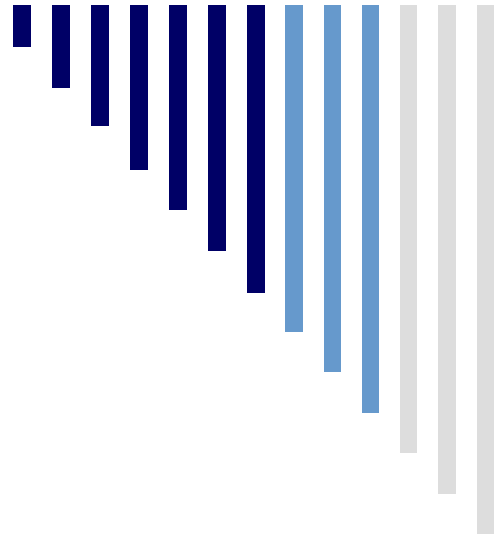



Session 7

'Rules & Roles'

Surgeons and the Industry



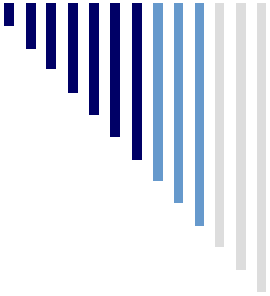


Rules & Roles

Simple guidelines for surgeons

Kai Olms
Bad Schwartau
Germany





Compliance is an important tool ?

- At the end of this talk you may understand
 - Education – industry relationship
 - Advamed
 - Eucomed
 - APEC
 - Simple guidelines to live with compliance





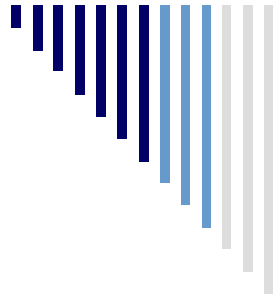
Who is operating on us??

Education costs money
but then so does ignorance

Claus Moser,*1922

Qualification – surgical skills – imperilment of patient





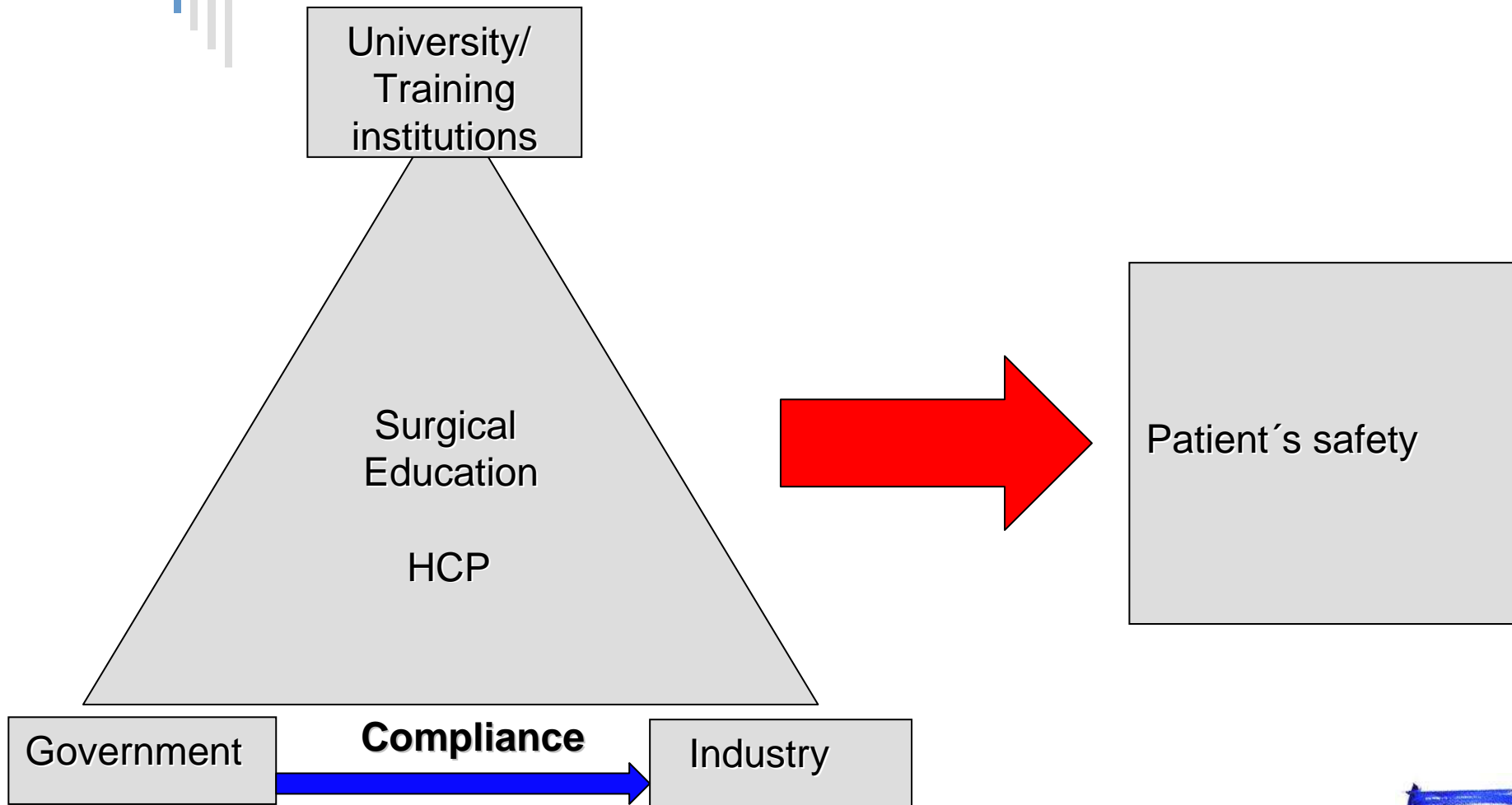
Where are we now??

