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#EAHP2021
VIRTUAL

25th EAHP ANNIVERSARY CONGRESS
HOSPITAL PHARMACY 5.0 -
THE FUTURE OF PATIENT CARE
23-28 March 2021

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SDP1: New strategies to overcome drug shortages

Thursday, 25 March 2021 - 1:00pm to 1:45pm CET

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Disclosure of conflicts of interest

- This work was funded by public grants
 - *COST Action CA15105*
 - *SNSF / COST CH Grant C16.0038: Medicine Shortages - Reframing and negotiations of agreement between key players and stakeholders*
 - *BFH internal funding*
- Otherwise nothing to declare
 - My main interest is the patient's outcome (according to the Hippocratic Oath)
 - No research funding from private sources



Control of learning success

- ▶ Statement: As root causes (of shortages) are critically related to supply from Indian and Asian countries, national hospital production is recommended to backup the supply chain. (true / false ?)
- ▶ Statement: Stockpiling under a National Economic Supply authority is a suitable tool to provide products being on shortage. (true / false ?)
- ▶ Statement: Hospital Pharmacies can manage each case of shortage by importation of medicinal products from European countries. (true / false ?)

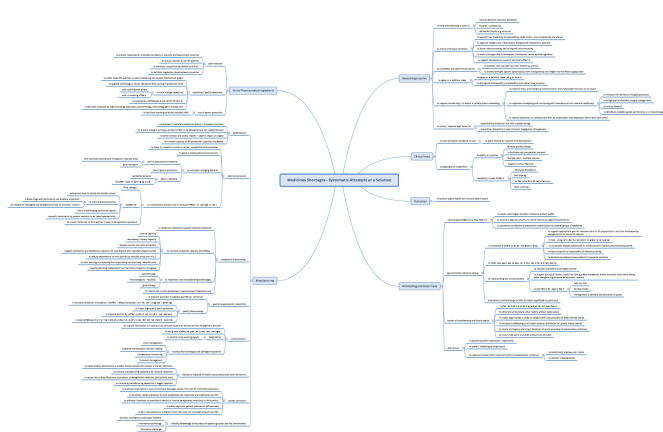
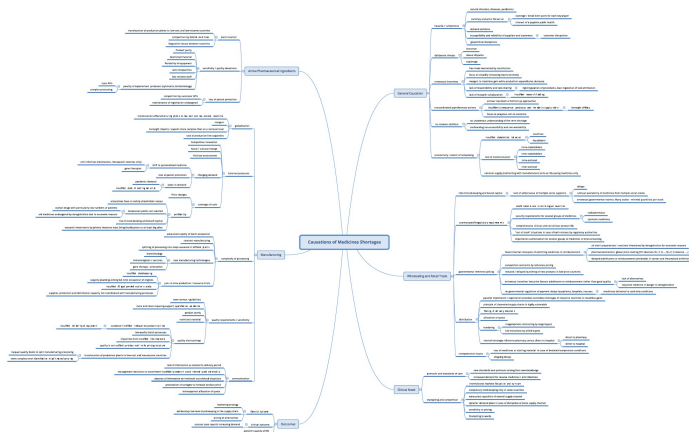
Contents

- ▶ Background and Aim of the research project
- ▶ Methodology
 - ▶ Qualitative methods (Expert Interviews and Delphi rounds)
 - ▶ Quantitative methods (quantification of agreements)
 - ▶ Simulation (-> Business engineering's part)
- ▶ Results (approaches to increase supply safety)
 - ▶ Step 0: **Governance** and Responsibility Sharing
 - ▶ Step 1: Synthesis of **APIs**
 - ▶ Step 2: **Manufacturing** of medicinal products
 - ▶ Step 3: **Distribution** ((Pre-)Wholesalers), National Economic Supply
 - ▶ Step 4: **Health Care Providers**
 - ▶ Step 5: **Outcomes** (clinical, financial, quality of life)
- ▶ Conclusion / Take home messages

