What is the price of a drug ?

Paul M. Tulkens, MD, PhD
Professor of Pharmacology and Drug Development
Université catholique de Louvain, Brussels, Belgium
Former Member of the Belgian Drug Reimbursement Committee

- Principles of health economy
- How do you decide a price ?
  - viewed from the Industry
  - viewed from the Social Security
  - what if they do not agree ?
- How do we reimburse drugs in Belgium
- Pharmacoeconomy: a rational approach

UCL

University of Pharmacy, Hanoi, 20 April 2011

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What is Economy and its political inceptions ?

- Economy refers to the human activities related with the **production**, **distribution**, **exchange**, and **consumption** of **goods** and *services*.

- The composition of a given economy is inseparable from civilization's history and social organization

- Marxists (Karl Marx [1818-1883]) described economy as the "system of capitalism". The exploitation of **labour** and **nature** by the **capitalist** is creating a surplus value. This should be taken over by the State in order to avoid uncontrolled capitalism.

  ➔ The first centrally planned economy was established after the Russian Revolution of 1917 by Lenin. Other countries launched **Social Security** systems in order to minimize the effects of uncontrolled capitalism, called Manchester capitalism.

- Milton Friedman (1912-2006) pleaded for a global free trade (**market economy**). In contrast, John Maynard Keynes (1883-1946) argued for a stronger control of the markets by the state.

  ➔ In most of the countries the economic system is called a **Social Market Economy**.

Comparison of consumption activities in an Free Market economy *vs.* a Social Market Economy

Analysis of the demand

- demand often foreseeable
- initiated by the consumer
- corresponding to a desire that often exceeds the real need
- is limited by the available resources

Travel, Restaurant, Leisure

- demand most often non foreseeable
- rarely initated by the consumer
- corresponding to a need that cannot be modulated
- difficult to limit

Housing (basic), food (basic), education

Comparison of consumption activities in an Free Market economy . a Social Market Economy

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Health

Comparison of consumption activities in an Free Market economy *vs.* a Social Market Economy

Analysis of the demand

- quality highly variable
- price highly variable
- supply is dependent from the circumstances
- quantities are variable and can be adapted

- offer of a standard, sufficient quality and under control
- fair and constant price
- supply must be stable and constant
- quantities muts be constant or in relation to the needs

Travel, Restaurant, Leisure

water, public transport, mail, protection against disasters

Comparison of consumption activities in an Free Market economy *vs.* a Social Market Economy

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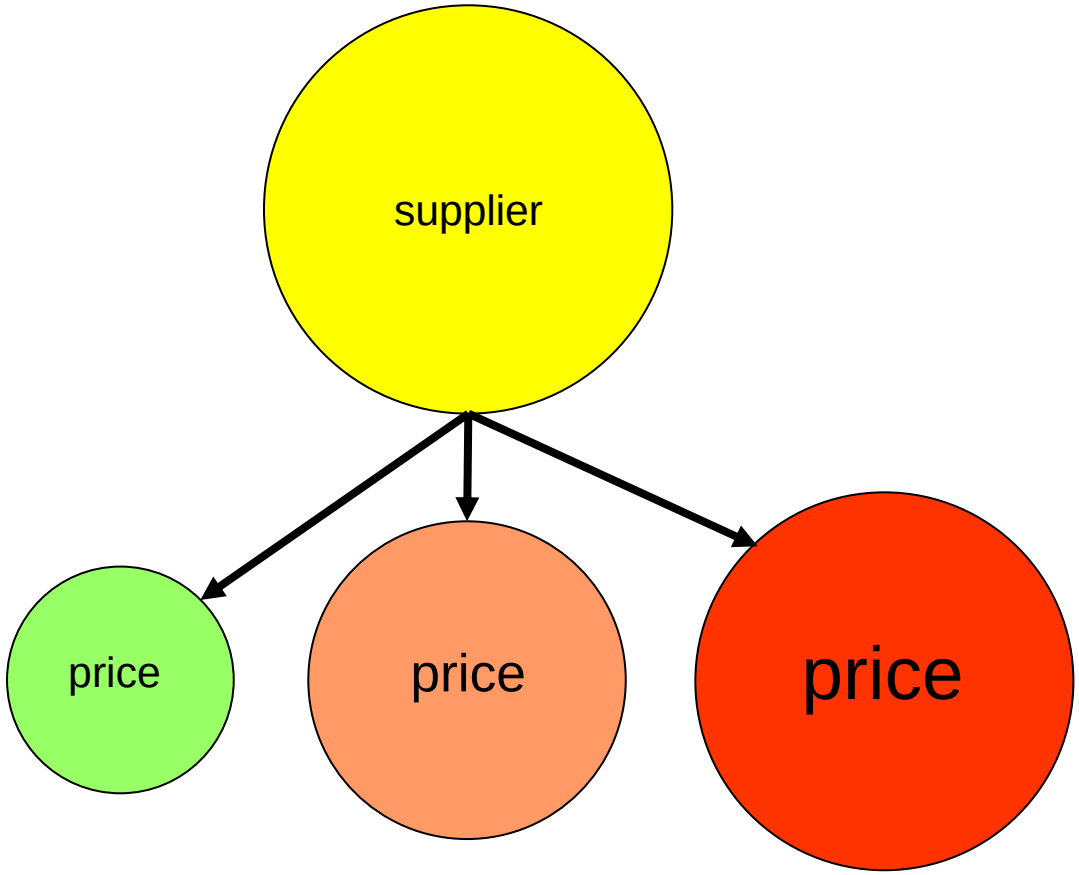
Health (?)

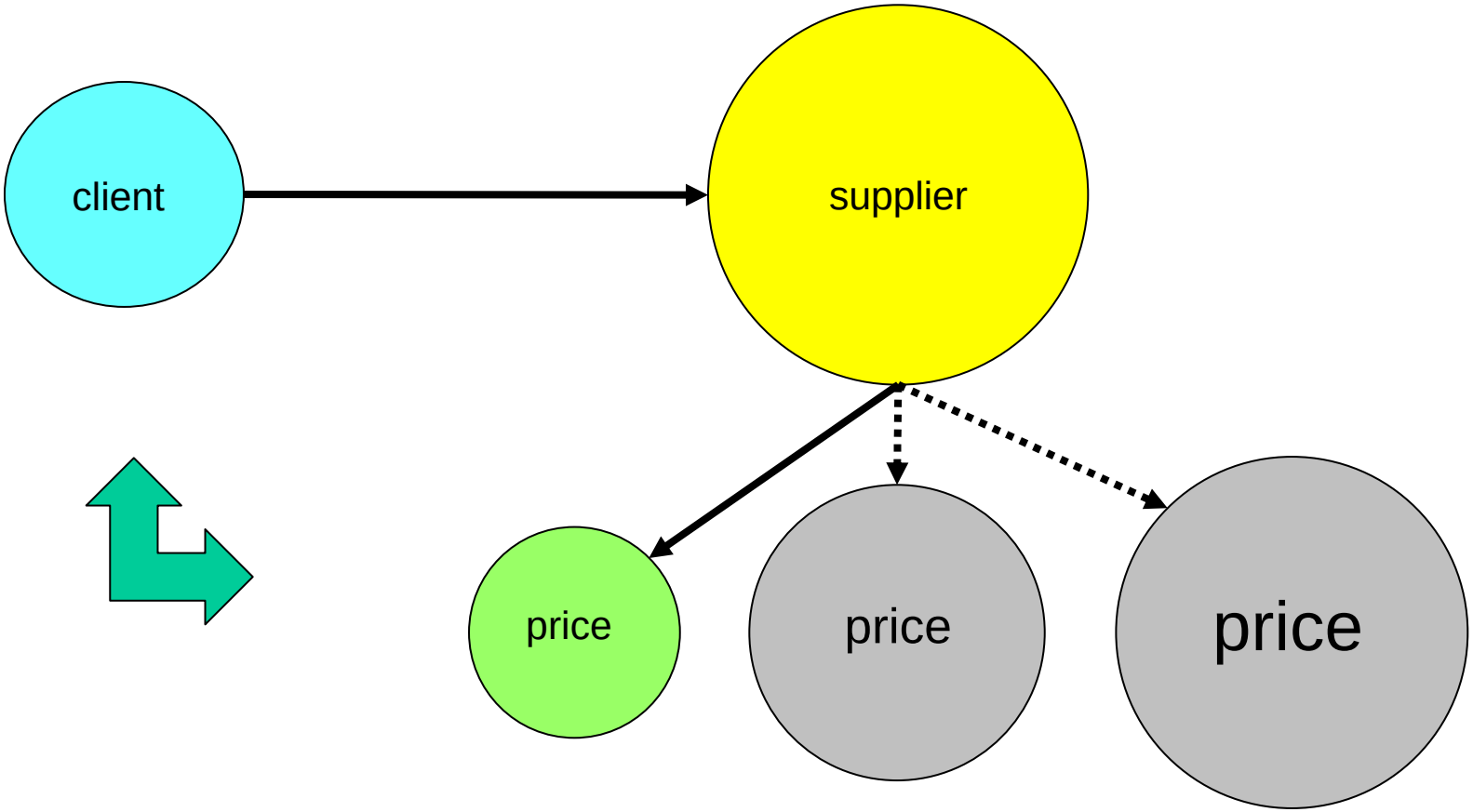
Relationships in a Free Market Economy where the client is also the payer (1)

client



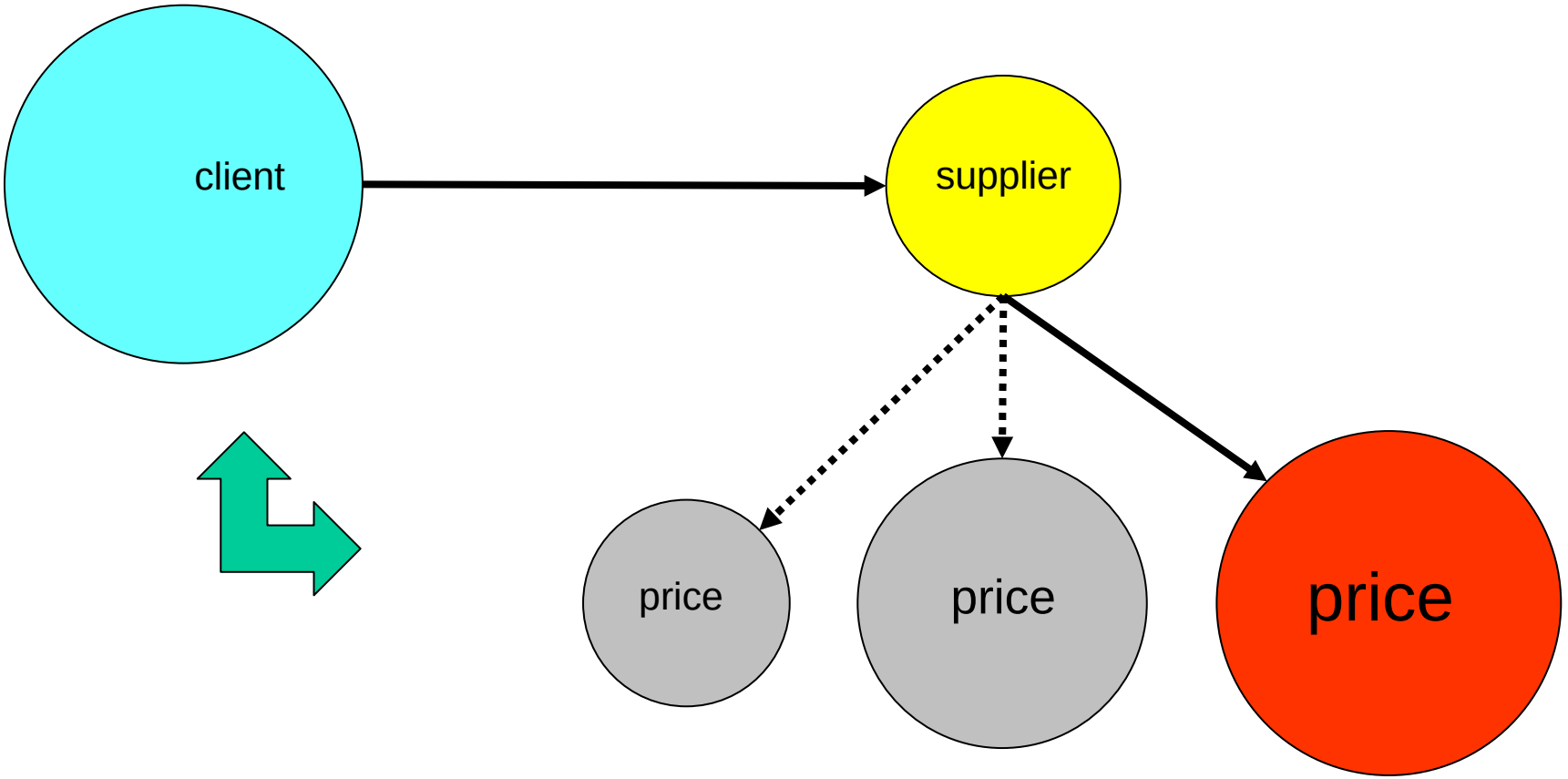
At which price will you sell ?