realistic situation of education

- Industry, Government, Teaching institutions, Insurance companies :**
- Consensus on the need of education



The ideal world

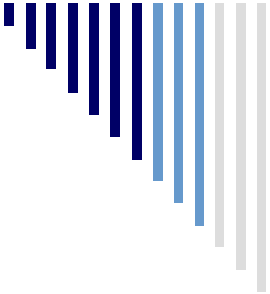




The priorities are different

- University
 - Reputation for best education
 - Science /rating
 - External funding
- Government
 - Legal regulations/certification
 - Taxes from Healthcare business
- Industry
 - Developing new products
 - Increase sales





Industry is the motor of healthcare and education

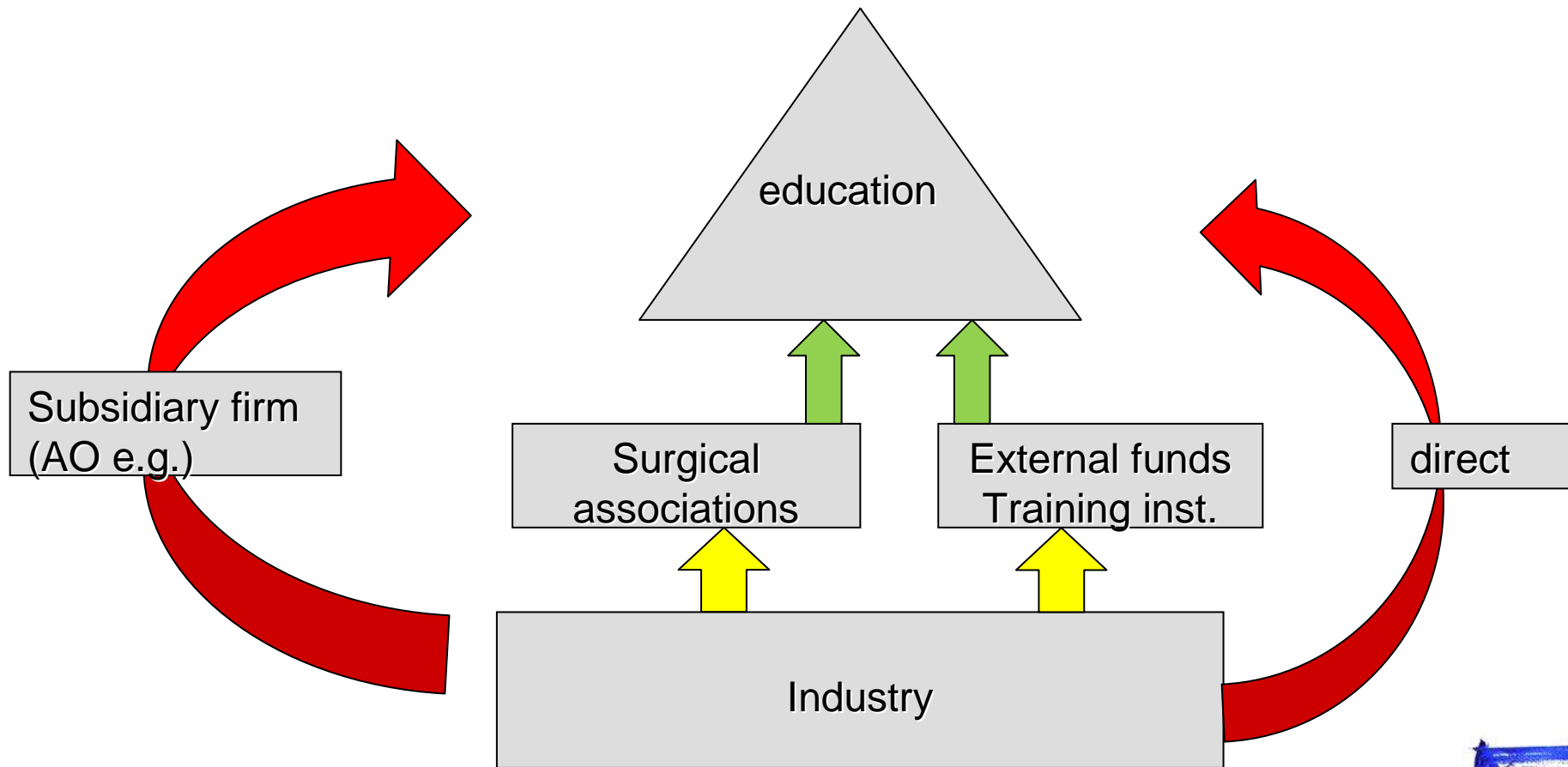


Education should be fun like a strong motor



The reality today

