Technische Universität Berlin

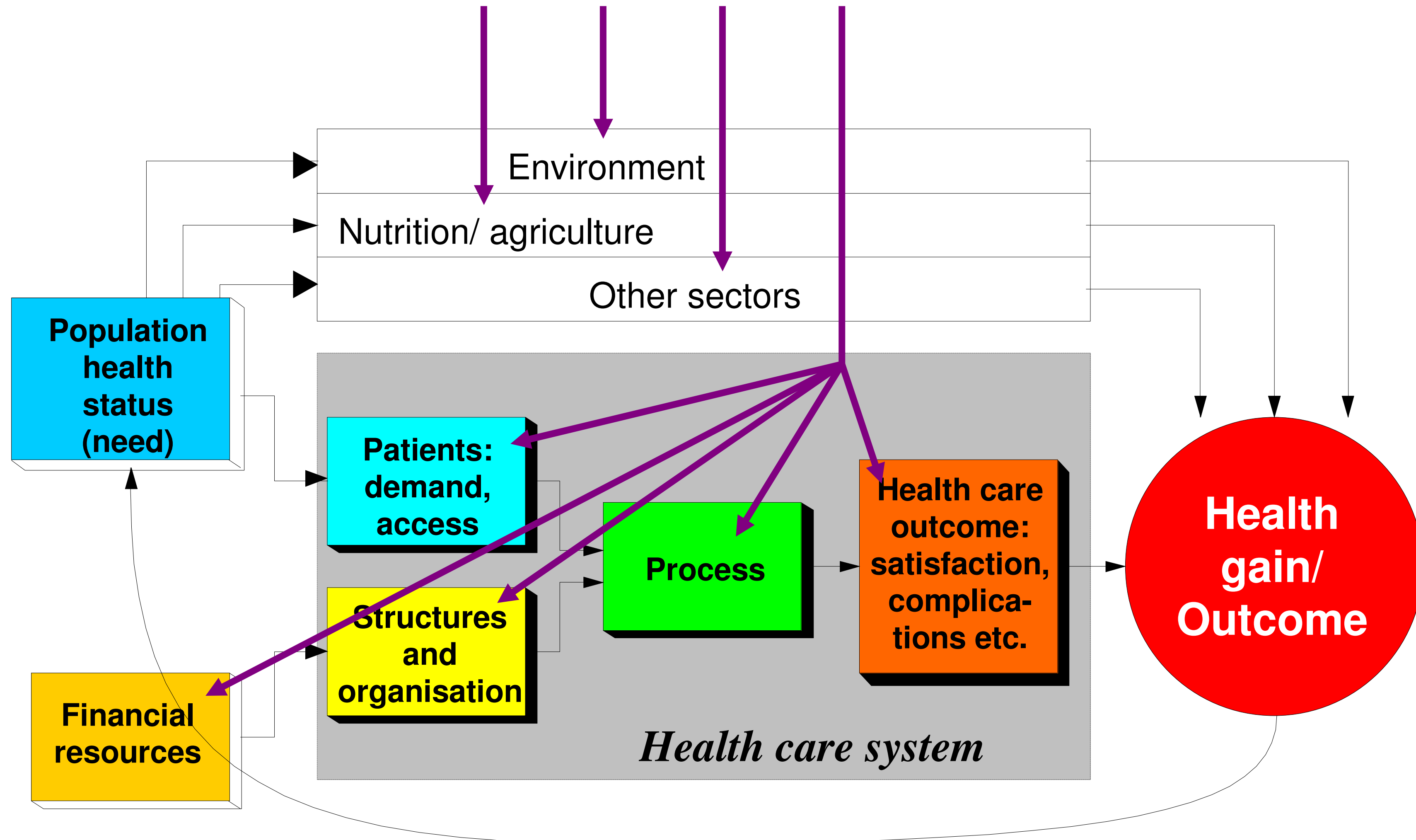
TEC, ECJ and OMC – an introduction into European health policy

Reinhard Busse, Prof. Dr. med. MPH FFPH

Professor of Health Care Management,
Technische Universität Berlin & Charité – Universitätsmedizin

Associate Research Director,
European Observatory on Health Systems and Policies

Health policy =
all measures to specifically protect/ improve health of population, i.e. prevention, cure (“health care“) and rehabilitation

