

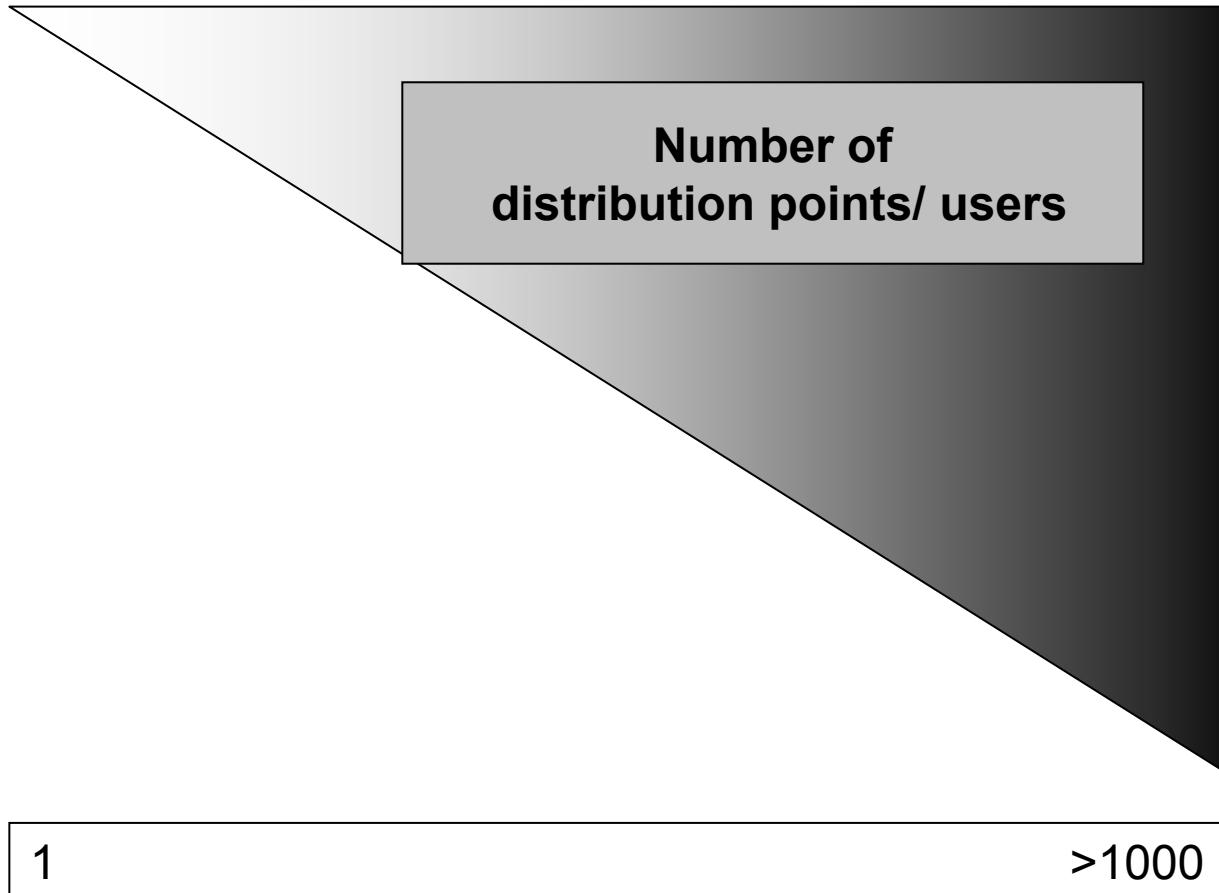
Legislation, Regulators and the safety of the distribution chain