No education without industry





The motor needs fuel

- What is the ROI \$\$
- How can we measure the „value“ of education \$\$\$
- Individual company course better than independent group training \$\$





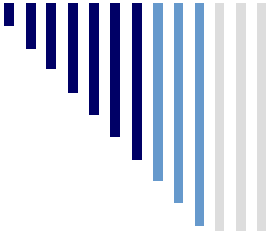
Education costs money but.....

- \$ 3.56 is generated of each \$ spent for education

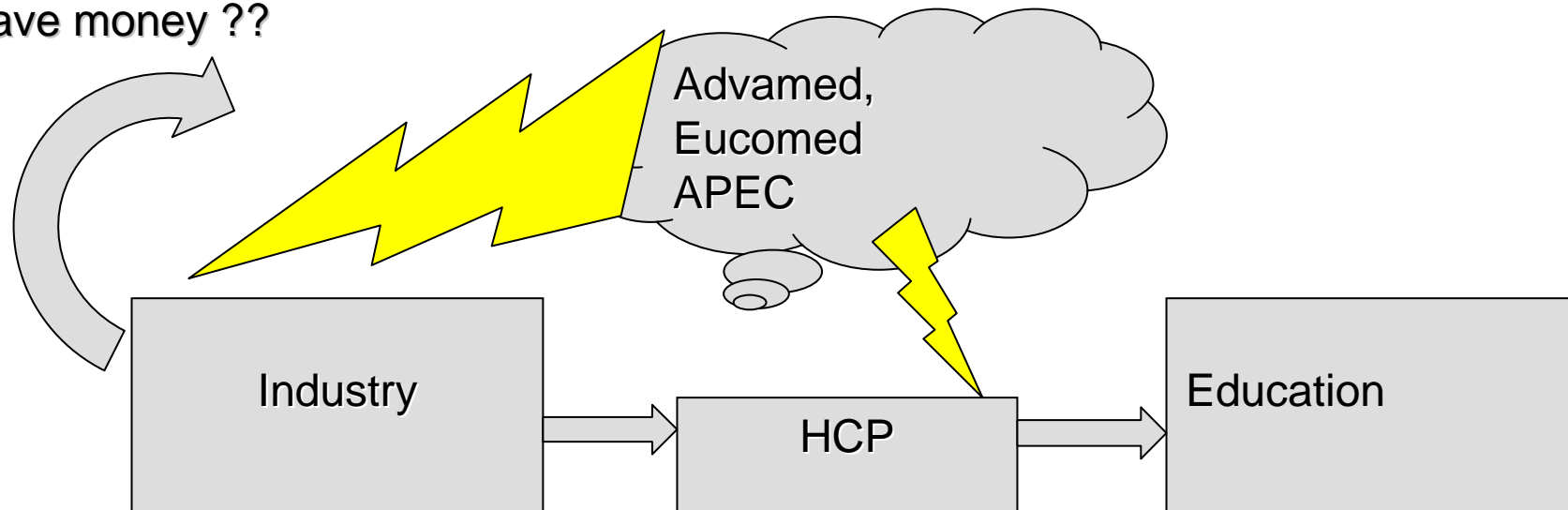
- Without education there is no sales
 - HCP wants to be superior to competitor
 - HCP does not need 5* ,but fun
 - That is the dilemma of our school system



The relationship must be regulated



Easy excuse to save money ??