Aim of the project

- ▶ **Identify erroneous incentives and system leverages**
 - ▶ **Free trade warranted by the constitution**, high pharma regulation, low delegation of leadership
 - ▶ ... but support of macro-economy only
 - ▶ ... but capital bound in stocks is kept lean
 - ▶ ... but no shared responsibility
 - ▶ ... but intervention option of authorities only in case of epidemics or pandemics
 - ▶ **Mergers** to maximise gain while production expenditures decrease
 - ▶ ... but risk of chain disruption increases
 - ▶ Focus on **steadily increasing macro-economy**
 - ▶ ... but creates problems on a micro-economy level
 - ▶ ... but favours competition original - generic
 - ▶ **National economic supply** (contracting with manufacturers) is highly estimated
 - ▶ ... but applicable **for medicines considered life-saving only**
 - ▶ ... only for buffering delivery delays
- ▶ **Doing the step from coping strategies to true solutions**
 - ▶ **Dealing with low supply security** and empty shelves
 - ▶ Propose solutions to **root causes**
- ▶ **Innovative approach**: combination of qualitative research and simulation
 - ▶ Expert interviews
 - ▶ **System dynamics simulation**

Method & Downloads



Medikamenten-Versorgungsengpässe (Medicines Shortages) in der Schweiz Ursachen und Lösungsansätze - Bericht zuhanden politischer Akteure und der interessierten Öffentlichkeit

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(Dienstagabendgesellschaften: Projektabschlussbericht des DMP² und EAMP³ Workshop)
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- COST Action CA15105
- Swiss National Science Foundation (Grant C16-06388)
- Berner Fachhochschule BFH (diverse Eigenleistungen)

¹F&E Entwicklung und Diätetik, Department Gesundheit, Berner Fachhochschule (Prof. Dr. Dorothea, Forschungsbereich BSG, bis 31.07.2020).
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³Fachbereich Wirtschaftswissenschaften, Department Technik und Informatik, Berner Fachhochschule (Prof. Dr. Fachbereichleiter und Dr. Leiter Strategisches Management, Simon Zumbühl).
⁴Fachbereich Wirtschaftswissenschaften, Department Technik und Informatik, Berner Fachhochschule.
⁵https://doi.org/10.1007/978-3-03-051000-0
⁶https://www.eahp.eu/events/academy/academy-seminar-2018-warsaw-poland/PresentationsS1

- The Political Report («Medikamenten-Versorgungsengpässe (Medicines Shortages) in der Schweiz - Politischer Bericht”)
 - <http://p3.snf.ch/project-174566>
 - To download the report in German with English and French Abstracts
<https://www.gsasa.ch/deliver.cfm?f=0CD89DA59212A7CBAEDB92D0485D989EB4704EB899A238A49E58A3BB8FC6BD7E2C8FAC5A9D8D89AB4198D7B0BE45AA98F89391F6918F99A08AC342BDAF&type=.pdf>
- The original mindmaps (causations and systematic attempts at a solution) in English
 - <https://www.eahp.eu/events/academy/academy-seminar-2018-warsaw-poland/PresentationsS1>

ad Governance

leadership, responsibility sharing, reframing / commonalities

- ICT specialists
- government representatives
- healthcare
- professional organisations
- industry federations
- trade associations
- patient organisations

Where are the α ?
Where are the β ?

- providers
- wholesalers
- procurement officers
- logistics specialist

- professional associations (provider)
 - medical professionals
 - health professionals
 - patient organisations
 - hospital directors
- health service, policy & politics experts
 - ethicists
 - sociologists
 - economists
 - governmental administration
 - regulatory representatives & inspectors
 - insurers

PROCESS STEPS RELEVANT FOR MEDICINES SHORTAGES

API
MANUFACTURING

MEDICINES
MANUFACTURING

TRADE
LOGISTICS
WHOLESALE

PHARMACOTHERAPY

OUTCOMES
CLINICAL
FINANCIAL
QUALITY OF LIFE



- active ingredient manufacturers
 - managers
 - directors of industrial associations
 - chemists
- business managers
- economists

- manufacturing pharma enterprises
 - managers multinational enterprises
 - manufacturing SME
 - directors of industrial associations
 - chemists, industrial pharmacists
- business managers
- economists

- prescribers and providers
 - physicians
 - pharmacists
 - therapists

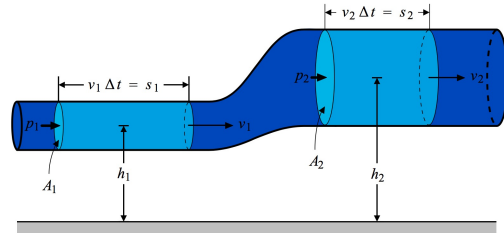
ad Governance

nature and physical laws show us how to manage logistics

springs for therapeutic agents

capacity allocation

repositories, stockpiling



What we must omit

turbulences
low capacities

What we need

large tubular cross-sections
laminar flow



ad API synthesis and supply

as important root cause of shortages: API's inavailability

GSASA – industry agreement on API provision in case of medicines shortages



Absichtserklärung

der Verbände der pharmazeutischen Industrie in der Schweiz:

- **ASSGP** (Schweizerischer Fachverband für Selbstmedikation),
- **Intergenerika** (Verband der Hersteller- und Vertriebsfirmen von Generika/Biosimilars in der Schweiz),
- **interpharma** (Verband der forschenden pharmazeutischen Firmen der Schweiz),
- **scienceindustries** (Wirtschaftsverband Chemie Pharma Biotech),
- **vips** (Vereinigung Pharmafirmen in der Schweiz)

gegenüber folgenden Organisationen in der Schweiz:

- **FMH** (Verbindung der Schweizer Ärztinnen und Ärzte),
- **GSASA** (Schweizerischer Verein der Amts- und Spitalapotheker),
- **H+** Die Spitäler der Schweiz,
- **pharmaSuisse** (Schweizerischer Apothekerverband).

Im Bewusstsein, dass

- die Versorgung mit Arzneimitteln, die individuelle Herstellung von Arzneimitteln für bestimmte Patienten und die defekturenässige Herstellung von Arzneimitteln in Kleinen Mengen (gemäss Art. 9 Abs. 2 HMG) zu einem wesentlichen Teil von Apotheken gewährleistet wird,
- für bestimmte Patientengruppen (Pädiatrie, Geriatrie) geeignete Arzneimittel-Anwendungsformen nicht als Fertigpräparate verfügbar sind,
- es weder ethisch vertretbar noch gesundheitspolitisch erwünscht ist, die Versorgung mit Arzneimitteln unangemessen einzuschränken,

und unter Berücksichtigung der in diesem Zusammenhang massgebenden staatlichen Vorschriften erklären die oben erwähnten Verbände der pharmazeutischen Industrie Folgendes:

1. Diese Verbände und ihre Mitgliedsunternehmen setzen sich dafür ein, dass die Apotheken in der Schweiz mit Wirkstoffen beliefert werden, die sie zur individuellen oder defekturenässigen Herstellung von Arzneimitteln brauchen, die für die Versorgung der Bevölkerung notwendig, als Fertigpräparate jedoch nicht verfügbar sind.
2. Diese Verbände empfehlen ihren Mitgliedsunternehmen, Apotheken, Ärzte und Spitäler auf Anfrage hin über laufende Patente eines Wirkstoffs (Laufzeit und Indikation) und autorisierte Bezugsquellen zu informieren sowie in oben erwähntem Zusammenhang auf die Durchsetzung von Patentrechtsansprüchen zu verzichten. Im Einzelfall können Lizenzgebühren erhoben werden.

3. Ergeben sich im Zusammenhang mit dieser Absichtserklärung praktische Probleme, so verständigen sich die oben erwähnten Verbände und Organisationen wo immer möglich auf eine geeignete Lösung.
4. Die oben erwähnten Verbände informieren ihre Mitgliedsunternehmen über diese Absichtserklärung.

Organisation	Ort und Datum	Unterschrift
ASSGP Hans-Rudolf Fuhrer	Rothenz, 26.8.13	H. Fuhrer
Intergenerika Dr. Peter Huber	Rothenz, 26.8.13	P. Huber
interpharma Thomas B. Cueni	Rothenz, 26.8.13	T. Cueni
scienceindustries Dr. Dieter Grauer	Rothenz, 26.08.13	D. Grauer
vips Walter P. Hölzle	Rothenz, 26.08.13	W. Hölzle
FMH Dr. med. Jürg Schup	Bern, 29.8.2013	J. Schup
GSASA Prof. Dr. Pascal Bonnabry	Bern, 30.08.13	P. Bonnabry
H+ Charles Favre	Bern, 3.9.13	C. Favre
pharmaSuisse Dominique Jordan	Bern, 3.9.2013	D. Jordan



Pharmaceutical industry contract partners are not willing to provide APIs! “We are not equipped to keep stocks of APIs”



EMA and/or Swissmedic to request stock-keeping of APIs and designation of backup API suppliers from licence holders

ad API synthesis and supply

the importance of keeping backup sources



Licence holders should keep APIs on stock!