Relationships in a Free Market Economy where the client is also the payer (2)



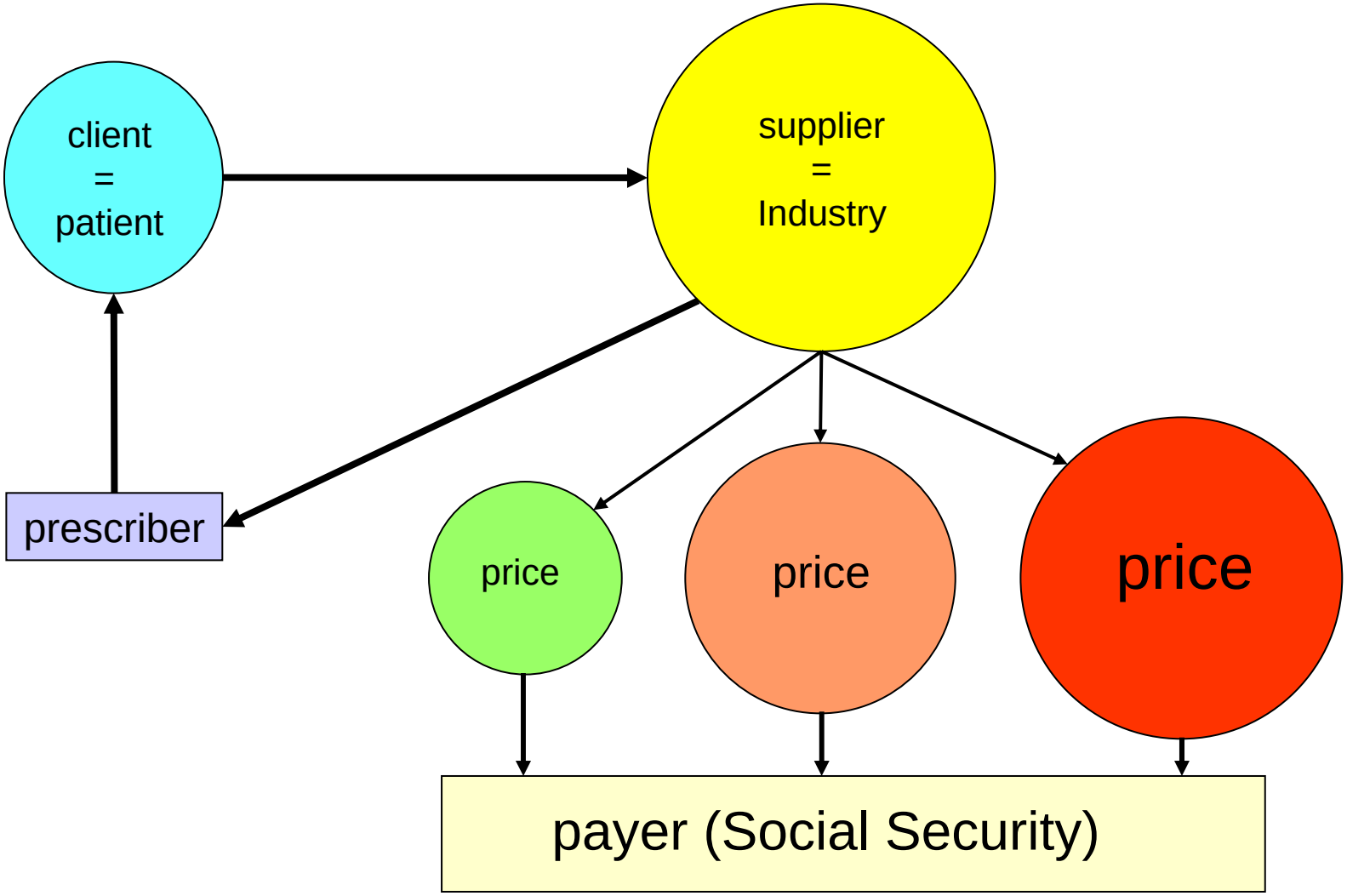
if the choice is by the client, the price goes down

Relationships in a Free Market Economy where the client is also the payer (3)

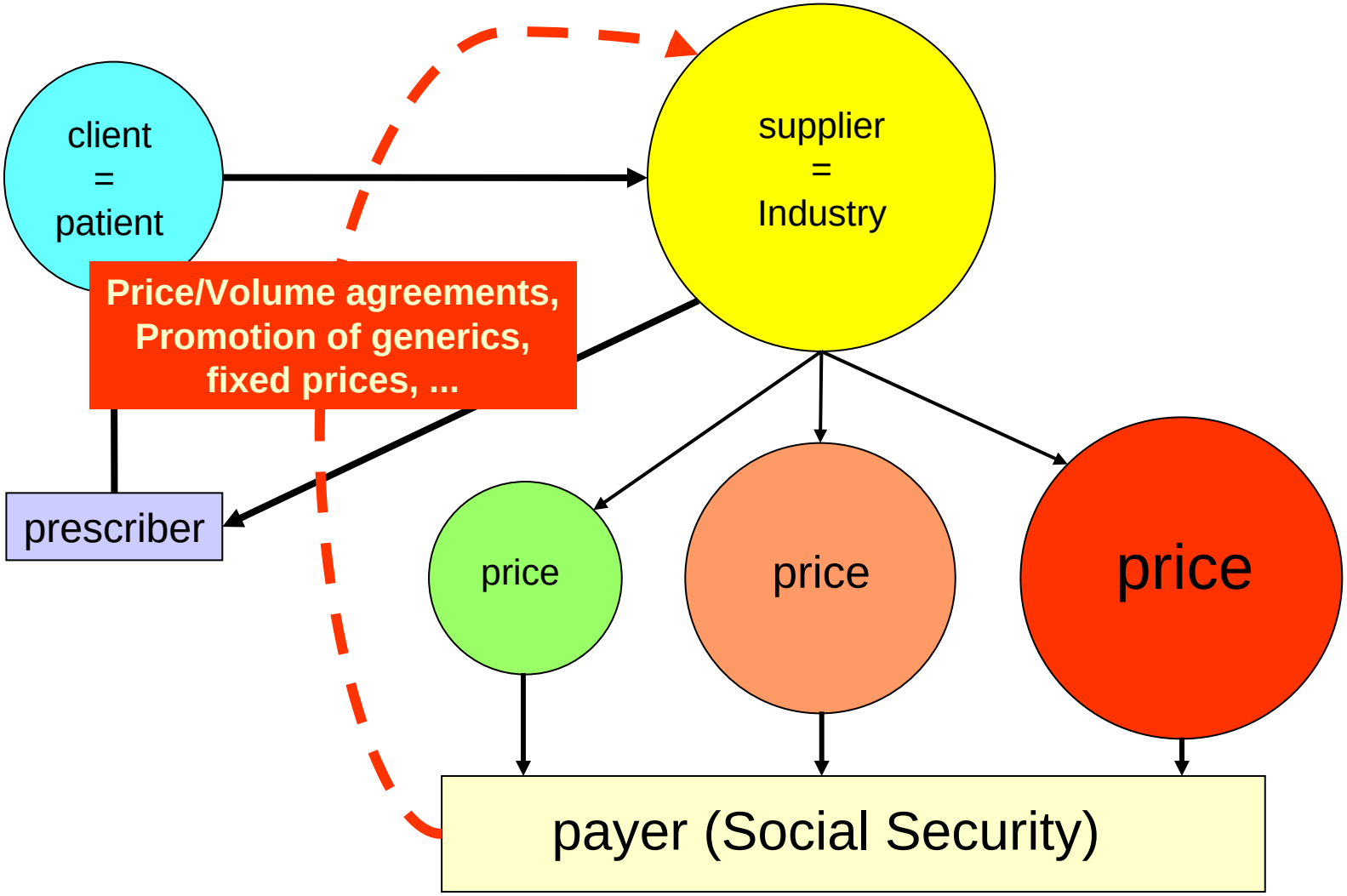


if the choice is by the supplier, the price goes up

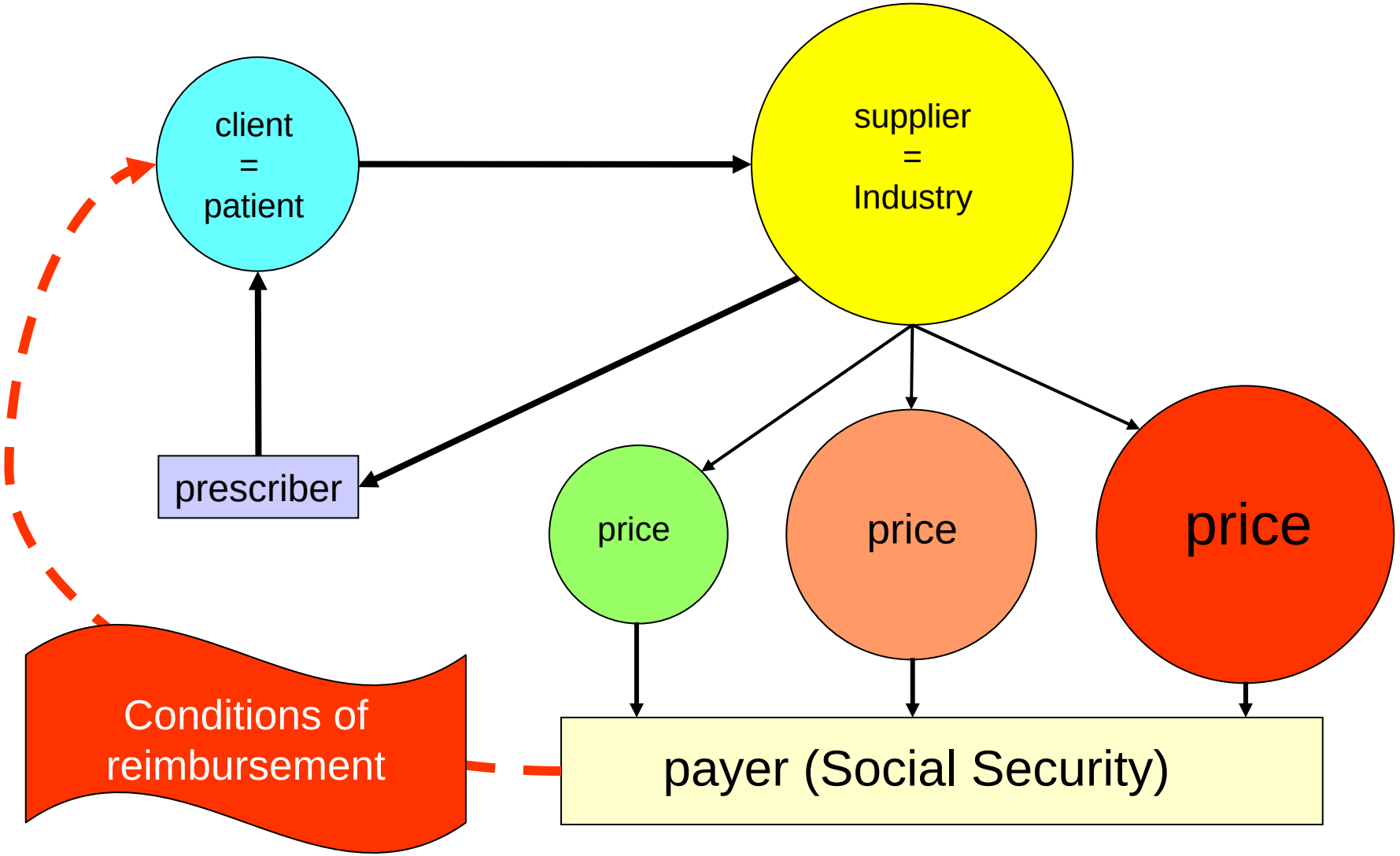
Relationships in Social Health Economy (1)