HCP/Industry relationship is regulated

- Eucomed
 - The European Medical Technology Industry Association -25.000 companies
- Advamed
 - Advanced medical technology association
 - Global ethical business practice compliance
- APEC
 - Asia Pacific economic cooperation

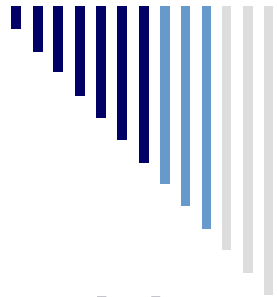




The general behaviour is clear

- Stay at home
 - Or travel as cheap as possible
- Stay at Youth Hostel
 - Or max.4*hotel
 - Not resort,no sea view...
- Starve
 - Or fixed price for menue/wine??
- No gifts – no guests





Advamed vs Eucomed

Education- product training

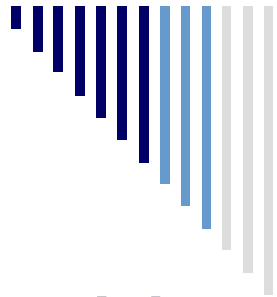
Advamed

- Conductive setting
- Hands on training
- Modest meals and refreshments
- Travel and lodging
- No guests

Eucomed

- Conductive setting
- Qualified staff
- Reasonable hospitality
- Regulators compliance
- No guests





Advamed vs. Eucomed

3rd party events

Advamed

May be sponsored

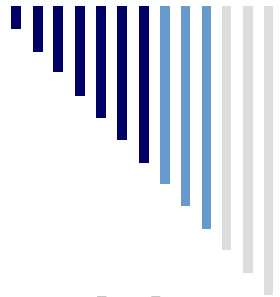
- Conference grants
 - To reduce costs for HCP
- Faculty expenses
 - Honoraria, travel, lodging

Eucomed

May be sponsored

- Conference support
 - To reduce costs
- Direct HCP sponsoring**
 - **Registration fee, travel etc.**
- Satellite symposia**
- Scholarship awards**





Advamed vs. Eucomed

Research and educational grants

Advamed

- Research
 - Objectives, milestones,

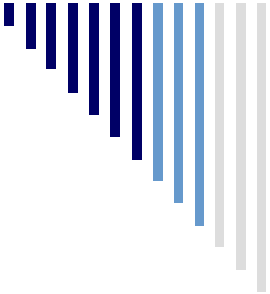
- Educational grants
 - To training institutions

Eucomed

- Research
 - Not to individual HCP`s

- Educational grants
 - To institutions that provide training





A very comprehensive suggestion

- **The Kuala Lumpur Principles,2012**

*Medical Device Sector Codes of Ethics ,
APEC*

- Integrity .
- Independence
- Appropriateness
- Transparency .
- Advancement





Surgicon`s suggestion

Surgicon's Simple Guidelines

- just a tool
- 5 Principles, 1 page
- Extract of existing Ethical Codes
- Collaboration with specialized lawyers at Swedish and European level:





Surgicon's Simple Guidelines

5 Principles, 1 page

- Transparency*
- Documentation*
- Proportionality*
- Moderation*
- Mutual Benefit*
- T D P M M**

Congress Book, Code references pages 138-139





Humans like to be a little bit non-transparent

□ **Principle of Transparency**

means that Interactions between HCP and Industry have to be

- Compliant with
 - applicable law
 - Code of conduct
 - Code of business behaviour





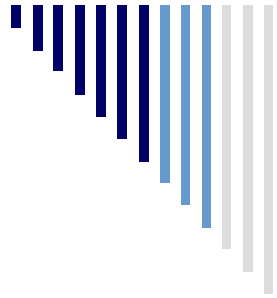
Humans rather like to talk than document

□ **Principle of Documentation**

means the service provided must be documented:

- Purpose
- Description
 - Due diligence
- Compensation
 - Based on a contract
 - Consultant/single event
- Invoice





Humans like to be out of proportion

- **Principle of Proportionality**

means that

- Agreements should be in in good proportion
- Compensation must correspond to fair market value





Humans like to be treated nicely

□ **Principle of Moderation**

- Benefit must not influence HCP`s decision
- HCP must stay independent





Humans have a strong EGO

- Principle of Mutual Benefit***
- Arrangements
- company's normal activities
- equally of value to the healthcare provider.



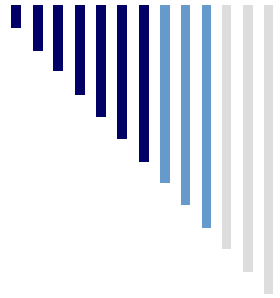


Are there interesting options

- Education tax ??
 - Why should the industry take the burden ??

- Education is initiated by the Hospitals
e.g. Helios, Germany:
0.4% of the revenue

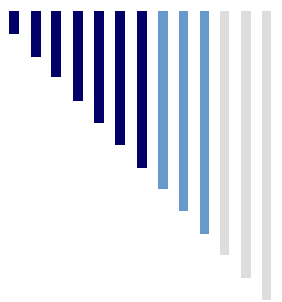




Compliance is our manual for business relationship

- Different from aircraft manuals
- not self- explanatory
- always changing
- difficult to understand
- easy to violate





K.I.S.S

Keep it short and simple

