Issues for discussion

- Medicines policies in Europe
- Possibilities for European collaboration and exchange of information
- Access to medicines (including ARVs) in new EU member states and EU neighbourhood
- R&D and Priority medicines project
- TRIPS
- Patient information and G10 initiatives
- …

Challenges for pharmaceutical policies in Europe

- Equitable access for patients to effective, safe and good quality medicines
- Enhancing appropriate use of medicines for better health outcomes
- Ensuring value for money
- Balance with industrial policy and EU single market objectives

- Underpinning values : equity, solidarity, access, quality, participation

Pharmaceutical policies and the EU

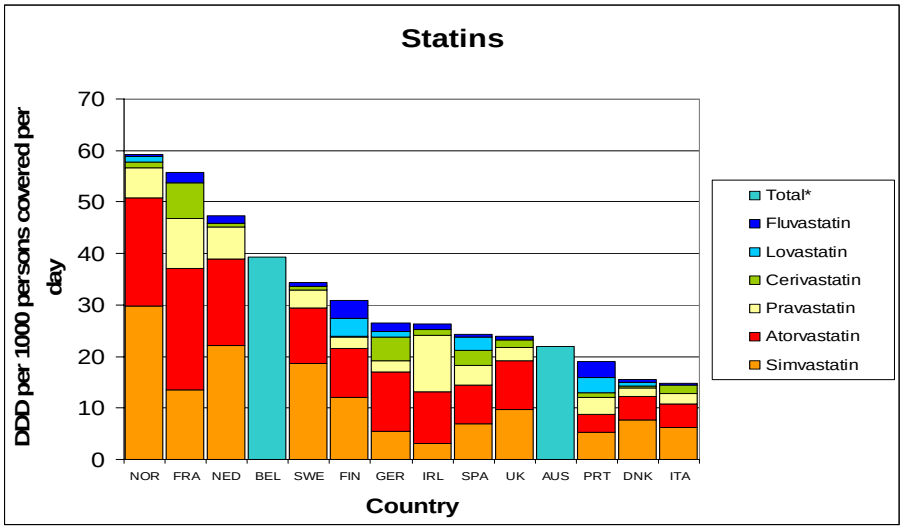
- EU regulatory framework and legislation (Review 2001-03)
- National responsibilities on pricing and reimbursement ("subsidiarity"), but
  - Transparency directive
  - Single market communication 1998
  - Public health communication 2000,2003
  - Portugal 2000, DG SANCO/ High Level committee Health,
  - G 10 group on provision and innovation
  - …

Recent political interests on medicines provision

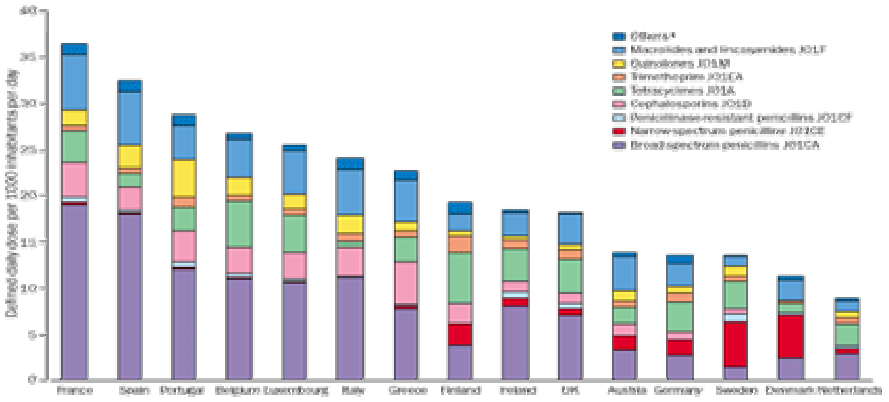
- Initiatives at European level : EU G10, DG SANCO, WHO
- Lisboa agenda, and Priority Medicines (public health based R&D-agenda)
- Quick access for patients
- Safety concerns
- Cost containment & maintaining equity
- Rationalizing resources

The use of Statins in Europe 2000

(EURO-MED-STAT data)