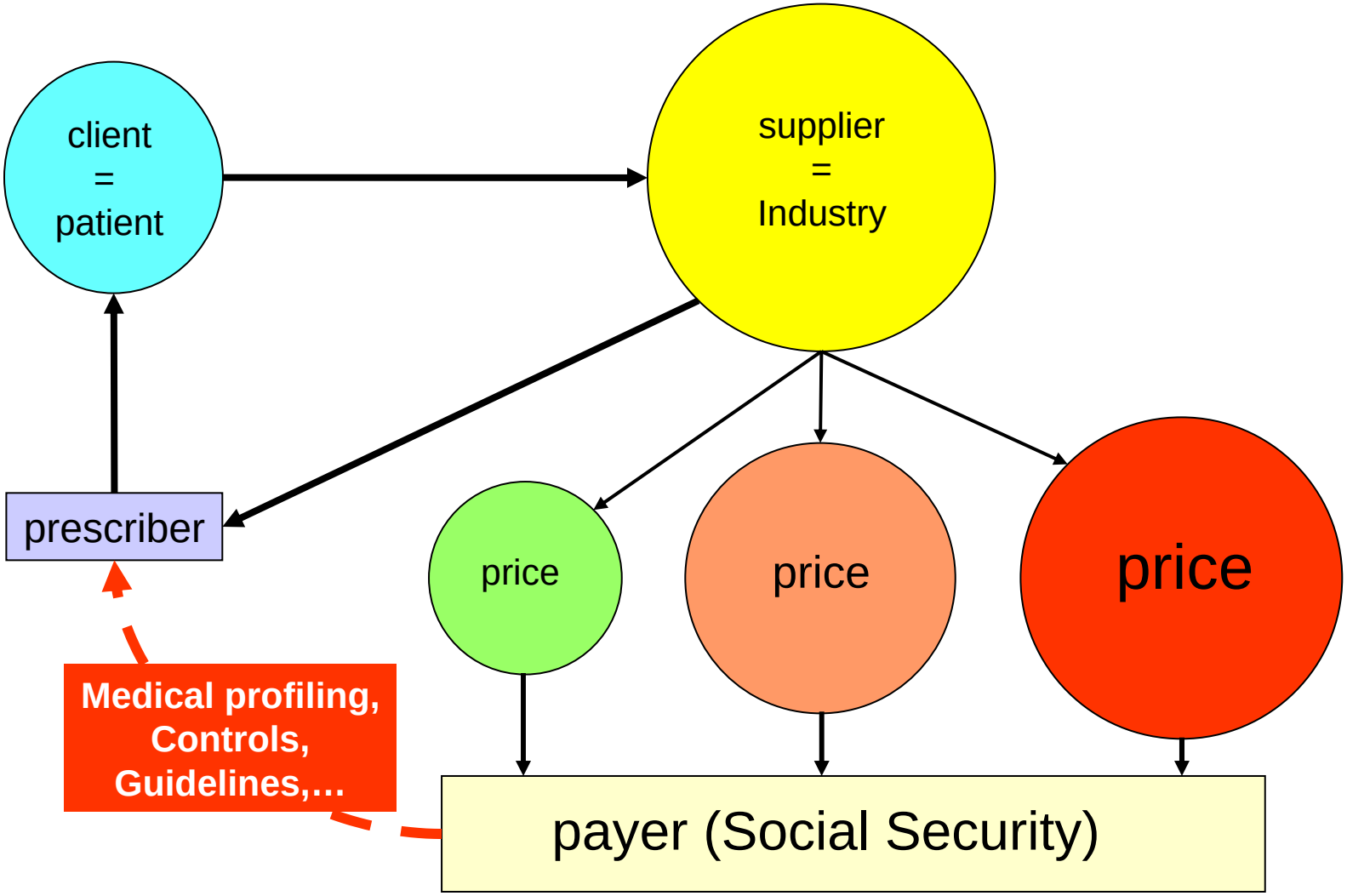
Relationships in Social Health Economy (2)



Relationships in Social Health Economy (3)



Relationships in Social Health Economy (4)



Points to consider if you are in YOUR country

- are decisions national or local ?
- is the price the same throughout the country ?
- is the price applicable to the majority of the population ?
- are they many important drugs falling outside of the reimbursement schemes ?
- are all important drugs "under prescription" only ?
- are all important drugs delivered by pharmacists only ?
- is "parallel" economy important ?

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Now, what will be the price of that drug ?

What is a drug ???

do not get confused !

- A drug is a compound that injected to an animal gives rise to a publication …

What is a real drug ???

- A chemical entity …
- Tested painstainkingly *in vitro*, in animals, etc…
- Having demonstrated curative properties in clinical trials…
- Devoid of unacceptable side effects given the target population…
- Administered to patients to heal their diseases in real life…
- Providing sufficient money back to sustain those who discovered, tested, distributed, marketed it, pay taxes on all these activities, … and reward the investors …
- Paving the way and securing resources for a better one …

Do not get confused …

very few drugs have been discovered and brought to the clinic without INDUSTRIAL support

A few ideas of the necessary budget

- 1 university researcher with her/his technician and functioning

100,000 euros

- one small-sized Belgian pharmaceutical Industry

490,000,000 euros

- one reasonably-sized European pharmaceutical Industry

4,880,000,000 euros

- an "international" society

> 16,000,000,000 euros

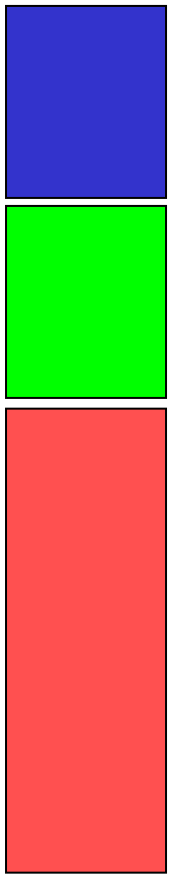
So now, what is really a drug ???

- A drug is a compound that injected to an animal gives rise to a publication …

- A drug is a chemical entity which you have brought through the whole process to demontrate that it is useful (and safe) for treating (or preventing) a disease or another health hazard, and which you sell to recoup your investment …

What is the price of a drug in retail pharmacy ?

(Belgium as an example)

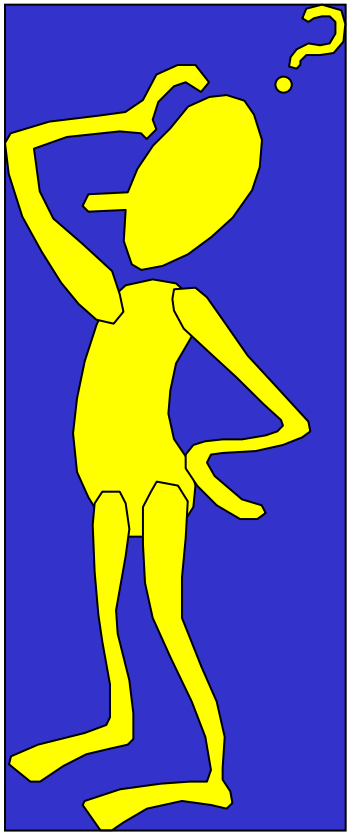


miscellaneous…

pharmacist

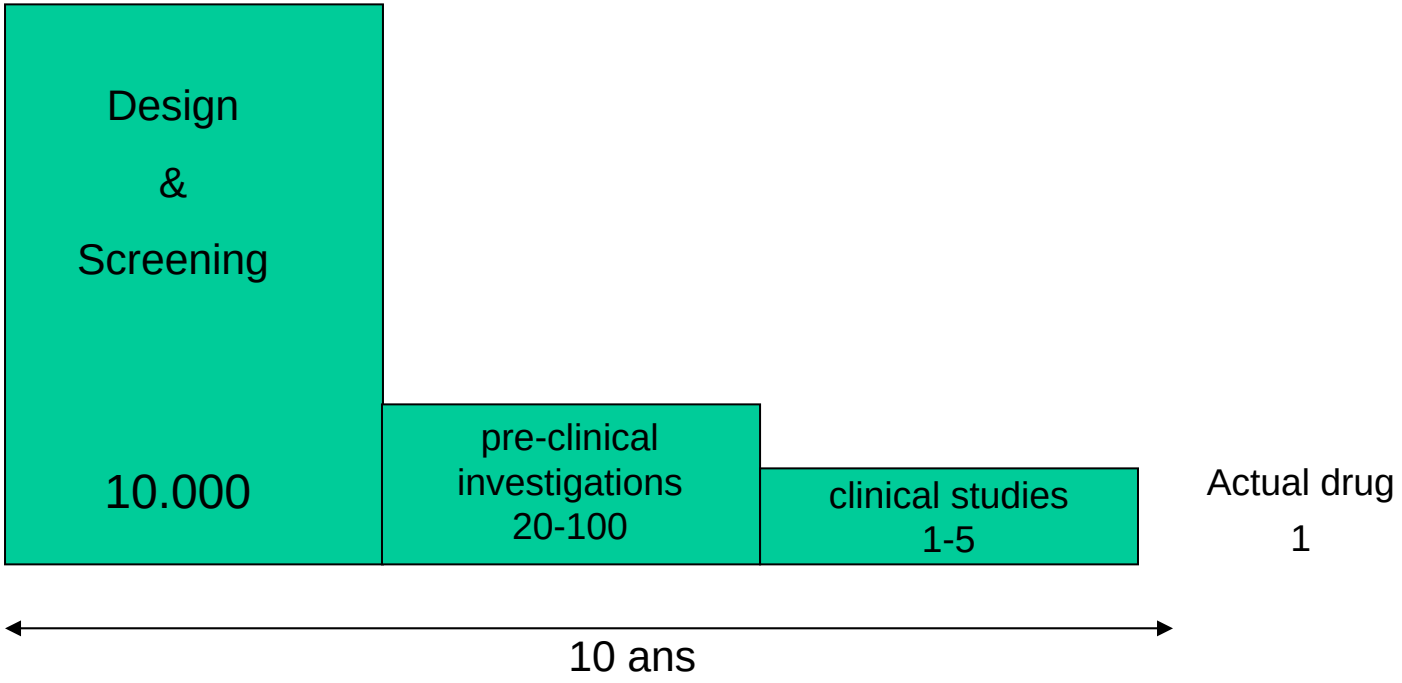
Industry

This is what Industry is interested in



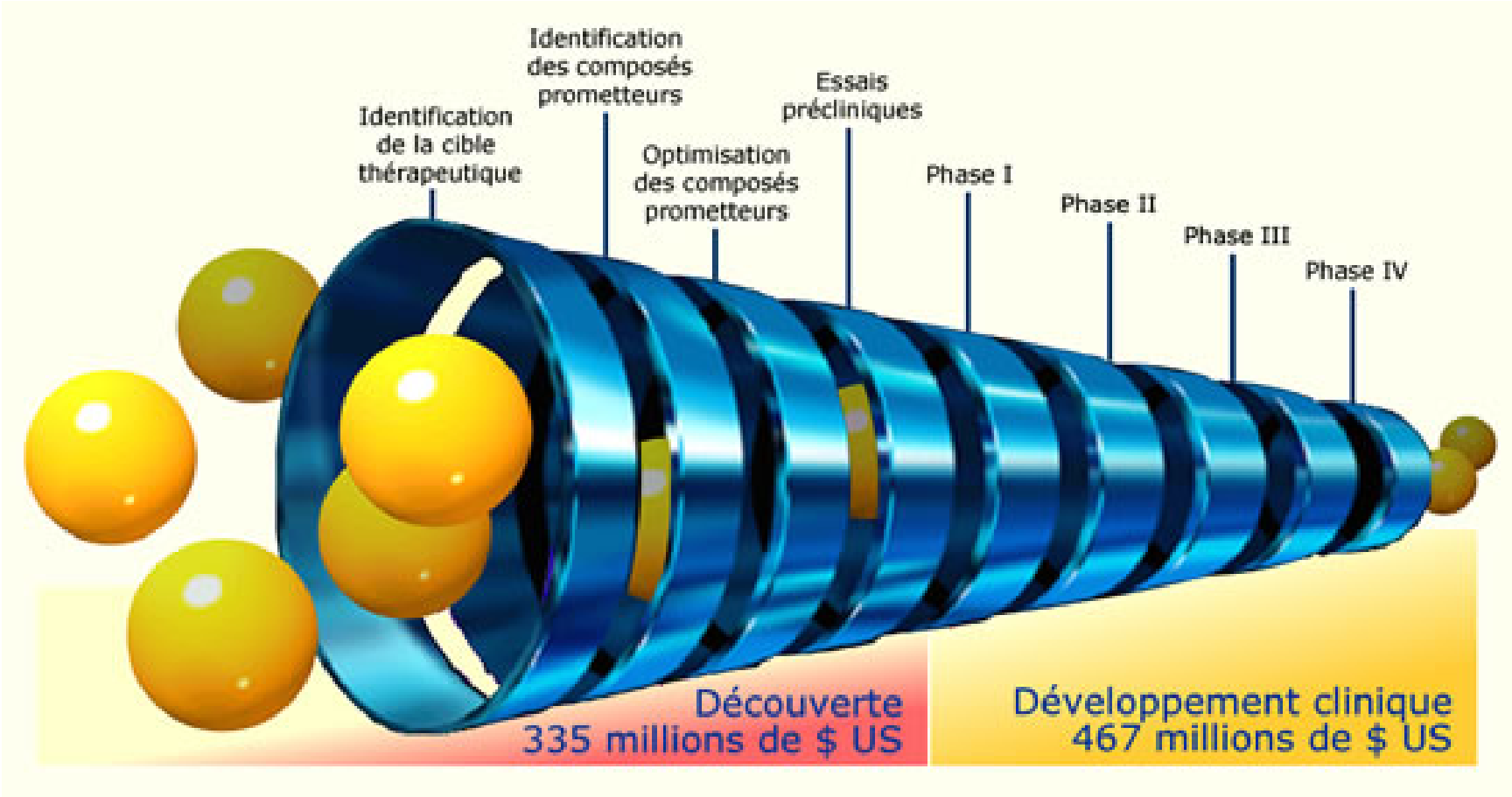
Why is the cost of development so high?