Abichtserklärung

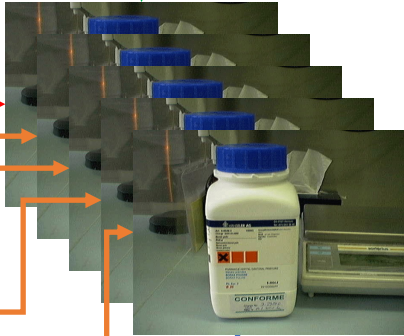
Zweck (Zwecksetzung) der Zusammenfassung ist die Bereitstellung von Informationen über die Eigenschaften, die Herstellung und den Vertrieb von Arzneimitteln, die in der Europäischen Union (EU) in Verkehr gebracht werden sollen.

Rechtliche Grundlage (Rechtsgrundlage) der Zusammenfassung ist die Richtlinie 2001/83/EG des Rates vom 29. Oktober 2001 über die Herstellung, den Vertrieb und die Verwendung von Arzneimitteln in der Europäischen Union (EU) (Richtlinie 2001/83/EG).

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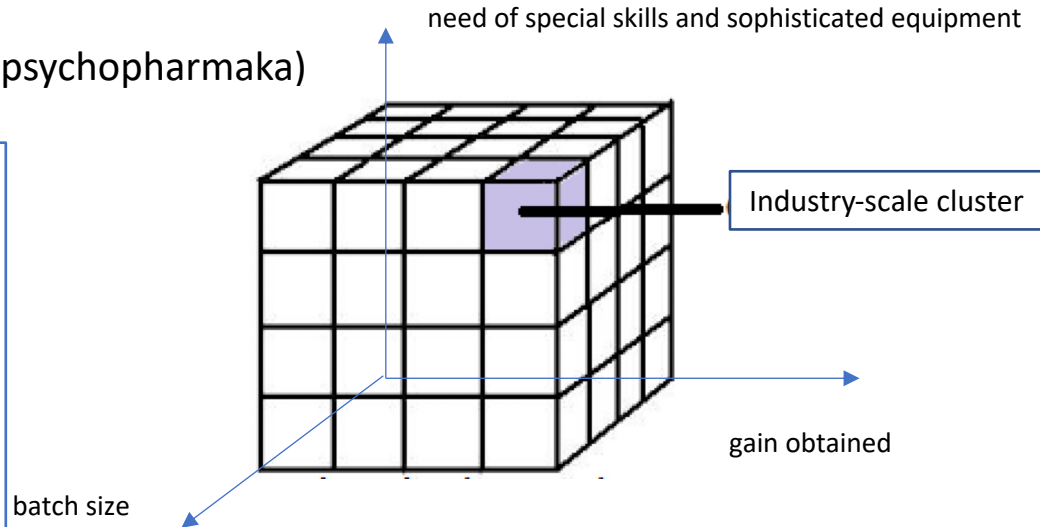
Start-ups
Universities
Non-Ph.Eur Quality
National Economic Supply

ad manufacturing of licenced medicinal products

Keeping products in the market - Resizing of production scale and release licences to SME

- Industry-scale cluster:
 - big number of items to produce (blockbusters)
 - high return on investment (patent protected medicinal products)
 - sophisticated equipment (ATM, gene and cell therapies)
- SME-scale cluster (includes hospital pharmacy production):
 - small-scale
 - Low return on investment (e.g. old psychopharmaka)
 - polyvalent traditional equipment

- Instead of withdrawing from market, multinational enterprises should transfer licences to small and medium enterprises (SMEs)
- Requirement for deregistrations by Admission Authorities?
- Cave: liability is a risk for SMEs

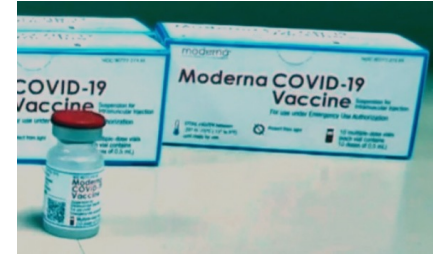


ad (pre-)wholesalers and trading providers

freedom of trade vs regulation vs risk management

- **To learn from the Covid-19 pandemic** and contingencies initiated by states
 - **By-passed traditional supply-chains** for vaccines programs or masks supply
 - Legal basis: epidemics act
 - **Result: a disaster ...**
- **Need of high capacities to buffer shortages vs low stock-bound capital**
 - incentives to be implemented for stockpiling, losses due to peremption, ...
 - Short one-step supply pathways better than multiple serial or parallel small stores
- **GPS monitoring of international medicinal products transportation** (see supply chain tv emission <https://www.srf.ch/play/tv/einstein/video/corona-und-die-logistik-die-versorgung-im-krisenmodus?urn=urn:srf:video:0a532b7e-0eb0-4e18-a957-4adbaace08eb>)