International differences in antibiotic consumption



Outpatient antibiotic sales in 1997 in the European Union

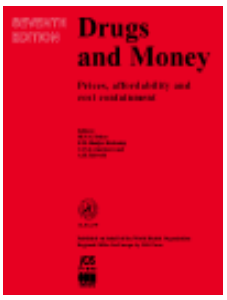
Cars et al Lancet 2001

Use of antidepressants in DDD's in Slovenia (SLO), in Sweden (S), in Norway (N), and in Denmark (DK)
and share of SSRI in relation to total use. (* = hospital use included) (Furst,Kocmur 2003)

Antidepressants	SLO 99	SLO 00	SWE 00	NOR 00*	DK 99
SSRI	6,4	8,9	36,0	29,9	21,3
Others	3,2	3,3	11,3	11,5	9,0
Total	9,6	12,2	47,3	41,4	30,3
Share SSRI (%)	67	73	76	72	70

Improving use of medicines and containing costs

- Education and information
- Managerial and administrative measures
- Financial measures



Mind the gap

- Public finance for increasing medicines expenditures
- Options for policy-makers
  - Increase health budgets : funding from …?
  - Limit range of drugs to be reimbursed : cave - medical need and quality treatment
  - Increase efficiency (regulation of prices, prescribing, use, …) : requires sustainable funding and programmes
  - Shift expenditures to patients :

    equity, solidarity …?

EU countries vis-à-vis USA : Medicines provision in the USA

- Reimbursement and pricing for drugs in the USA is complex due to a fragmented system with many varied payers (government and private).
- Negotiations for pricing and formulary placement are burdensome for industry because each of hundreds of payers must be dealt with individually.
- The MMA, which is making sweeping changes to Medicare by adding an outpatient prescription drug benefit, will have profound and diverse implications for drug benefit policies across the board as private insurers follow the government's lead on policies.

Increasing use of strategies to select medicines for public provision

- Positive list for reimbursement (NL, DK, Swe, …)
- Reference pricing, with generic or therapeutic groups (D, Ita, NL, Por, Rom, …)
- Differential reimbursement % (Fr, Bul, …)
- Economic evaluation of medicines (Fin, NL, Swe, UK,…)
- Promote use of generics (UK, DK, D, Fr, …)
- Co-payment mechanism (DK, N, Esp, …)
- Standard treatment guidelines (UK, DK, Esp, …)
- …

Selecting medicines for reimbursement

- Prof. Don Birkett (former chair of PBAC Australia)
  - “If you are going to buy a car, it makes sense to take a look at it first”

Evaluation criteria and medical decision making (1)

- For market entry :
  - quality, efficacy, safety
- For reimbursement
  - Medical need
  - Health gain and added therapeutic value
  - Cost-effectiveness
  - Budget impact
  - Equity considerations
  - …

Evaluation criteria and medical decision making (2)

- For medical practice
  - Evaluation by drug bulletins, professional associations on the “place in therapy” of a new medicine
  - Consistency between reimbursement indications and therapeutic guidelines ?
  - Reviews by national HTA commissions

Implications of cost-effectiveness analysis

- Health-based reason to justify a price premium for the proposed drug
- Relate extent and nature of health gain to justify price increase, including cost off-sets in health sector
- Common outcome measure (QALY, life year gained,..)
- Pristine value judgement

Economic evaluations

- Two main approaches
  - on a “cost-minimisation” basis
  - as “acceptably cost-effective”
- Two main “levers”
  - restrict to particular patients
  - price of the proposed drug

Reimbursement decision-making process : after the initial reimbursement decision …

- Post-listing reviews (at least annually)
  - prices
  - restrictions and listings
- Post-listing monitoring (at least annually)
  - usage (including predicted versus actual)
  - cost to reimbursement system
- Coordinate post-listing activities

Use of cost-effectiveness analysis in reimbursement in Europe

- CEA needs to relate to goals, values, and priorities of the health care systems
- Growing requirements and increasing need for resources
- RCTs do not provide all information needed
- How to deal with “point-decisions” vis-à-vis re-assessment of the evidence ?
- Major difficulties in implementation of CEA decisions in the health care environment ; “silo-budgeting” limits application
- Shift to conditional reimbursement with prospective trials : from paying for the medicine to buying an agreed upon therapeutic outcome