Steps in the discovery and development of drugs

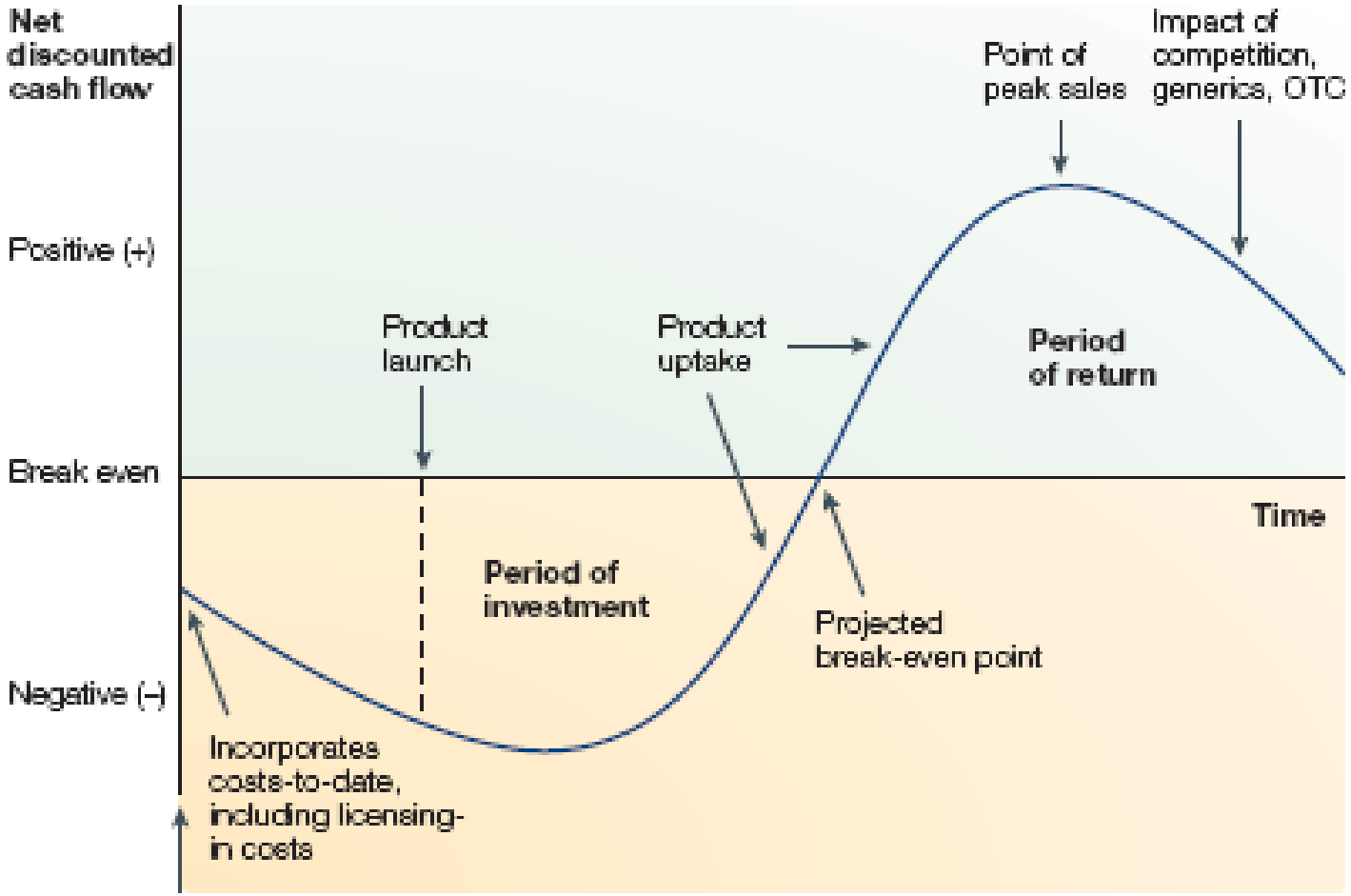


Why is the cost of development so high?

A rough idea of the costs



The investment ... and the return…



The profit of the Industry **must** be large enough to pay for discovery/development expenses and reward the shareholders

Financial summary

Results

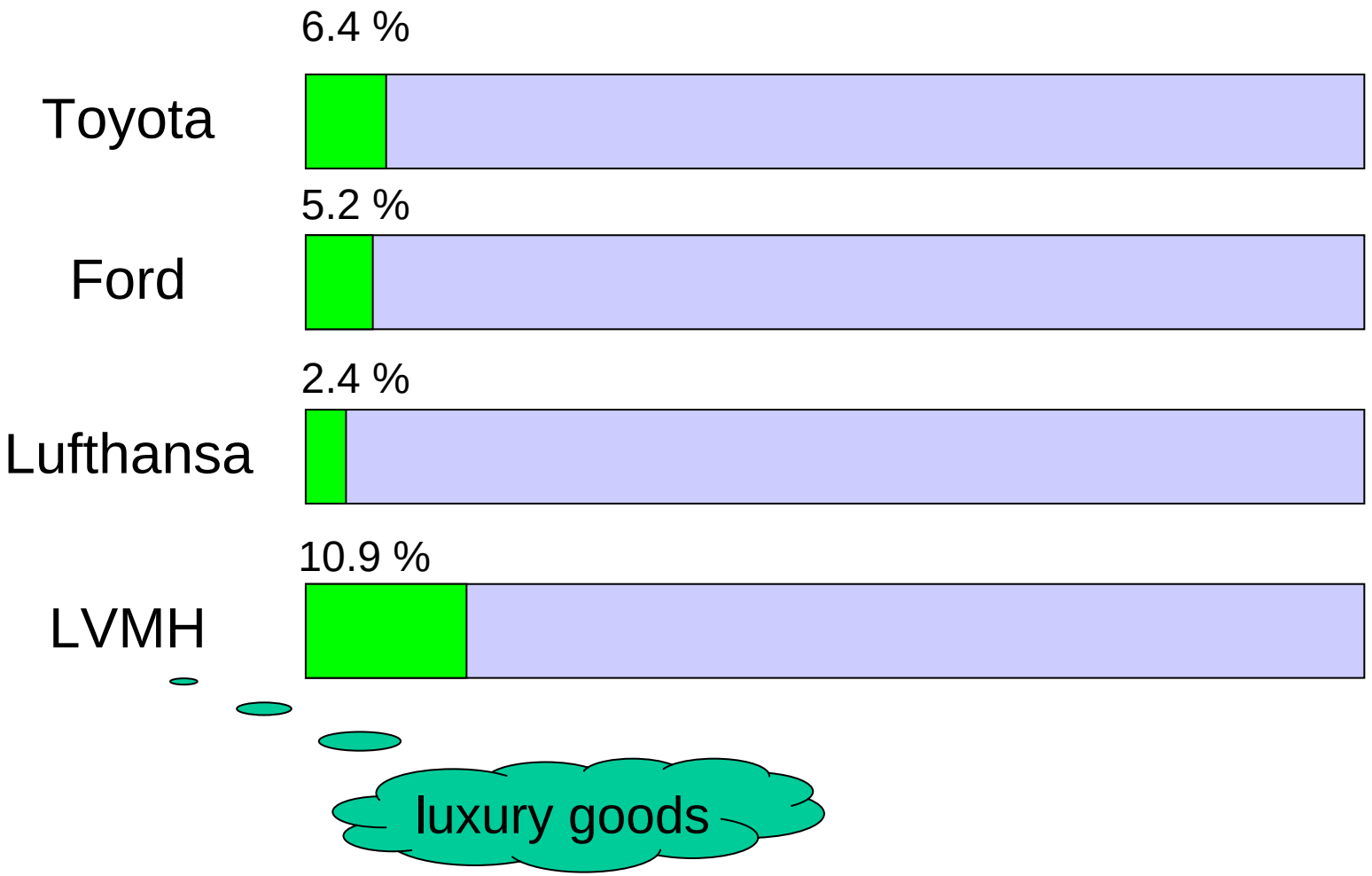
	2006 £m	2005 £m	Sterling % growth
Turnover	**23,225**	21,660	7
Research and development	**3,457**	3,136	
Operating profit	**7,808**	6,874	14
Profit before taxation	**7,799**	6,732	
Profit after taxation for the year	**5,498**	4,816	
Profit attributable to shareholders	**5,389**	4,689	

14.6 %

22.8 %

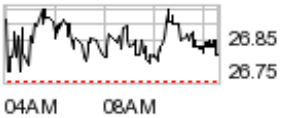
GSK Annual report 2006

What about the profit/turnover ratio of other large companies



Research is risky

UCB (UCB)



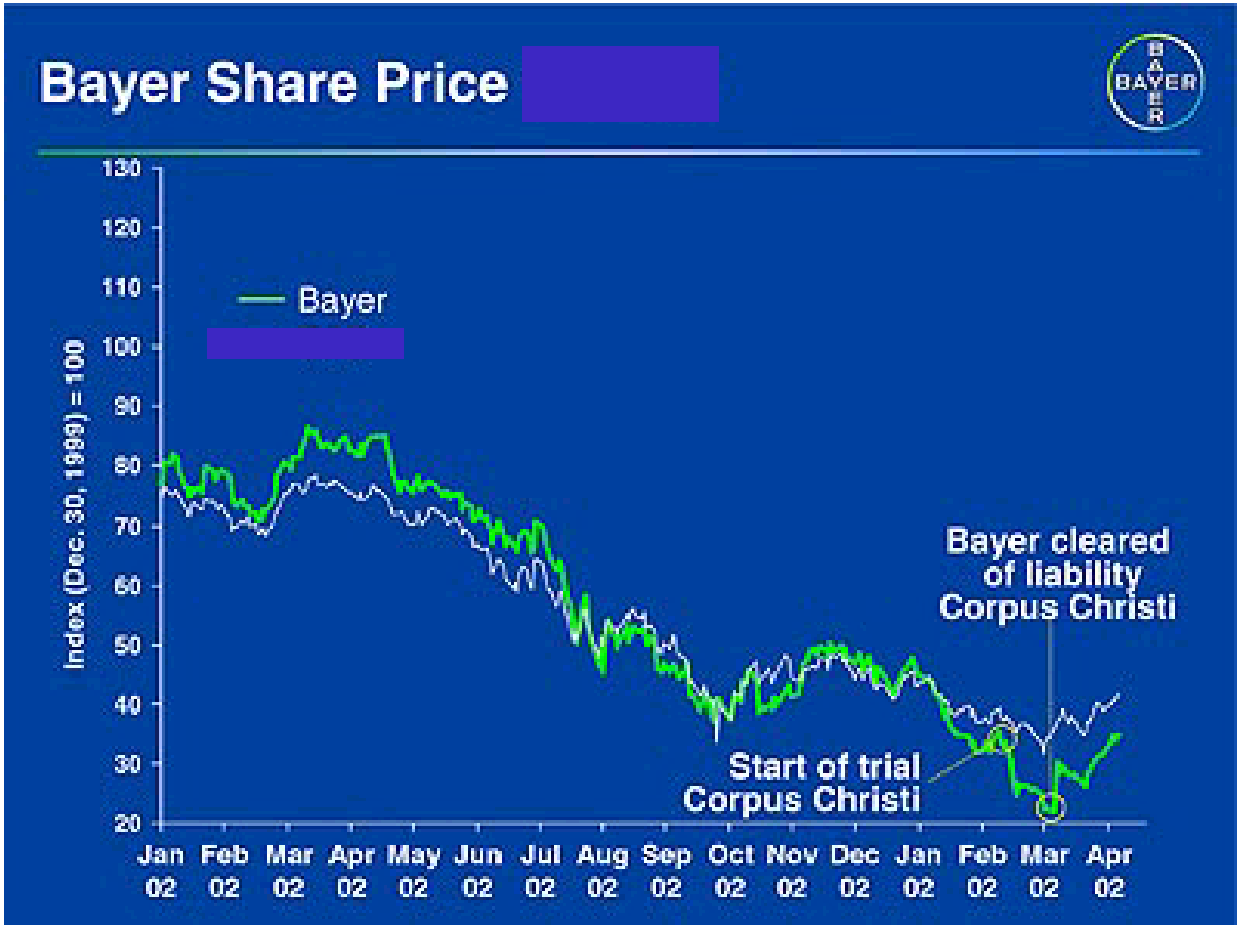
This was when UCB was struggling to get their new products registered

	12/2005	12/2006	12/2007	12/2008	12/2009
Net profit per share, group share	5	3	1	-	3
Diluted net profit per share, group share	5	2	1	-	3
Operating margin (%)	15,55	22,63	9,49	3,14	26,86
Financial profitability (%)	**31,34**	**7,68**	**3,78**	**1,07**	**11,64**
Indebtedness ratio	26,19	44,79	45,52	60,99	39,78
Year-end workforce	8525	8477	12102	11292	9324