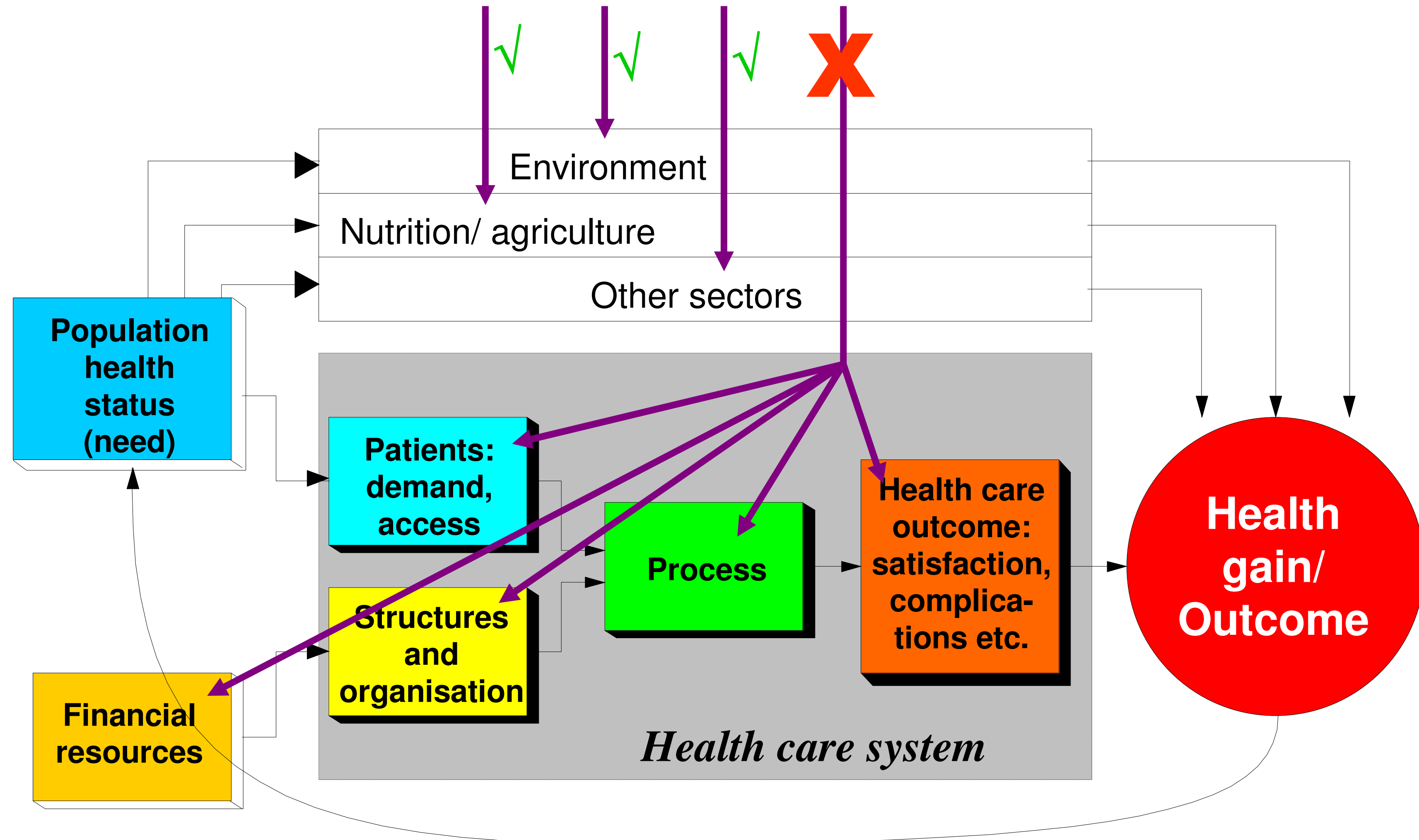

Health policy
Environment
Nutrition/ agriculture
Other sectors
Population health status (need)
Patients: demand, access
Structures and organisation
Financial resources
Process
Health care outcome: satisfaction, complica-tions etc.
Health gain/ Outcome
Health care system

Health (policy) in the EU Treaty

Article	Contents
3 par. 1 (p)	a contribution to the attainment of a high level of health protection
30	*restriction of free movement of goods in regard to health protection*
39 par. 3	*restriction of the free movement of workers in regard to public health*
46 par. 1	*restriction of right of establishment in regard to public health*
95 par. 3	attainment of a high level of health protection in regard to the approximation of laws
95 par. 6	*restriction of approximation of law in regard to public health*
95 par. 8	obligation to inform Commission in case of public health problems in field which has been a subject to prior harmonisation
137	health protection in the working environment
140	prevention of occupational accidents and diseases
152	**public health**
153	health protection as part of consumer protection
174 par. 1	health protection as part of environmental protection
186	*restriction of free movement of workers from associated overseas countries or territories in regard to health protection*

Article 152

- A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.
- Preventing human illness and diseases
  - fight against the major health scourges
  - promoting research into their causes, their transmission and their prevention
  - promoting research in health information and education
- "… excluding any harmonisation of the laws and regulations of the Member States. … Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care."