Paradigm shift

Patent = Innovation = Premium Price

- **No reimbursement for new products**
- **International price referencing & trade**
- **Therapeutic price referencing**
- **Tiered Formularies**
- **Additional market access hurdles**

- A new definition of innovation?
- Can industry maintain/achieve free pricing?
- Can reimbursement continue to be separate from registration?
- Will Outcomes Research/Health Technology Assessment be the solution?
- Will decisions converge towards a similar EU and US policies ?

Conclusion and challenge : promote efficiency, maintain equity

- Reaffirm goals and values of health systems and pharmaceutical policies : quality treatment at affordable cost, as needed
- Be selective – need and efficiency – on which medicines get reimbursed
- Enhance the use of generics
- Strengthen appropriate prescribing
- Increase efficiency and negotiation capacity of buyers, while protecting patients
- Shift to reference pricing schemes

International collaboration on evaluation of medicines

- Each health care system different
  - different levers
  - different solutions
- Problems tend to be the same
  - similar cost drivers
  - similar evidence
- Basis for common guidance, and exchange of information, and "lessons learned" ? !

Collaboration on Medicines policies and medicine assessment for reimbursement (1)

- EU G10 initiative
- WHO annual meetings with EU country policy makers and EU Commission
  - Proposal for permanent funded collaborative mechanism among countries, drawing in resources from national and international level (Vienna September 2005)
- DG SANCO Pharmaceuticals WG

Collaboration on Medicines policies and medicine assessment for reimbursement (2)

- DG SANCO : research projects
  - PPRI
  - EURO MED STAT

But

  - Sustainability ?
  - Who are the partners ?

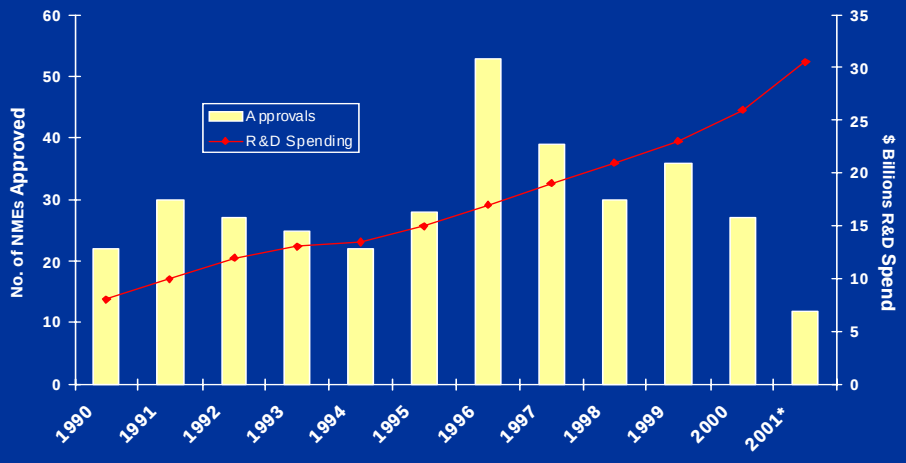
- MEDEV group : joint medicines assessment by Social Insurance Partners (A, B, D, Fr, NL, Su)