Small pharma is a profitable but risky business…

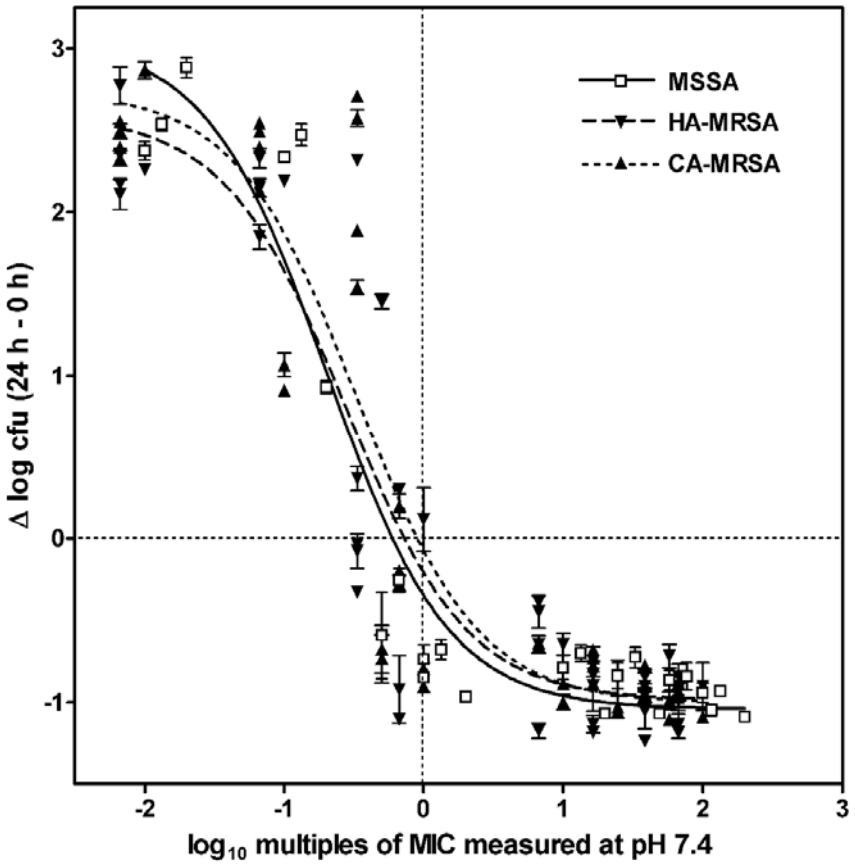
You encounter severe failures… with severe financial consequences

Forced withdrawal of cerivastatin (LIPOBAY®)

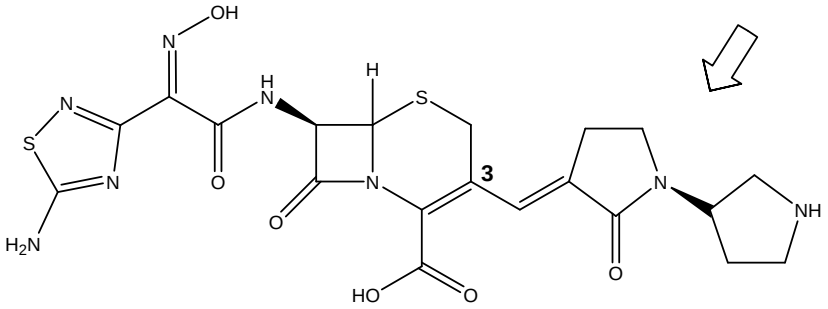


The sad story ceftobiprole

(a novel anti-MRSA cepahlosporin)



Lemaire *et al.* Kill effects of ceftobiprole on intracellular S. aureus. Antimicrob. Agents Chemother. 2009, in press.



Ceftobiprole rejected by the FDA and the EMA

FDA Issues Complete Response Letter for Ceftobiprole for Treatment of Complicated Skin Infections

Raritan, NJ (November 26, 2008) - Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), today announced that it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for ceftobiprole for the treatment of complicated skin and skin structure infections, including diabetic foot infections.

The FDA has indicated that they cannot approve the NDA for ceftobiprole at this time. They have asked J&JPRD to conduct additional audit work of clinical investigator sites and to address specific questions related to site monitoring.

J&JPRD and its co-development partner, Swiss-based Basilea Pharmaceutica Ltd., are reviewing the Complete Response letter and will continue to work with the FDA to resolve questions that are outlined in the Complete Response letter.

The NDA for ceftobiprole was submitted to the FDA in May 2007, and, in March 2008, J&JPRD received an Approvable Letter regarding the ceftobiprole filing. J&JPRD responded to the FDA's Approvable Letter in August 2008.

May 2007

Nov 2008

PRESS RELEASE

Zevtera™ review process delayed in EU

Basel, Switzerland, February 24, 2009 - **Basilea Pharmaceutica Ltd. (SIX:BSLN) announces that the EU Committee for Medicinal Products for Human Use (CHMP) has indicated that the European Commission decision process on Zevtera™ (ceftobiprole) for the treatment of complicated skin and soft tissue infections (cSSTI) is delayed.**

Basilea received information that the CHMP will delay the European Commission decision process relating to the Marketing Authorization Application for Zevtera™ by Janssen-Cilag International NV, a Johnson&Johnson company, pending Good Clinical Practice (GCP) inspections by the European Medicines Agency (EMEA). As soon as a written confirmation from the EMEA is available Basilea will provide an update with more details. Basilea anticipates the inspections to be completed by the second half of this year.

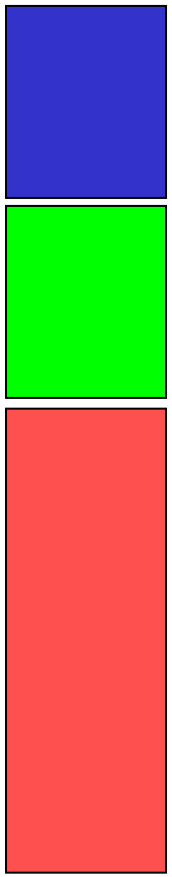
Oct 2009 ?

What happened with the investment ?

preclinique

post-rejection by FDA/EMA

Thus, what is the conclusion ?

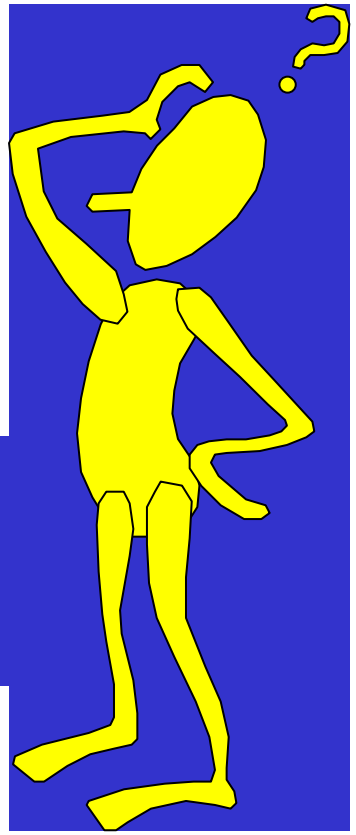


miscellaneous…

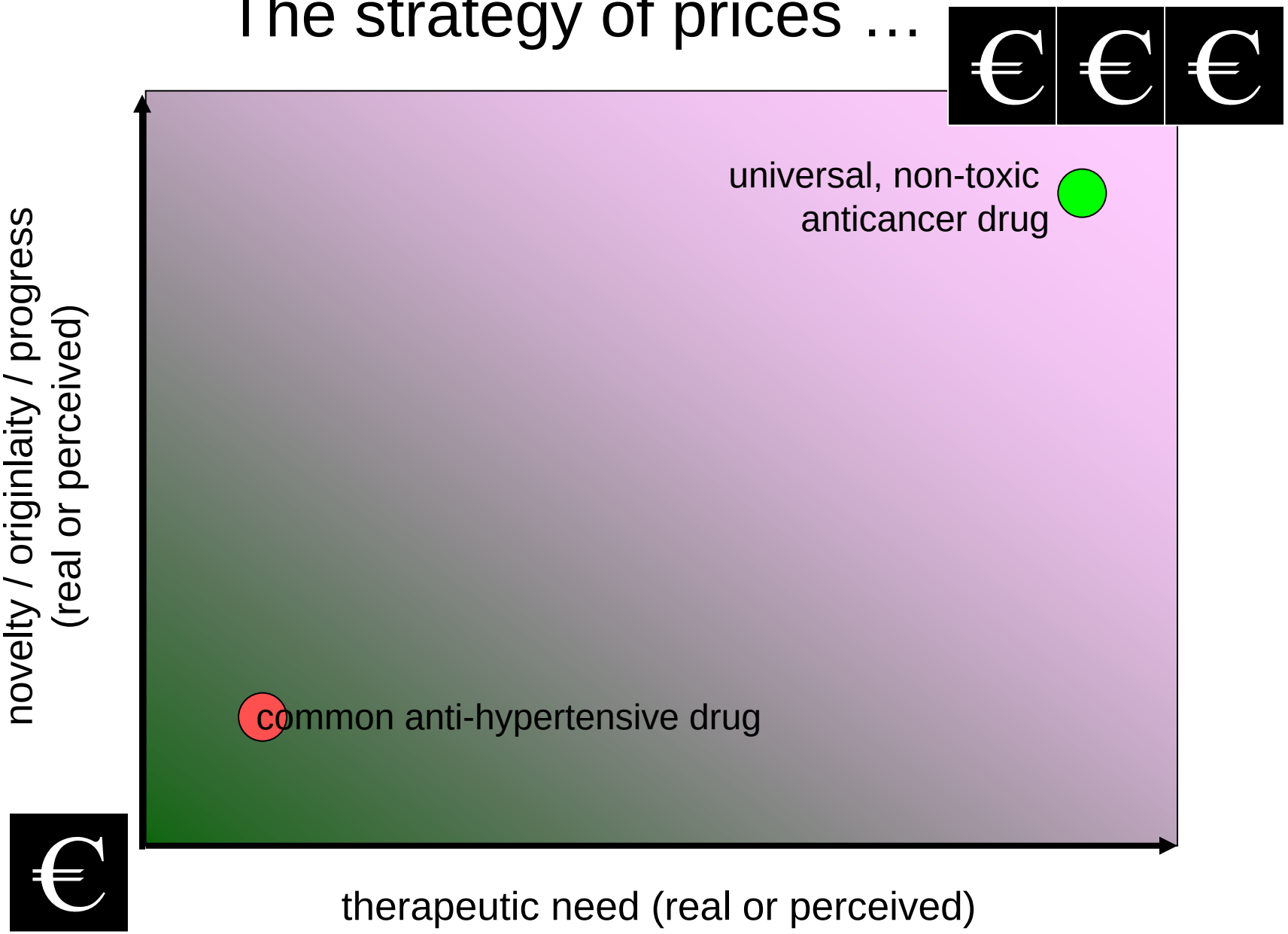
pharmacist

Industry

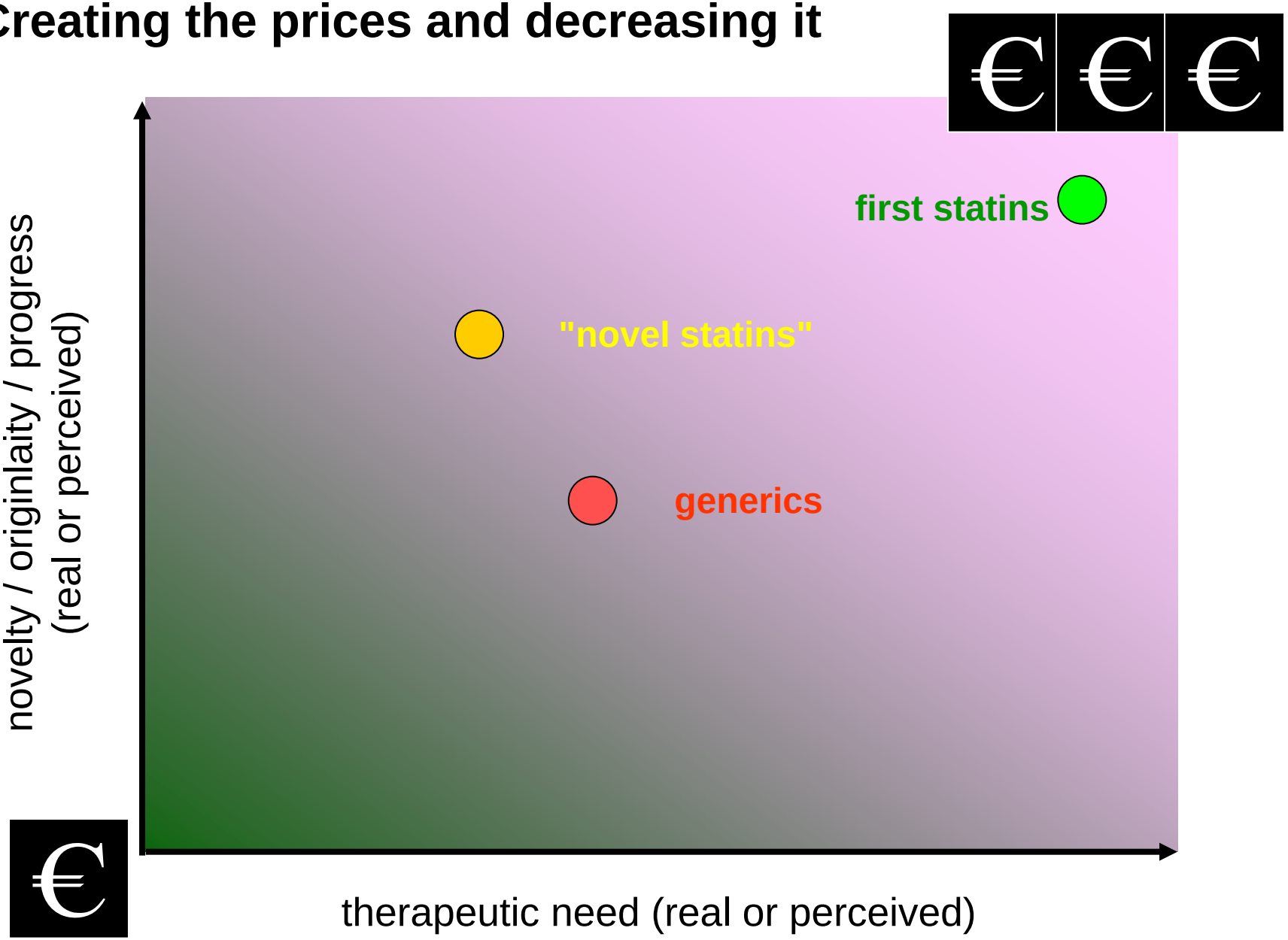
How high can the price be ?