EU health policy
√
√
√
x
Environment
Nutrition/ agriculture
Other sectors
Population health status (need)
Patients: demand, access
Structures and organisation
Process
Health care outcome: satisfaction, complica- tions etc.
Health gain/ Outcome
Financial resources
Health care system

BUT:

- Article 152(5) only relates to Public Health measures
- Other EU policies do interfere with health systems, i.e. do not fully respect the responsibilities of the Member States:
  - occupational law (working times in hospitals!)
  - competition law (reference price setting)
  - Single European Market (internal market) – *especially as interpreted by the European Court of Justice*

Many difficulties for persons moving between EU Member States but EU guarantees freedom of persons, goods, services and capital

Country A

Benefit Package A
using
Service Taxonomy A
and
Fee Schedule A

Country B

Benefit Package B
using
Service Taxonomy B
and
Fee Schedule B

Solution: EU Regulation 1408/71

but increasingly this is seen as insufficient – as demonstrated by the cases in front of the European Court of Justice (ECJ)

Table 4: Instruments of Community policy

	Instrument				
	Regulation (No./Year)	Directive (Year/No.)	Decision	Recommen-dations	Other resolutions
Addressees	All citizens of the European Community	All Member States	All or individual Member States	All Member States (and in rare cases individual Member States)	EC institutions and the administration
Effective-ness	Generally and directly effective	Binding objectives, but free selection of the means	Individual or specific regulation of the individual case	Statement which is not binding, but which is politically authoritative	Internally effective
Content	Of an abstract and general nature	Skeleton legislation	Individual Member States, administrative acts, all Member States, skeleton legislation	Random	Autonomous resolutions, organisational acts

Situation 1: Person wants to live (with his/ her family) in Country A but to work in Country B.