Reseach and development the Priority Medicines report 2004

Priority Medicines : Background

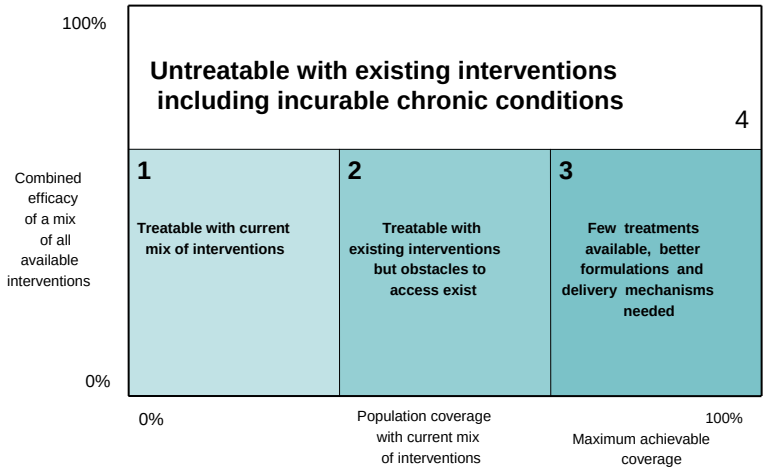
- R&D pipeline is drying up
- Pammoli, G-10 and EU Commission Reports
  - Europe was "lagging behind in its ability to generate, organize, and sustain innovation processes that are increasingly expensive and organizationally complex."
- The Lisbon and Barcelona European Councils: the "3% solution"
- Responses by EMEA : "Roadmap to 2010…"
- US FDA "Innovation or Stagnation…?"
- Framework Programmes
- European and Developing Countries Clinical Trials Partnership (EDCTP)

R&D Spending Increases But New Molecular Entity Approvals Have Not



**NME (new molecular entity) total is through August 22, 2001. R&D spend for 2000 and 2001 are estimates. Source: Washington Analysis, LLC and PhRMA*

Identifying gaps
(unmet therapeutic needs): public health perspective



Why are there Pharmaceutical gaps ?

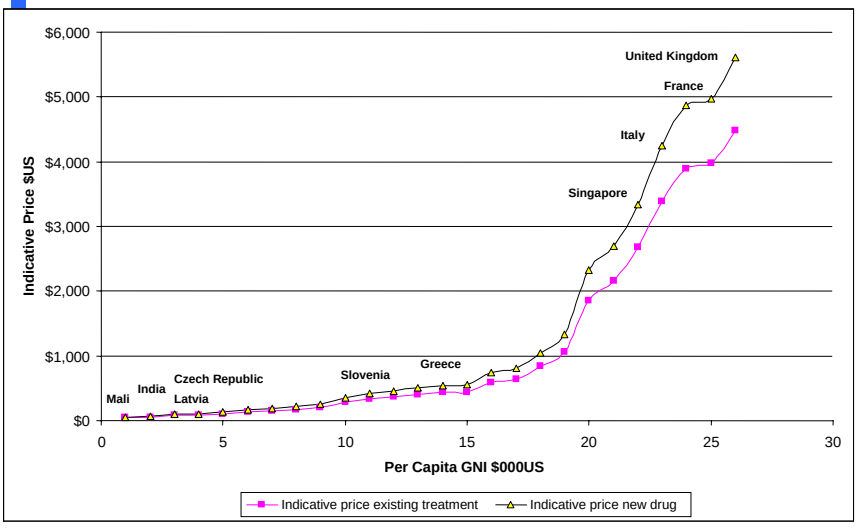
- The science is not there
- High burden disease, but no market
- Low burden of disease and no market

- Explore new ways of rewarding innovation

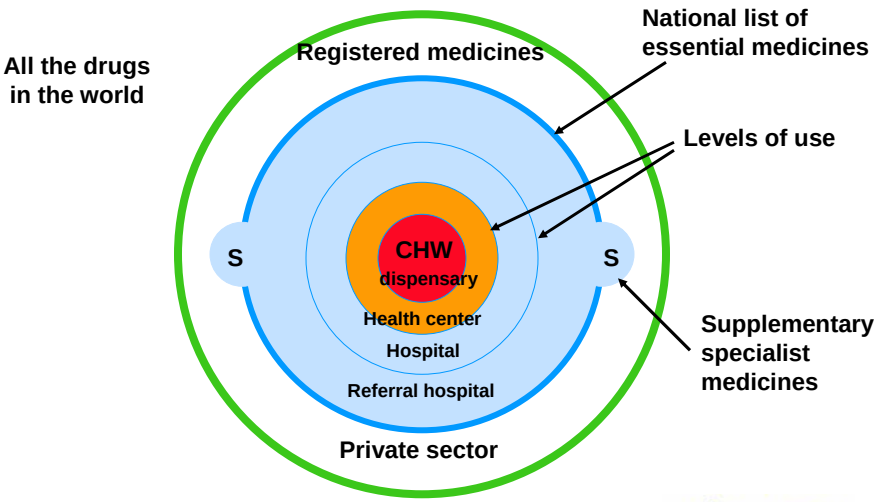
Conclusions: Preliminary List of Priority Diseases for which "priority medicines" are needed