Jos Kraus

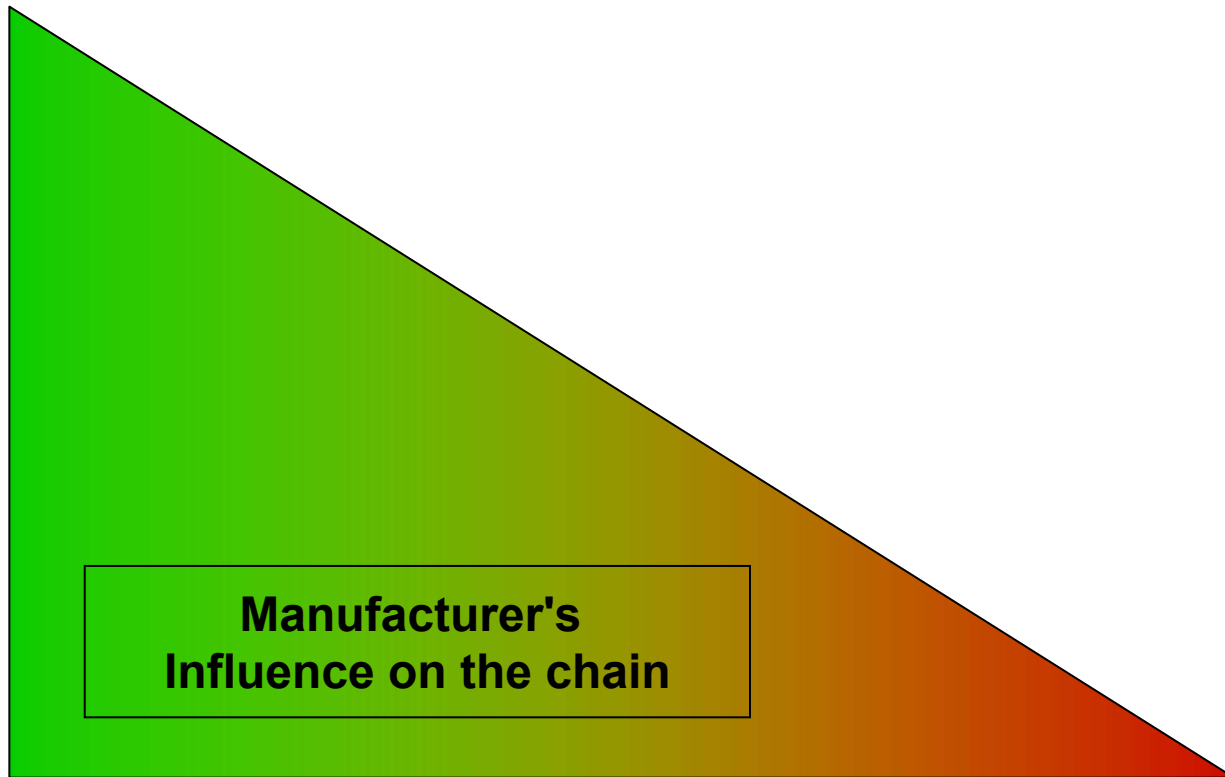
Inspectorate of health care

The Netherlands

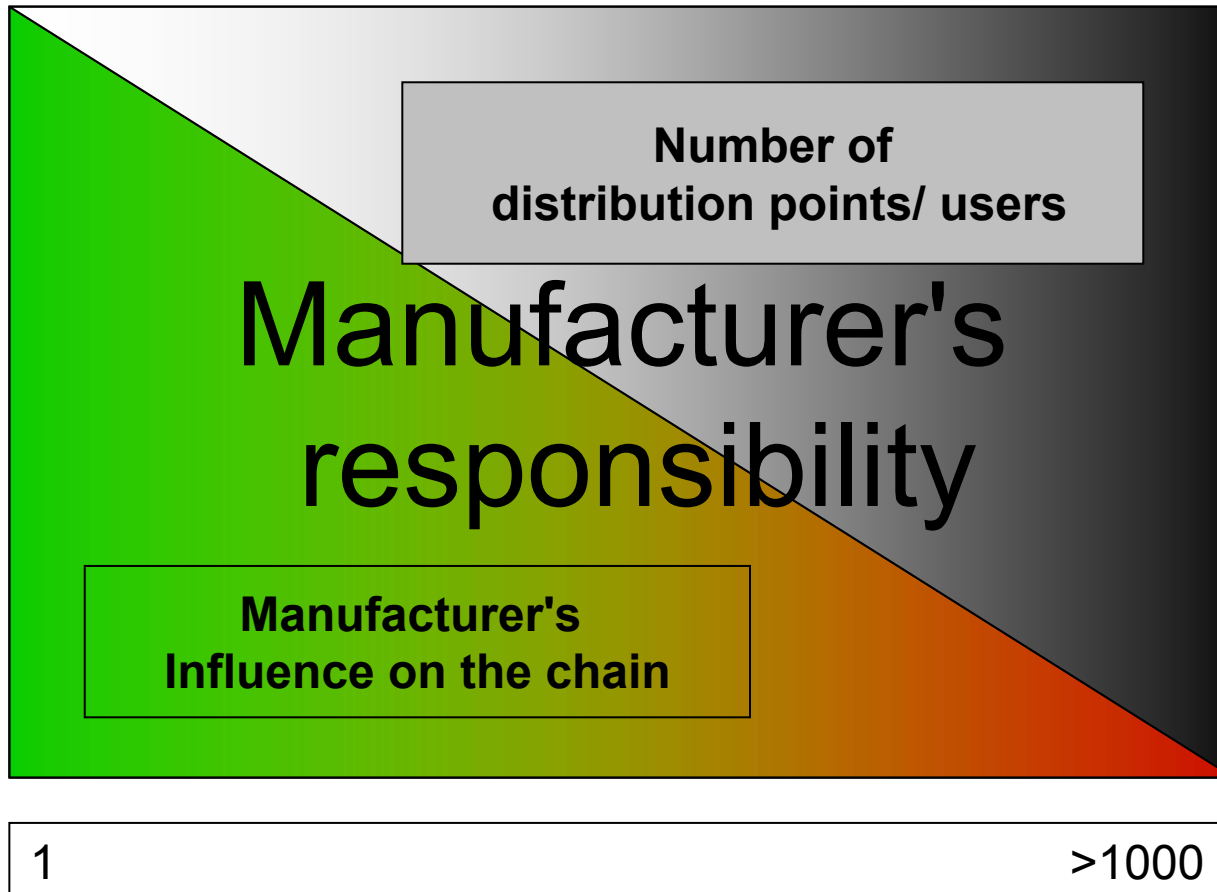
Number of entities



Manufacturer's influence on the chain



Practice



Europe versus USA

Europe

- Important historical roots
- **Open borders**
- Post Market emphasis on
 - Vigilance
 - Post marketing system
- Importers, distributors
 - Recently in regulation defined

USA

- There are differences between some States
- **Closed borders**
- Pre Market system
 - PMA
 - 510 K
- Establishment registration

What are the real motives?

- Purpose of the legislator:
 - Public Health
 - Patient safety
 - “Active or reactive” legislation
 - Vigilance
 - PMS
 - Medical Doctors
 - Trade
 - Unemployment
 - Local industry
 - Tax income
 - Import tax
 - VAT
 - Cost of Health Care