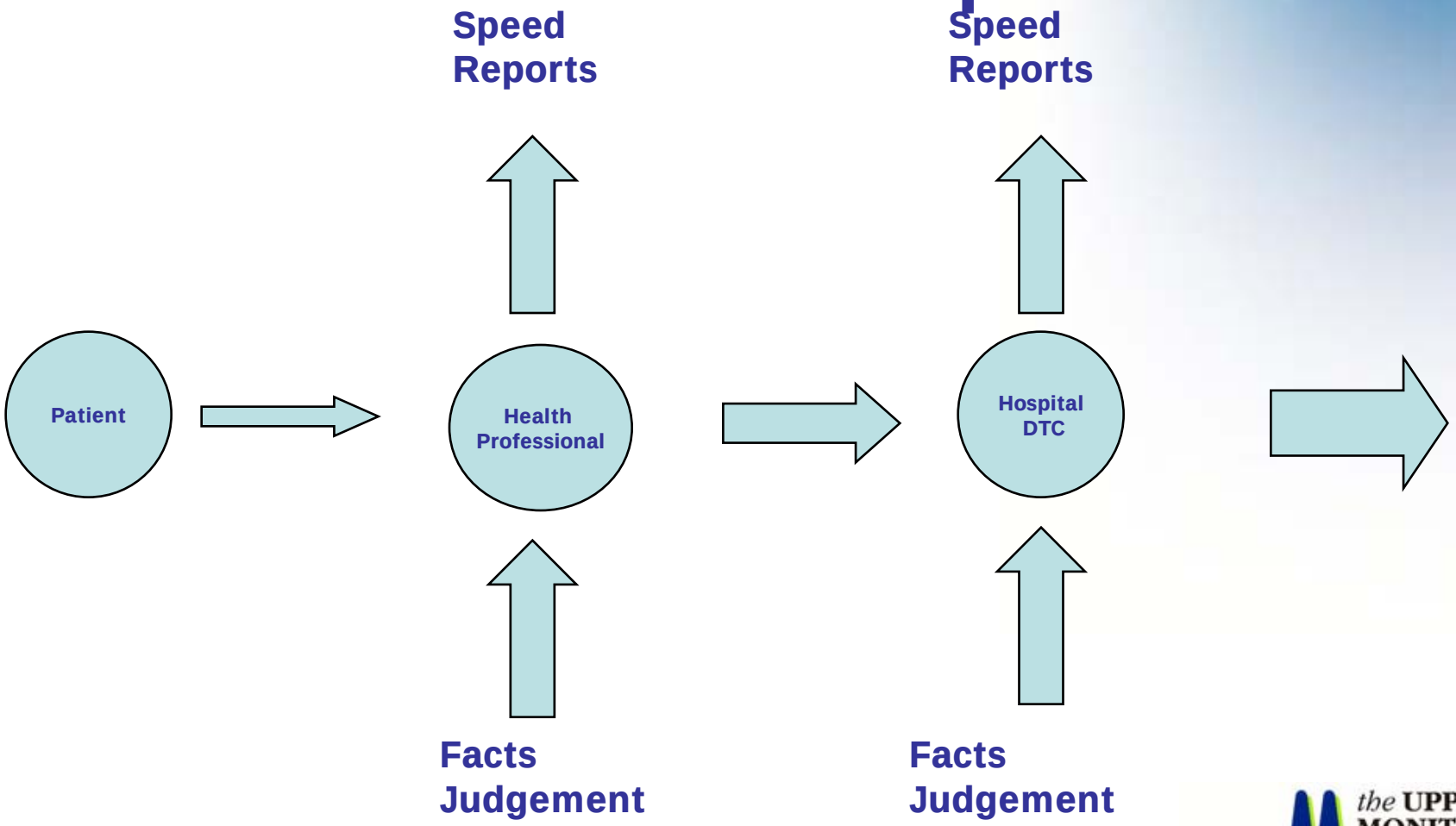
Gains and losses in report chain



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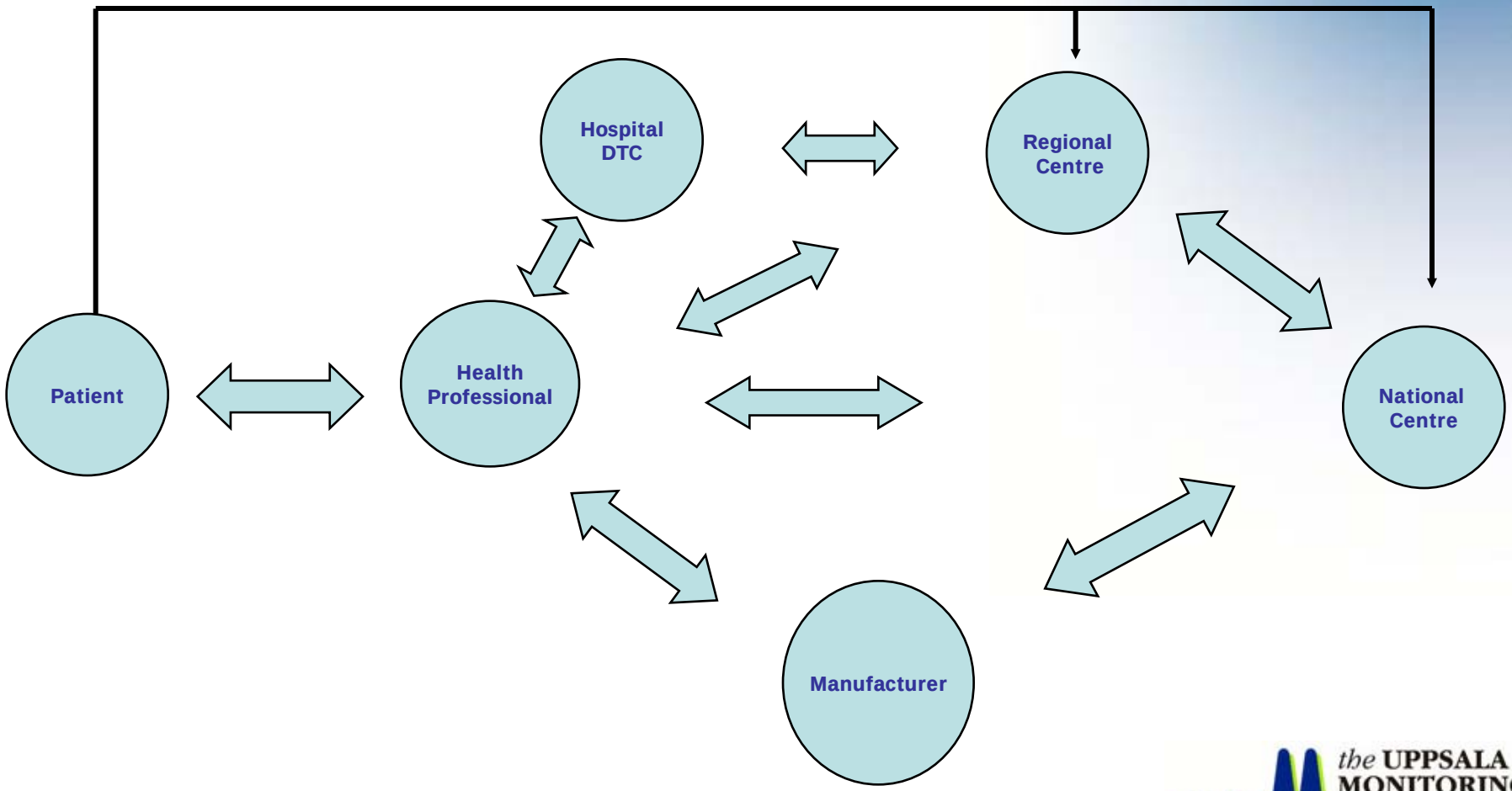
Where to report?



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Countries accepting direct patient reports *(list not exhaustive)*

- Australia
- Belgium
- Canada
- Denmark
- Ireland
- Malaysia
- The Netherlands
- New Zealand
- Norway
- Sweden
- UK
- USA (MedWatch)
- several others

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Thank you for your attention!

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