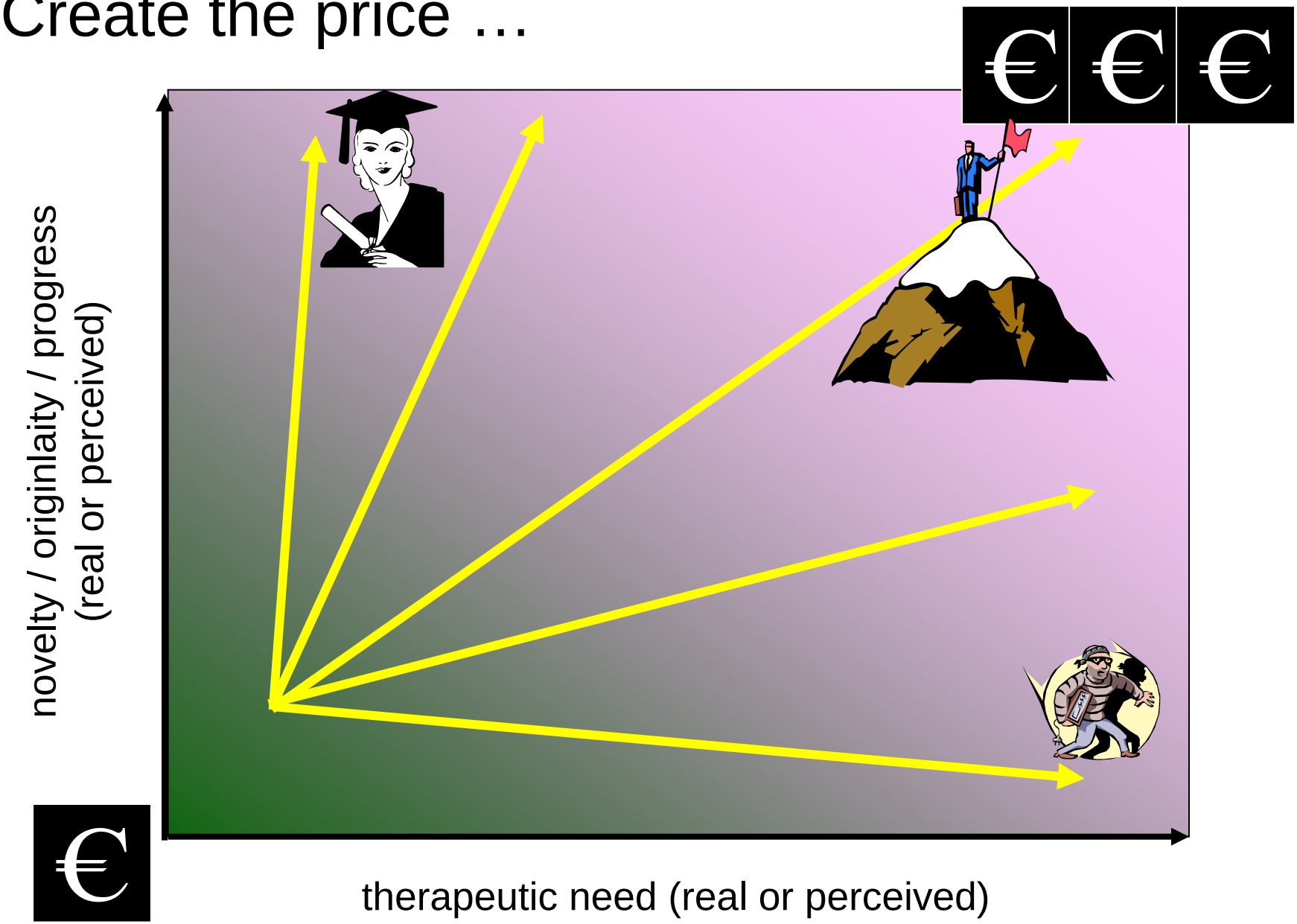
The strategy of prices …



Creating the prices and decreasing it



Create the price …



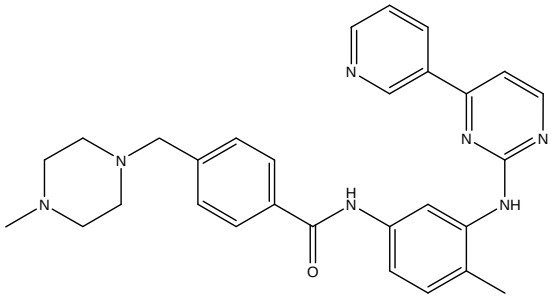
What are the Industry strategies …

1. Define the need (real or perceived)
2. Define the feasibility
3. Define the acceptable price
4. Define the level of effort to invest
5. Launch the program
6. STOP if points 1 through 3 are not met…
7. Prepare the marketing campaigns…

Last word: there is little relationship between the price of a drug and the price of the raw product

Glivec (Novartis Pharma)

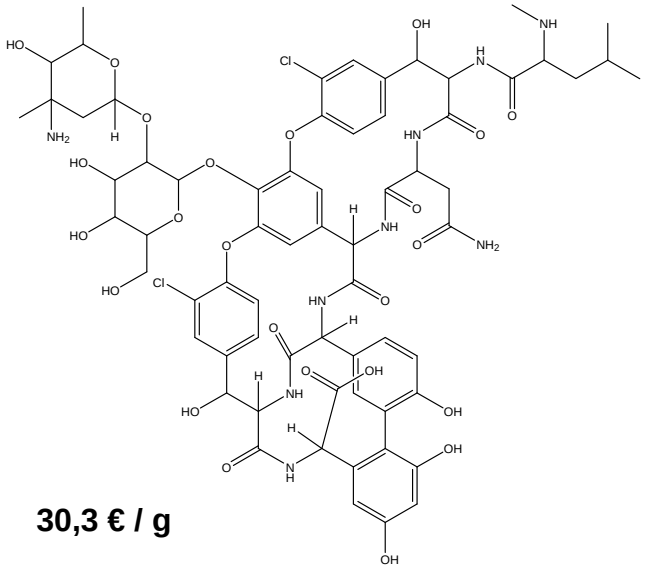
[imatinib]
caps.
€ 120 x 100 mg — Rx — € 2717,02
compr.
€ 30 x 400 mg — Rx — € 2660,08
(risque de rétention hydrique, myalgies, éruptions cutanées)



221 € / g

Vamysin (Teva)

[vancomycine]
flacon perf.
€ 1 x 500 mg poudre — Rx — € 18,67
€ 1 x 1 g poudre — Rx — € 30,37



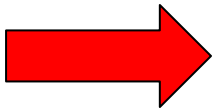
30,3 € / g

What happens if you refuse to pay the price ?

Ertapenem (as an example in Belgium)

- a new penem
- with once-daily dosing !!
- efficacious in abdominal infection
- proposed at 45 euros /day

The Belgian authorities refuse the price because you can have similar results with once daily dosing with ceftriaxone and twice daily oral metronidazole ... for a price of 26 euros/day



The company withdraws the product from Belgium

What can the authorities do ?

(Belgium as an example)

- impose price reductions for all drugs

  you may kill the Industry … by sending investors elsewhere

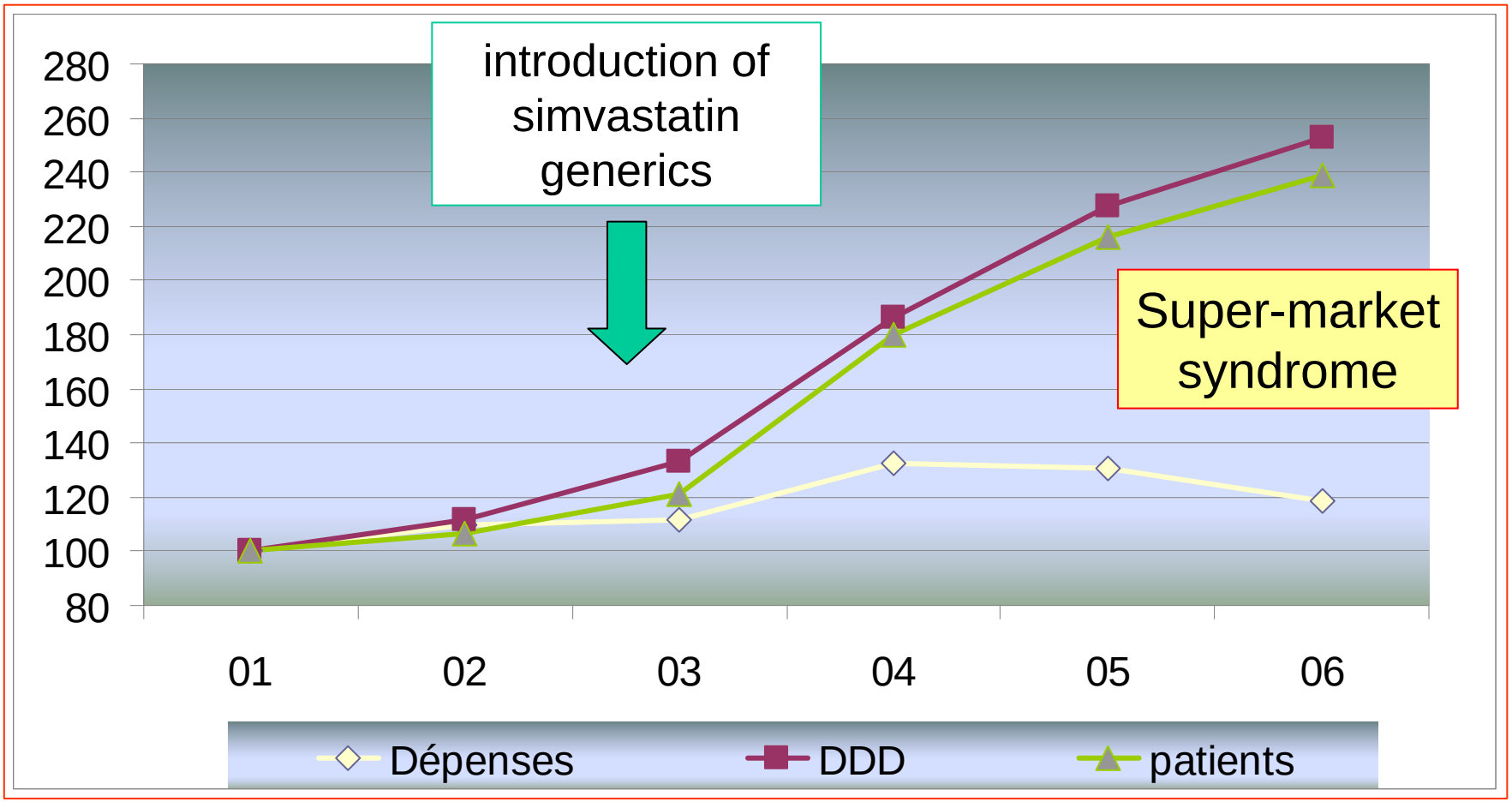
- force price decrease for "old" compounds

  you need one by one negociations

- promote generics

  beware of the upsurge problems !

An example of upsurge: statins in Belgium and introduction of generics



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Remboursement: commission fédérale

ROYAUME DE BELGIQUE

—

MINISTERE DES AFFAIRES SOCIALES,
DE LA SANTE PUBLIQUE ET
DE L'ENVIRONNEMENT

—

21 décembre 2001- Arrêté royal portant modification de l'arrêté royal du 3 juillet 1996 portant exécution de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994

ALBERT II, Roi des Belges,

A tous, présents et à venir, Salut.