Country A

Benefit Package A
using
Service Taxonomy A
and
Fee Schedule A

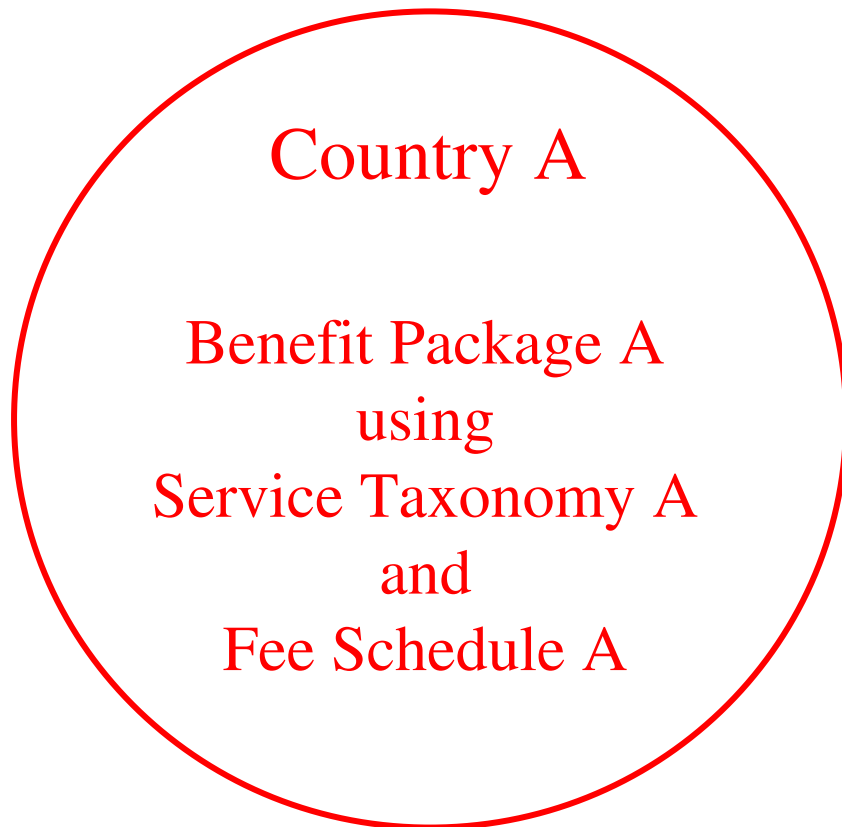
Country B

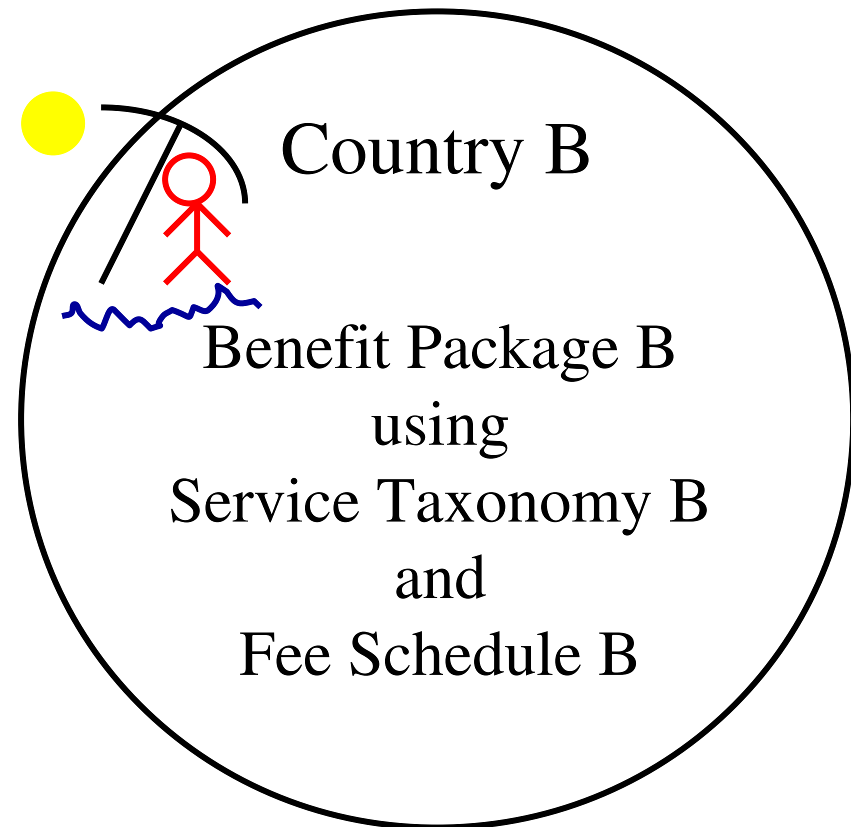
Benefit Package B
using
Service Taxonomy B
and
Fee Schedule B

Solution: Form E106

- Insurance in country of work place (Country B)
- Enables frontier workers and their dependents have choice to receive services in both countries (under national conditions)
- Patient presents E106 to provider in Country A (but insurance card in Country B)
- Sickness fund in B will reimburse providers in A based on fee schedule in Country A

Situation 2: Person from Country A happens to be in Country B (for tourism, business ...) when he/she falls ill and needs treatment.