- Infections due to antibacterial resistance
- Pandemic Influenza
- Smoking-related diseases/interventions for smoking cessation
- Cardiovascular disease
- Diabetes
- Cancer
- Acute stroke
- HIV and AIDS
- Tuberculosis
- Neglected diseases
- Malaria
- Alzheimer disease
- Osteoarthritis
- Chronic obstructive pulmonary disease
- Alcohol dependency, alcohol liver disease
- Depression in Children and the Elderly
- Postpartum hemorrhage

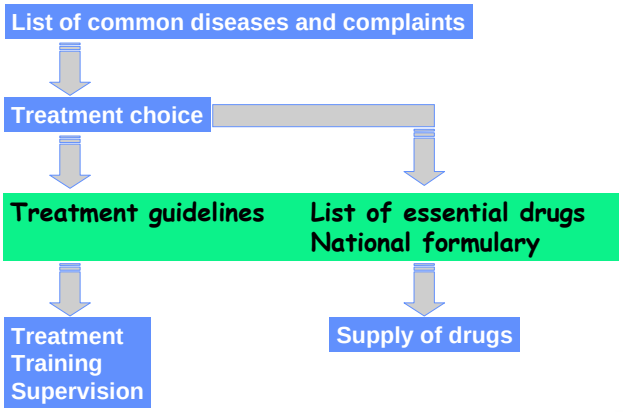
Differential Pricing : setting prices according ability to pay : Indicative prices in US$/annum of existing antidepressant treatment and a hypothetical new drug with greater efficacy



The Essential Medicines Target

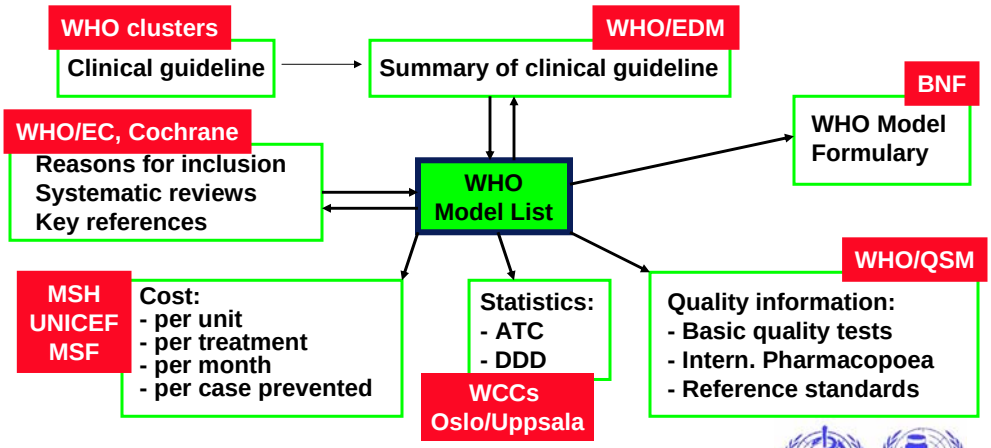


Relation between treatment guidelines and a list of essential medicines



The WHO Model List of Essential Medicines is a model process, model product and public health tool

The WHO Essential Medicines Library



The WHO Model List is a Model Process

- List linked to evidence-based treatment recommendations
- List follows WHO Recommended Process for Developing Clinical Practice Guidelines
  - * Guidelines development group with wide representation
  - * Transparent declarations of interest
  - * Systematic search and review of evidence
  - * Linked references, graded recommendations
  - * External review
- Two-yearly review
- Rapid dissemination, electronic access