NOUS AVONS ARRETE ET ARRETONS :

Article 1er. Dans le titre II, chapitre I, de l'arrêté royal du 3 juillet 1996 portant exécution de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994, est insérée une section XV, rédigée comme suit:

"Section XV – Commission de remboursement des médicaments"

KONINKRIJK BELGIE

—

MINISTERIE VAN SOCIALE ZAKEN,
VOLKSGEZONDHEID EN LEEFMILIEU

—

21 december 2001 - Koninklijk besluit tot wijziging van het koninklijk besluit van 3 juli 1996 tot uitvoering van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen, gecoördineerd op 14 juli 1994

ALBERT II, Koning der Belgen,

**Aan allen die nu zijn en hierna wezen zullen,
Onze Groet.**

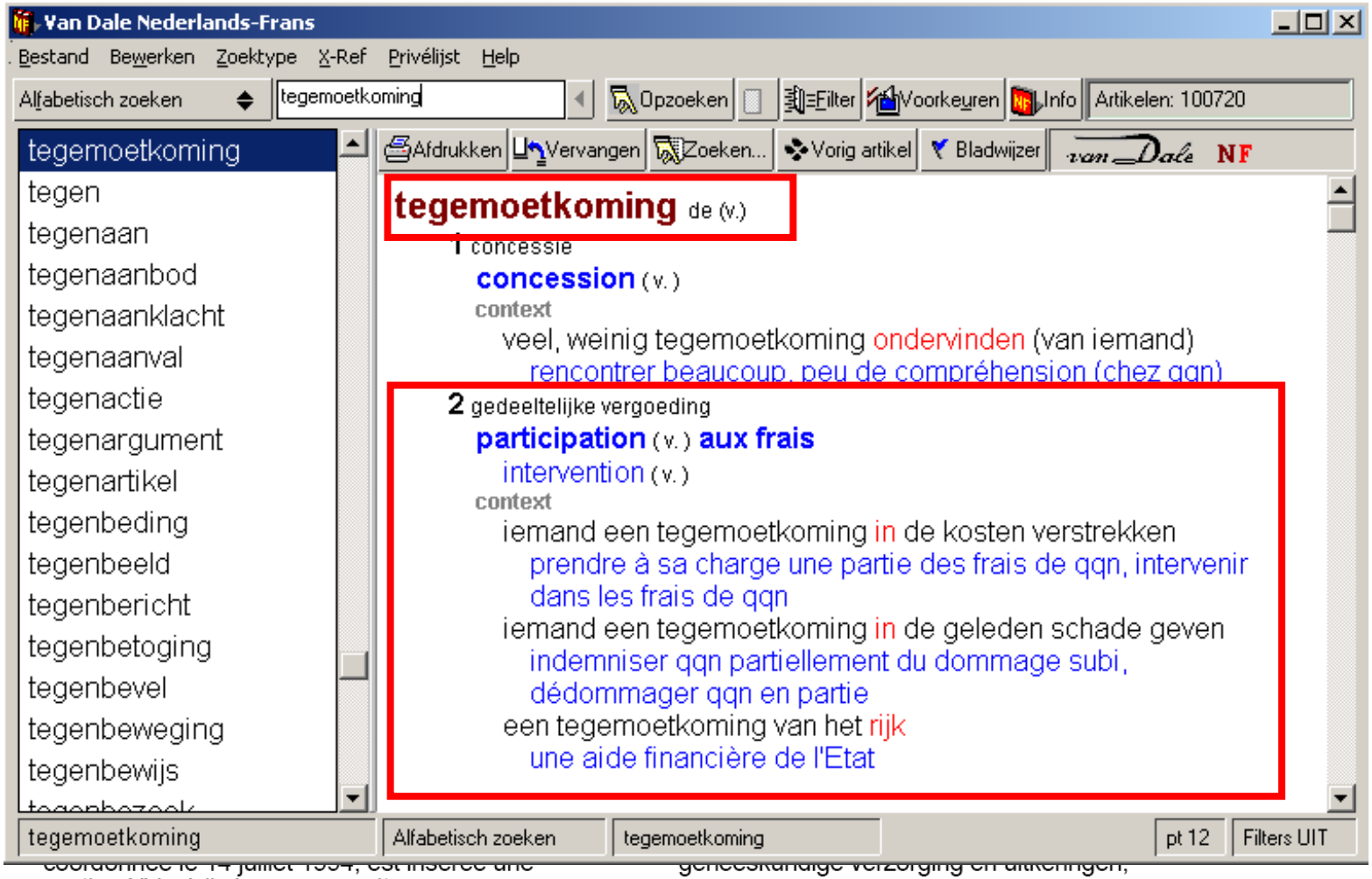
HEBBEN WIJ BESLOTEN EN BESLUITEN WIJ:

Artikel 1. In titel II, hoofdstuk I, van het koninklijk besluit van 3 juli 1996 tot uitvoering van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen, gecoördineerd op 14 juli 1994, wordt een afdeling XV ingevoegd, luidende:

"Afdeling XV – Commissie Tegemoetkoming Geneesmiddelen"

Ceci est plus précis que le terme français

Remboursement ... ou participation



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Tegemoetkoming

Ceci est plus précis que le terme français

COMMISSION de REMBOURSEMENT des MEDICAMENTS / COMMISSIE voor TEGEMOETKOMING van GENEESMIDDELEN

Missions

FORMULER DES PROPOSITIONS DE MODIFICATION DE LA LISTE DES SPECIALITES REMBOURSABLES

FOURNIR DES AVIS AU MINISTRE SUR DES ASPECTS DE LA POLITIQUE DES MEDICAMENTS

FORMULER DES PROPOSITIONS DE REGLES INTERPRETATIVES

COMMISSION de REMBOURSEMENT des MEDICAMENTS

COMPOSITION :

22 membres avec droit de vote

7 membres ⇨ “académiques” belges
8 membres ⇨ O.A.
3 membres ⇨ "corps" des pharmaciens
4 membres ⇨ "corps" des médecins

COMMISSION de REMBOURSEMENT des MEDICAMENTS

COMPOSITION:

6 membres avec voix consultative

2 membres ⇨ AGIM
1 membre ⇨ Ministère Affaires Sociales
1 membre ⇨ Ministère Santé Publique
1 membre ⇨ Ministère Aff. Economiques
1 membre ⇨ représentant le SCM de l' INAMI

PROCEDURE de MODIFICATION de la LISTE des SPECIALITES REMBOURSABLES

Principe de Base: Demande déposée par la firme commercialisant la spécialité

La décision porte toujours sur:

- **La base de remboursement**
- **Les conditions de remboursement**
- **La catégorie de remboursement**
- **Le “groupe” de remboursement**
- **Type de révision prévue**

La décision est prise après EVALUATION de :

- Valeur thérapeutique
- Prix et la Base de remboursement proposée
- L'importance de la spécialité dans la pratique médicale
- L'impact budgétaire pour l'AMI (en tenant compte de l'objectif budgétaire)
- Rapport entre le coût pour l'AMI et la valeur thérapeutique

La VALEUR THERAPEUTIQUE est exprimée en “Classe de plus value”

Classe 1: Plus value thérapeutique démontrée

Classe 2: Absence de plus value thérapeutique et pas de Classe 3

Classe 3: Enregistrement suivant art. 2, 8°, 2° en 3° tiret de l’AR du 3 juillet 1969
= génériques et copies

NB : Chaque classe thérapeutique a sa propre procédure, amorcée sur base de la classe annoncée par la firme

Eléments à fournir par le demandeur (1ère partie)

1. **Domaine d'application**
   - 1.1 Présentation de la pathologie
   - 1.2 Données épidémiologiques
   - 1.3 Modalités thérapeutiques actuelles
   - 1.4 Rationnel de développement de la spécialité
2. **Mécanisme d'action et place dans le groupe pharmaco- thérapeutique**
3. **Données cliniques et Expérience avec le produit**
4. **Prix (ex-usine) et statut de remboursement dans les autres pays européens à la date de la demande**
5. **Positionnement du produit par rapport aux thérapies existantes**

Eléments à fournir par le demandeur (suite)

6. Proposition relative au remboursement

6.1 Classe de plus-value

6.2 Conditions de remboursement

6.3 Base de remboursement

6.4 Catégorie de remboursement

6.5 Groupe de remboursement

7. Justification de la proposition

8. Données cliniques et pharmaco-économiques (classe 1)

9. **Estimation du volume annuel et de l'impact budgétaire pour les 3 premières années**

Classe 1: Etudes économico-sanitaires ...

class 1 will get a higher price i

"The drug itself has no side effects … but the number of health economists needed to prove its value may cause dizziness and nausea"

Classe 1: Etudes économico-sanitaires ...

Préciser clairement

- l'objectif défini
- la perspective choisie et la justification du choix
- la population-cible et le rationnel
- les alternatives thérapeutiques et la justification par rapport à la situation belge
- les sources utilisées pour démontrer l'utilité (*effectiveness*) (ex. étude clinique randomisée, données observationnelles)
- la méthodologie utilisée (ex. étude coût-efficacité, minimisation des coûts ,coût-utilité)
- ...

Classe 1: Etudes économico-sanitaires ...

- l'horizon temporel et sa justification
- la méthodologie de collecte des éléments coûts et conséquences
- la valorisation des coûts
- l'analyse de sensitivité
- le taux de discount utilisé
- la méthodologie statistique utilisée
- dans le cas d’utilisation d’une technique de modélisation, la structure du modèle et les hypothèses utilisées

A quoi arrivez-vous …

- Pas de remboursement …
- Remboursement en catégorie A, B, ou C ….
  (voir dia suivante)
  - sans conditions
    (tous les médecins peuvent prescrire à tous les patients)
  - avec conditions mais vérification à postériori
    (les médecins doivent conserver une preuve qu'ils ont suivi les recommandations)
  - avec conditions à priori
    (le patient doit avoir l'autorisation d'un service d'inspection)

- Refus de classe 1 pour cause de prix suivi d'accord avec l'INAMI

Catégories de remboursement (nationales)

Il existe **5 catégories de remboursement différentes** :

	Bénéficiaires ordinaires Non hospitalisés	**Bénéficiaires préférentiels Non hospitalisés**
Catégorie A	Remboursement à 100%, pas de ticket modérateur	Remboursement à 100%, pas de ticket modérateur
Catégorie B	Remboursement à 75%, 25% de ticket modérateur avec un maximum de € 10,20 of € 15,30 pour des grands conditionnements	Remboursement à 85%, 15% de ticket modérateur avec un maximum de € 6,80 ou € 10,20 pour des grands conditionnements
Catégorie C	Remboursement à 50%, 50% de ticket modérateur avec un maximum de € 17,00	Remboursement à 50%, 50% de ticket modérateur avec un maximum de € 10,20
Catégorie Cs	Remboursement à 40%, 60% de ticket modérateur sans maximum	Remboursement à 40%, 60% de ticket modérateur sans maximum
Catégorie Cx	Remboursement à 20%, 80% de ticket modérateur sans maximum	Remboursement à 20%, 80% de ticket modérateur sans maximum

Médicaments utiles…

Médicaments considérés comme essentiels

Contents

- **Principles of health economy**
- **How do you decide a price ?**
  - viewed from the Industry
  - viewed from the Social Security
  - what if they do not agree ?
- How do we reimburse drugs in Belgium ?
- **Pharmacoeconomy: a rational approach**

Pharmacoeconomy
or a rational (re)action to the price proposed by Industry

Pharmacoeconomy: definitions

- description and analysis of the costs of drug therapy to health care and society
- process of identifying, measuring, and comparing the costs, risks and benefits f programs, services, and therapies
- determining which alternative produce best health outcome for the resource invested

Outcomes, Pharmacoeconomy and Pharmaceutical care

- *Outcomes research* is about attempting to identify, measure and evaluate the results of health care services (in medical terms)…

- *Pharmacoeconononomic research* is about quantifing (in monetary terms) the value of pharmaceutical services assuming the outcomes are known and agreed upon.

- *Pharmaceutical care* is about the responsible provision of drug therapy for the purposes of achieving definite outcomes

What is a cost and what is a consequence ?