ad (pre-)wholesalers and trade the odyssey of Moderna vaccines around the world



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit

Eidgenössische Kommission für
Impffragen (EKIF)

+ from Portland NH via Visp and Madrid to Brussels

+ fine distribution from Brussels

- European countries
- Nationally by Swiss Army to Kantone
- No professional supply chain stakeholder involved!
- **The army-government way does not work!**
- **Direct-to-hospital is the measure!** (idem for masks)

Covid-19-Impfstrategie (Stand 24.12.2020)

Bundesamt für Gesundheit (BAG) und Eidgenössische Kommission für Impffragen (EKIF).

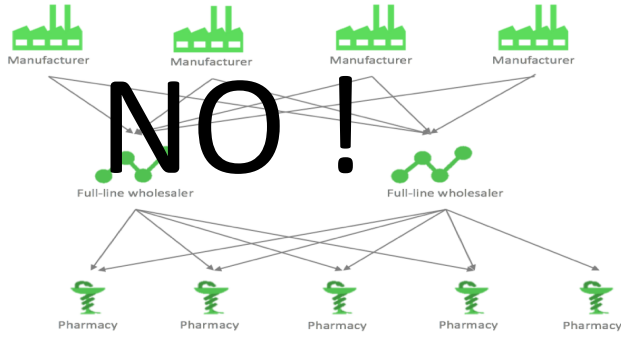
Number of involved staff not familiar
with usual hospital procedures?

=> Efficiency???

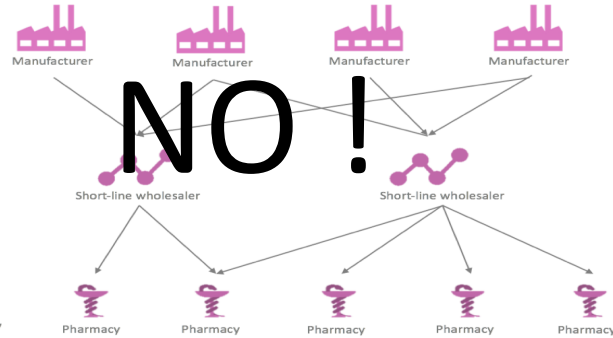
ad (pre-)wholesalers and trading providers