Seven steps to get a new medicine on the WHO Model List of Essential Medicines

1. Identification of public-health need for a medicine
2. Development of the medicine; phase I - II - III trials
3. Regulatory approval in a number of countries
   > Effective and safe medicine on the market
4. More experience under different field circumstances; post-marketing surveillance
5. Price indication for public sector use
6. Review by WHO disease programme; define comparative effectiveness and safety in real-life situations, comparative cost-effectiveness and public health relevance
   > Medicine included in WHO treatment guideline
7. Submission to WHO Expert Committee on Essential Drugs
   > Medicine included in WHO Model List

Special considerations

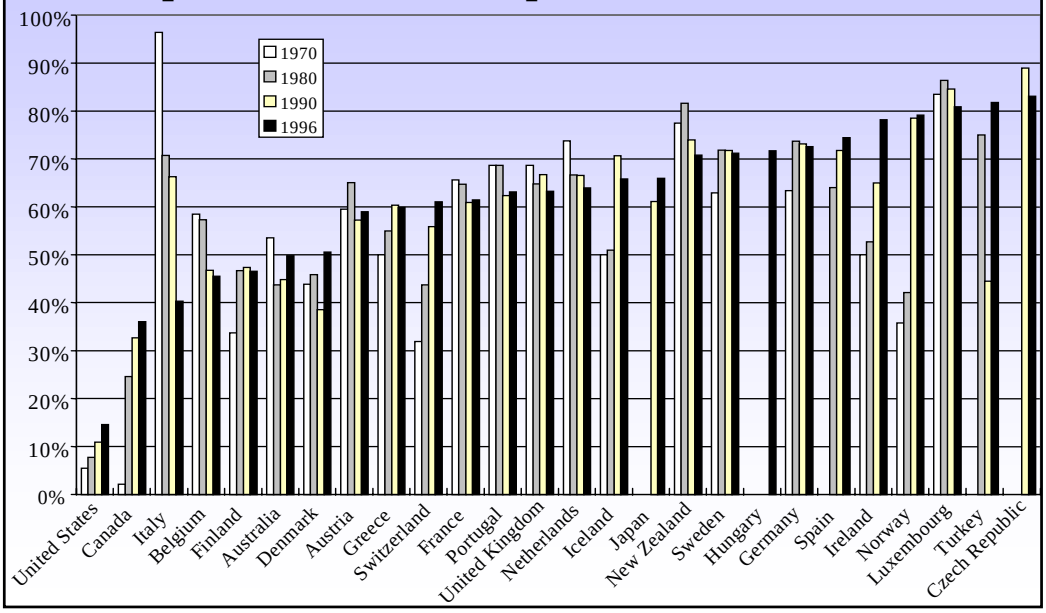
- The WHO model list of essential medicines is a “floor” not a “ceiling” : an instrument for prioritizing, not an instrument for categorically determining that other medicines are not needed
- Equity considerations : “medicines that satisfy the majority of the health needs for the majority of the population” while “every patient has a right to health care, independently on how common her/his condition is”
- In Europe reimbursement decisions need be made upon market entry, when therapeutic value may be difficult to assess

Challenges for pharmaceutical policies in Europe

- **Equitable access for patients to effective, safe and good quality medicines**
- **Enhancing appropriate use of medicines for better health outcomes**
- **Ensuring value for money**
- **Balance with industrial policy objectives**

- **Underpinning values : equity, solidarity, access, participation**

Public pharmaceutical expenditure within total pharmaceutical expenditure (OECD 2000)



The rising costs on medicines
Higher volumes and higher price component

- **Ageing**
- **Shift to new medicines in same therapeutic category**
- **“Life-style drugs”**
- **New drugs for diseases that could not be treated e.g. AIDS, MS**
- **Hospital - primary care shifts**

How much therapeutic innovation ?