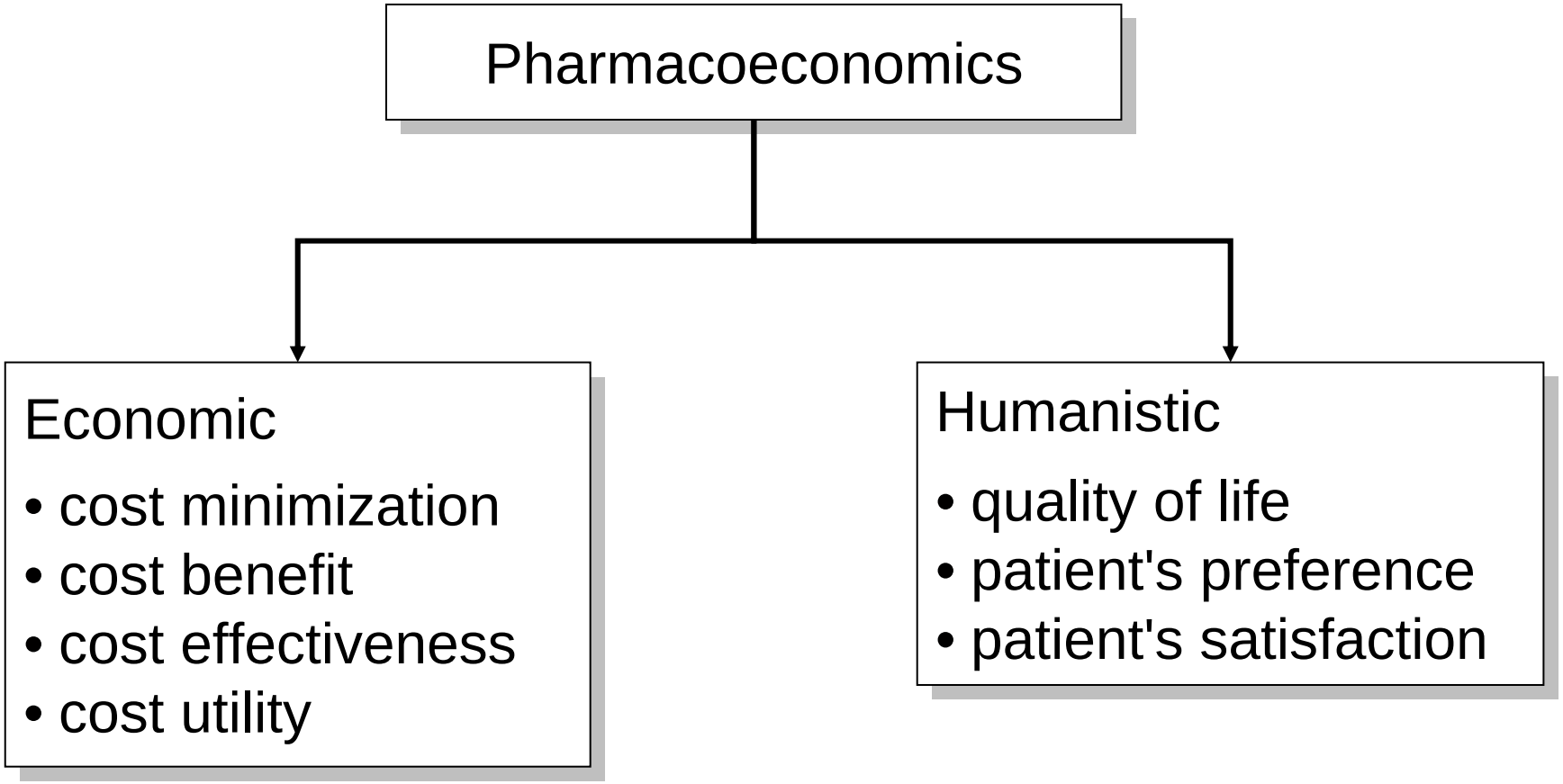
- **Cost** is defined as the value of the resource consumed by a program or a drug therapy of interest
- **Consequence** is defined as the effects, outputs, or outcomes of the program or of drug therapy

- Integration of consequences in the costs analysis differentiates pharmacoeconomic analysis from simple cost-containment strategies AND traditional drug-use evaluation approaches

Examples of Health Cost Categories

Cost category	Costs
Direct medical costs	• Drugs • Supplies • Laboratory tests • Health care professional time • Hospitalization
Direct non-medical costs	• Transportation • Food • Family care and Home aids
Indirect costs	• Lost wages (morbidity) • Definite lost income due to death (mortality)
Intangible costs	• Pain and suffering • Grief
Opportunity costs	• lost possibility to do something better • known resources lost because of choice made

What are the components of pharmacoeconomics



L. Sanchez, In Pharmacotherapy, DiPiro et al. eds, p.2, 2002

Economic evaluation methods

Method	Description	Application	Cost	Outcome unit
Cost-of-illness (COI)	costs of a disease in a defined population	baseline value to compare treatments vs. prevention	€€€	
Cost-minimization-analysis (CMA)	Finds the least expensive product	Use if outcomes ate the same	€€€	Spare money immediately with indentical outcomes
Cost-benefit-analysis (CBA)	Measures benefits in monetary units (net gain)	Use if outcomes or objectives of the treatments are not the same	€€€	€€€
Cost-effectiveness-analysis	Compares alternatives in therapeutic effects units	Compare drugs or programmes with different outcomes but the same unit of benefit	€€€	Natural units
Cost-utility-analysis (CUA)	Measures outcomes in utility rather than physical units	Compare life-extending programmes with different levels of side-effects	€€€	QUALY's
Quality-of-life-assessemnt (QOL)	Measures the physical, social, emotional aspects of the treatment	Examines areas not covered by laboratory of physiological measurements		QOL score

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Economic evaluation methods:
1. Cost-of-illness Analysis

- overall cost of a particular disease for a defined population ("burden of illness")
- measures the direct and indirect costs attributable to a specific disease

Useful for

- calculate the benefit of a prevention or a treatment strategy (vaccination, e.g.)

Not useful for

- comparing treatment alternatives…

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Economic evaluation methods:
2. Cost-Minimization Analysis

- determination of the least costly alternative when comparing 2 or more treatments with similar (assumed or demonstrated) equivalency in efficacy and safety
- all costs should be considered (drug acquisition, storage, preparation, administration, prevention measures to reach similar efficacy and safety)

Useful for

- comparing competing programs or drugs (and nothing more than the programs them-selves)

Not useful for

- comparing treatments with different efficacy or safety outcomes …

Economic evaluation methods

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Economic evaluation methods:
3. Cost-Benefit* Analysis

- identification, measurement, and comparison of the benefits and costs of a program or treatment alternative (both benefits and costs must be expressed in monetary units**)
- results are expressed as B/C ratio and treatment assessed as being of value if > 1
  Caveat: do not forget the absolute values of B and C …

Useful for

- comparing alternatives in which costs and benefits do not occur simultaneously
- comparing programs with different objectives (if translatable in monetary units)

Not useful for

- if benefits cannot be expressed in monetary units

*** benefit: a helpful or good effect, or something intended to help, but expressed here in monetary units**
**** in the year in which they will occur (future costs and benefits are subject to yearly increase or discount (5%)**

Economic evaluation methods

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Economic evaluation methods:
4. Cost-Effectiveness Analysis

- Comparison of programs or treatment alternatives with different safety and efficacy profiles BUT in which costs are expressed in monetary units and outcomes in physical, non-monetary units (lives saved, cases cured, increases in life expectancy, etc…)
- results are expressed as
  - average cost/effectiveness ratio (ACER)
  - incremental cost/effectiveness ratio (ICER)

  to inform about the costs of achieving a given medical outcome

Useful for

- balancing which treatment alternative provides the best outcome per unit of money spent (support to drug policy, formulary management, and individual patient decisions; largely used as such in Australia, New Zeland, and Canada)

Caveat/Limitations

- ignores patient's preferences and health-related quality of life

Economic evaluation methods

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Quality-of-life-assessemnt (QOL)	Measures the physical, social, emotional aspects of the treatment	Examines areas not covered by laboratory of physiological measurements		QOL score

Economic evaluation methods:
5. Cost-Utility Analysis

- Comparison of programs or treatment alternatives with different safety and efficacy profiles in which costs are still expressed in monetary units BUT outcomes are expressed in **patient-weighted utilities** rather than in physical units
- results are most often expressed as the cost of gaining one quality-adjusted life year (QUALY), combining morbidity and mortality data and using all monetary costs

Useful for

- comparing programs that
  - are life-extending while being associated with serious adverse effects (e.g., cancer chemotherapy)
  - produce reduction in morbidity rather than in mortality (e.g., AIDS in developed countries; osteo-arthritis)

Caveat/Limitations

- disagreements on measurements of utilities and quantification of patient's preferences

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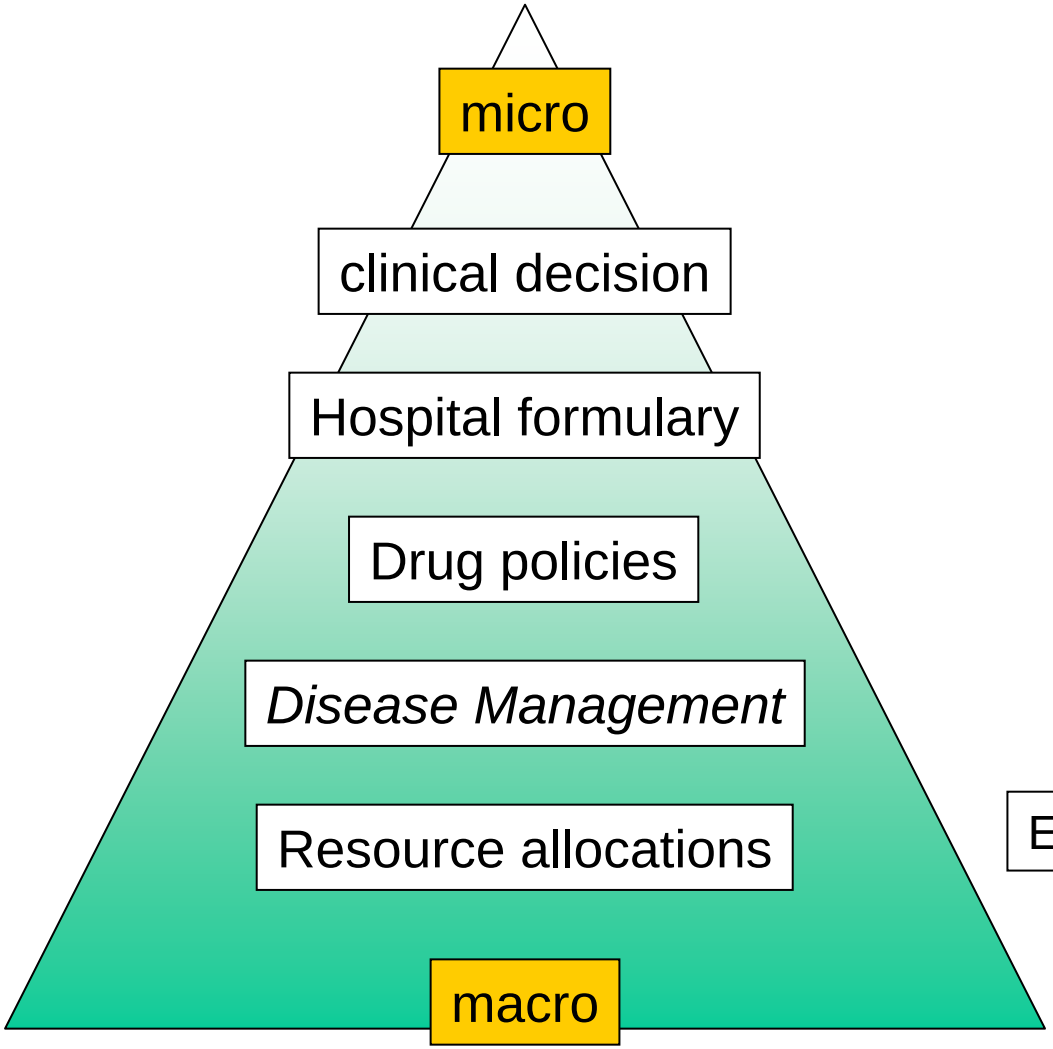
*** utility: fitness for some purpose or worth to some end; the usefulness of something, esp. in a practical way.**

Applications of Pharmacoeconomics

Method	Description	Application	Cost	Outcome unit
Cost-of-illness (COI)	costs of a disease in a defined population	One penumonia cost "so much" (used for "diagnostic-based price in hospitals)		
Cost-minimization-analysis (CMA)	Finds the least expensive product	will lead to systematically choosing the generic compound (or a branded compound with the same, low price)		
Cost-benefit-analysis (CBA)	Measures benefits in monetary units (net gain)	will suggest to use a drug that may be more expensive but which will cost less for its actual use (ex.: prefilled syringes)		
Cost-effectiveness-analysis	Compares alternatives in therapeutic effects units	will suggest to use a drug that is more expensive but for which the proven efficacy will be greater (ex.: novel anticancer drugs)		
Cost-utility-analysis (CUA)	Measures outcomes in utility rather than physical units	will compare two treatments (or a treatment alone vs. the teratment and an add-on) and choose what keeps the patient in a situation that is less costly (ex. moving out of the hospital)		
Quality-of-life-assessemnt (QOL)	Measures the physical, social, emotional aspects of the treatment	accepting to pay more for a drug that gives a better quality of life (this was the basis for the introduction of Cox-2 inhibitors for patients with oteoarthritis [less risk of side effects]).		

Decisions for pharmacoeconomic applications



physician / pharmacist

Institution / Hospital

Scientific Societies
Authorities

Economy "Decision Makers"

Strategies to incorporate Pharmacoeconomics into Pharmacotherapy

Strategy	Advantages	Disadvantages
Use published literature **Most often used by Public Health Agencies for setting guidelines**	• quick • inexpensive • subject to peer review • mostly from RCT • large variety of conditions	• RCT are rarely "real life" • lack of generalization • variations in quality • lack of applicability in a specific environment
Build an economical model **Most often used by Phamaceutical Industry**	• relatively quick • relatively inexpensive • yields country- or population specific results • bridges efficacy and effectiveness * • data collection is non-obtrusive	• highly dependent on assumptions • potential for researcher bias • often controversial • not easily accepted
Conduct a pharmacoeconomic evaluation **Should be used by Public Health Agencies**	• flexible and often comparative • yields country- or population specific results and can be tailored to "usual care" situations • can use multiple sources	• expensive • time consuming • difficult to control and randomize • potential for selection bias • size sample often insufficient

*** efficacy: the power to produce an effect; effectiveness: producing a decided, decisive, or desired effect**