efficiency means direct-to-hospital way and high buffer capacity

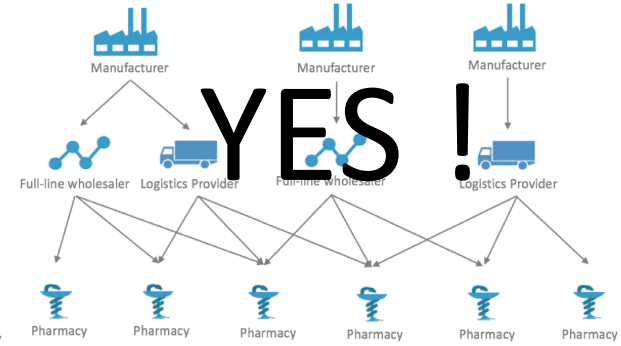
Full-line wholesalers



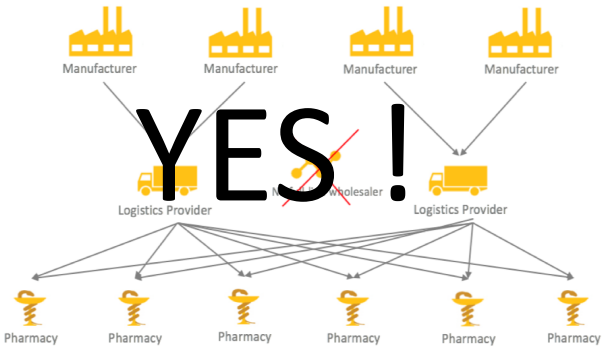
Short-line wholesalers



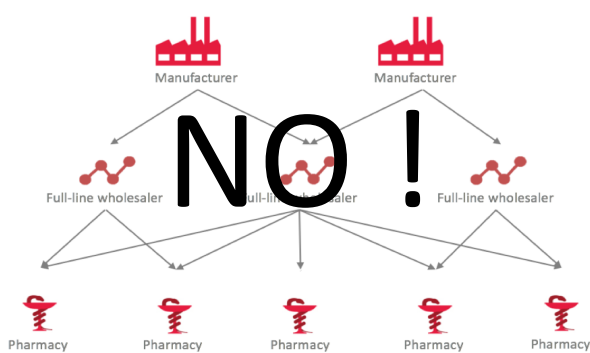
Direct sales



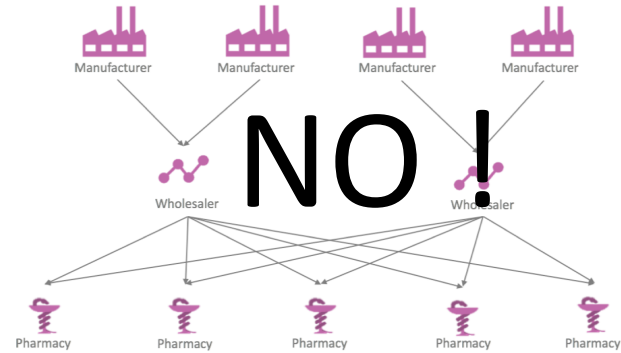
Direct-to-hospital-pharmacy



Reduced wholesale arrangement



Single channel system



ad health care providers (hospitals)

Stabilisation of the supply chain by procedural approach

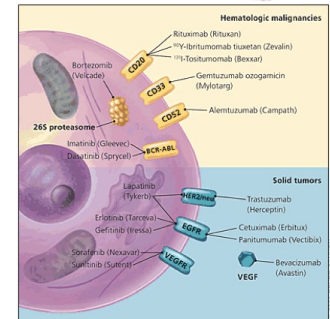
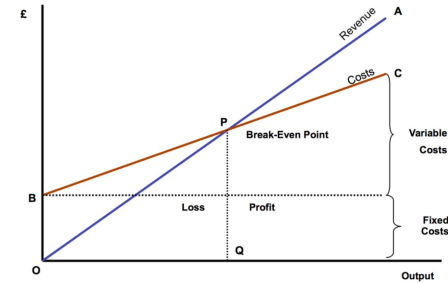
- ▶ Selection of medicinal products:
Consider security of supply
- ▶ Omit tendering
- ▶ DCI (not brands) prescribing
- ▶ Reviewing therapy paradigms
- ▶ Allocation of higher capacities:
Anticipating upcoming needs
- ▶ Diagnosis of responders / non-responders
(genetic profiling)



ad outcomes

clinical outcome / financial outcome / quality of life outcome

- ▶ Pharmacoeconomics
 - ▶ Cost-benefit
 - ▶ Cost-effectiveness
 - ▶ Cost-minimisation
 - ▶ Cost of additional QALYs
- ▶ Health Care Financing
 - ▶ Cost-neutrality of new treatments as compared to traditional therapies (Cost = Amount * Price)
 - ▶ To improve coverage over break-even
 - ▶ New pricing models (e.g. pay for performance)
 - ▶ Reassurances for capital bound in a stock
 - ▶ Billing national economy and/or enterprises for the clinical outcomes (patient's regained productivity)
- ▶ Property right
 - ▶ Do not outsource, keep capital in the hospital



Conclusion / Take home messages

- ▶ **Governance / Leadership** needed
 - ▶ **Macro**-economy runs well – false for **micro-economy**
 - ▶ **SHARING RESPONSIBILITIES** needed to improve the shortages problem
 - ▶ **NOMINATION OF LEADERS** by Supply Chains step
- ▶ **AVAILABILITY OF ACTIVE PHARMACEUTICAL INGREDIENTS** is a key issue to provide pharmacotherapy to patients in case of shortages
- ▶ **BETTER REMUNERATION** of manufacturers of deregistration-threatened medicinal products
 - ▶ New incentives for **LOW AND MEDIUM SCALE PRODUCTION**
- ▶ **Direct-to-hospital pharmacy delivery**
 - ▶ **Equilibrate costs and performance**

That's all folks - questions?