- **Germany 1998 , 35 new substances (Cologne Univ.)**
  - **12 novel**
  - **9 improvements**
  - **14 me-too`s**
- **The Netherlands 1999 (Drug info bulletin), 18 new substances**
  - **1 possible important innovation (ribavirine/interferon with Hep. C)**
- **USA (NIHCM)**
  - **65% of drugs introduced in 1989-2000 were me-too`s, and 15 % significant improvements**

Is the WHO List relevant to developed countries?
1. New essential drugs are expensive

Common generic drugs are not always effective anymore

Antibiotics for gonorrhoea:	**50-90x price of penicillins**
Antimalarial drugs:	**chloroquine $0.10 per treatment** **Coartem® $4/pp developing country (40x)** **Malarone® $45 per treatment (450x)**
Antituberculosis:	**$15 for DOTS vs $300 for MDR (20x)**
Antiretrovirals:	**$300-600/yr; but 38 countries have <$2 p.person/year for medicines**

Is the WHO List relevant to developed countries?
2. all new drugs are more expensive

- **Canada: 55% of prescription cost increase of 93% over 1987-1993 was due to introduction of new drugs**
- **USA: Pharmaceuticals market grew with 16% in 1999 and 18% in 2000; volume rise in 2000 expected to be 5.5%**

  Growth due to * elderly population * new therapies * increased prescriptions by managed care * direct-to-consumer advertising

- **Australia: Annual increase in drug costs for Pharmaceutical Benefit Scheme could pay for two new teaching hospitals**

Is the WHO List relevant to developed countries?
3.Dilemma

- Public finance cannot keep up with increase in drug expenditures
- Increase in Out-of pocket payments affect access, and equity of the health system
- Options for policy-makers
  - Increase health budgets : funding from …?
  - Limit range of drugs to be reimbursed : cave medical need and quality treatment
  - Increase efficiency (prescribing, use, ...) : requires sustainable funding and programmes
  - Shift expenditures to patients : equity, solidarity …?

Is the WHO List relevant to developed countries?
4. What ways of selecting medicines ?

- Positive list for reimbursement (NL, DK, Swe, …)
- Reference pricing, with generic or therapeutic groups (D, Ita, NL, Por, Rom, …)
- Differential reimbursement % (Fr, Bul, …)
- Economic evaluation of medicines (Fin, NL, Swe, UK, …)
- Promote use of generics (UK, DK, D, Fr, …)
- Co-payment mechanism (DK, N, Esp, …)
- Standard treatment guidelines (UK, DK, Esp, …)
- …

The future of the essential medicines concept lies with health insurance schemes

Increased use of economic evaluations of medicines

- Clinical effectiveness / cost effectiveness / affordability
- Not for EU marketing authorisations, but for reimbursement and drug subsidies decisions
- (Formal) guidelines on cost effectiveness :
  - Australia and Canada
  - Baltic countries, Portugal, Netherlands, Finland, Norway, Sweden …
  - Poland, Slovakia, …
- Request for cost-effectiveness studies for NDA and/or reimbursement
  - Belgium, France, Italy, Sweden…
  - Czech rep., Hungary, Bulgaria, …
- Voluntary guideline (as prescribing guideline)
  - UK (evaluation based on studies presented)

Reimbursement decisions

- Objective data
  - Clinical evidence
  - Incremental health gain per patient
- National assessment on
  - Need
  - Cost-effectiveness
  - Price
  - Affordability / budget impact
  - Health care environment

Conclusion

- WHO Model List of Essential Medicines is one of the most important contributions to public health in the last quarter of the 20th century *Dr Halfdan Mahler*
- New medicines are often very expensive, medicine costs are rising. The process of selection of medicines for reimbursement purposes becomes more and more important
- The WHO Model List of Essential Medicines is both a model product and a model process; the concept is global
- Many developed countries use the essential medicines concept but give it a different name

Conclusion and challenge : promote efficiency, maintain equity

- Reaffirm goals and values of health systems and pharmaceutical policies : quality treatment at affordable cost, as needed

- Be selective – need and efficiency – on which medicines get reimbursed
- Enhance the use of generics
- Strengthen appropriate prescribing
- Increase efficiency and negotiation capacity of buyers, while protecting patients
- Shift to reference pricing schemes

http://www.who.int / medicines

http://www.euro.who.int/pharmaceuticals

Thank you