The changing environment and regulatory systems.

Bjorn Beermann
MPA, SWEDEN
Topics to be discussed

• This presentation is solely based on my personal view
• Innovations
• Transparency
• Safety of drugs
• Parallel distribution of drugs
No innovations (1)?

• High number of new drug substances during previous decade
• But how innovative is
  – 16 ACE-inhibitors
  – 7 Angiotensin receptor antagonists
  – 10 SSR:s
  – 5 Protonpump inhibitors?
No innovations (2)?

Some Innovative drugs approved 2000-2008 for the treatment of:

- **Malignant diseases**
  - Soft tissue sarcoma
  - Hepatocellular cancer
  - Renal cancer
  - CML
  - AML
  - ALL
  - Multiple myeloma
  - Familiar adenomatous polyposis

- **Metabolic diseases**
  - Pompe’s disease
  - Hunter’s disease
  - Gaucher’s disease
  - NAGS deficiency
  - MPS I
  - MPS VI
  - Tyrosinemia
  - Wilson’s disease
Increasing Transparency on a central level?

- European Public Assessment Reports with summaries in a lay language
- Reader friendly package leaflets
  - But, why only warnings and side effects
  - A reader friendly Public SPC might be more informative
- EU has EudraCT open for very few
Safety of drugs

• A new drug for the treatment of a metabolic disease
  – Effect only shown on a surrogate end point
  – Several other drugs are available
  – Clinically relevant side effects
    • Ischemic heart disease
    • Heart failure
    • Edema
    • Anemia
    • Fractures

• Would you approve this drug?
Safety of drugs (1)

- A new drug for the treatment of a metabolic disease
  - Effect only shown on a surrogate end point
  - Several other drugs are available
  - Clinically relevant side effects
    - *Ischemic heart disease*
    - Heart failure
    - Edema
    - Anemia
    - *Fractures*

- Would you approve this drug?
  - Probably not!

- The drug is on the market. The side effects in *italics* were not known at the time of approval. All problems are solved by adding warnings in the SPC!

- It is very hard to get rid of approved drugs.
Safety of drugs (2)

• Every application for approval must nowadays include a Risk Management Plan including Safety issues, pharmacovigilance activities and risk minimisation activities.

• This is definitely an important advance.
Safety of drugs (2)

- Every application for approval must nowadays include a Risk Management Plan including Safety issues, pharmacovigilance activities and risk minimisation activities.
- This is definitely an important advance.
- New studies are often parts of the pharmacovigilance activities.
- What happens if the studies are never made?
- Nothing?
- Withdrawal? Hardly!
Parallel distribution

- Company A sells drug X for a little cheaper price in country 1 than in country 2.
- A parallel importer can buy the drug in country 1 and sell it in country 2 for 10% lower price than the price of company A.
- Good for the economy!
Parallel distribution

• Company A sells drug X for a little cheaper price in country 1 than in country 2.
• A parallel importer can buy the drug in country 1 and sell it in country 2 for 10% lower price than the price of company A.
• Good for the economy!

• But
  – The parallel distribution means long distribution chains and there are many cases where fake drugs have been placed into the chain.
  – The economic situation is very different in the EU member states. The drug price must be much lower in some MS for equal possibility to use the new drugs.