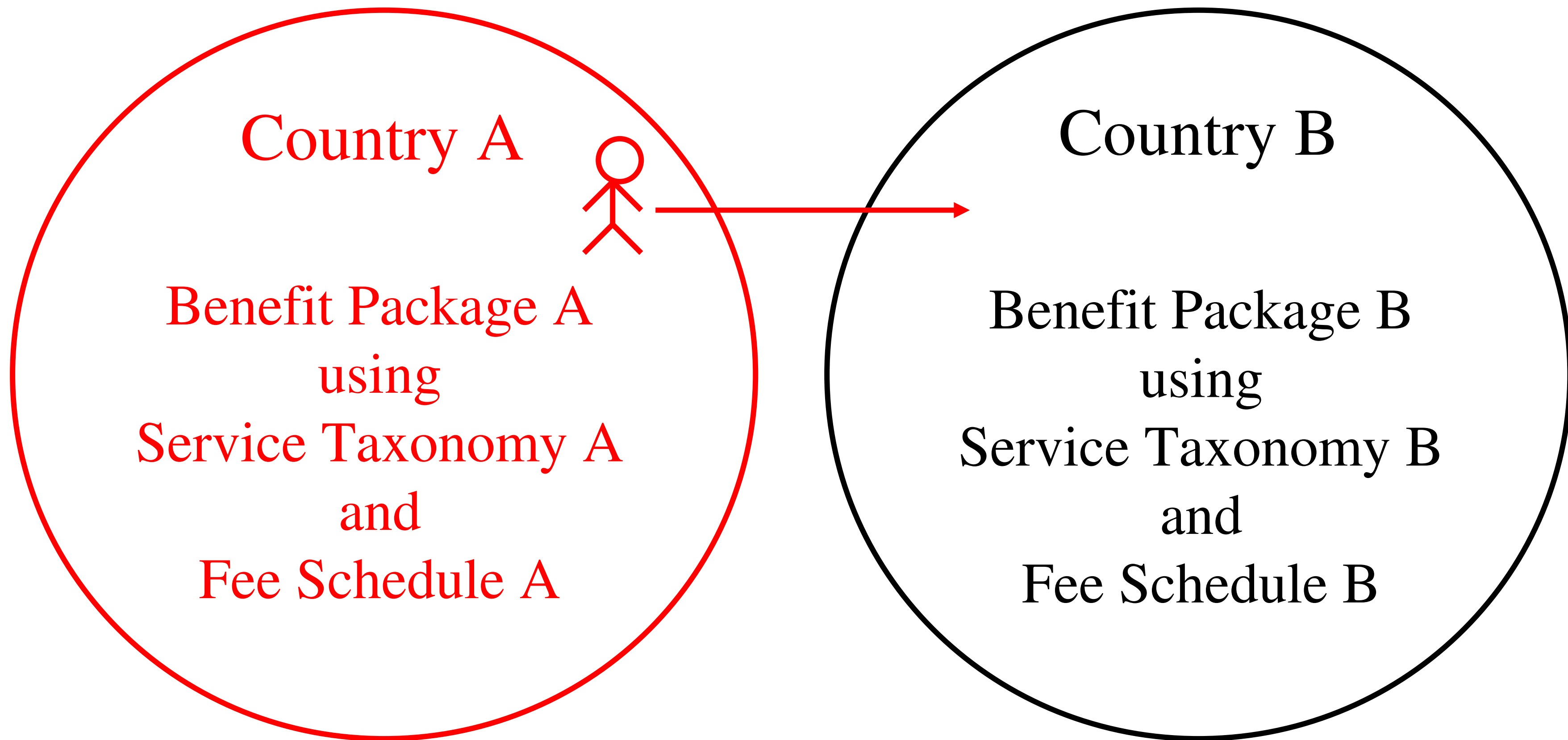




Solution: Form E111

- Patient takes E111 from his/her sickness fund in Country A and gives it to provider in Country B
- E111 entitles to benefits covered in Country B which are immediately necessary (copayments etc. as in Country B)
- Sickness fund in A will reimburse Country B (via national offices) – if there is no waiver agreement
- CAVE: Country B has to ensure that money reaches providers (e.g. Spain keeps money in Madrid!)

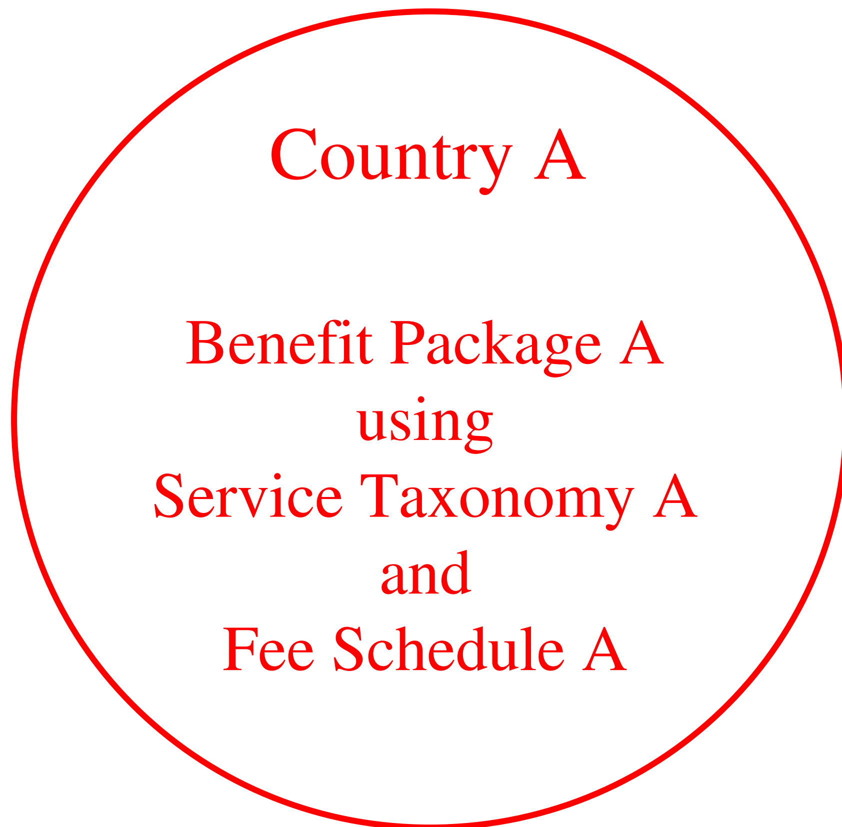
Situation 3: Patient from Country A needs go to Country B for treatment as it is not available in Country A.

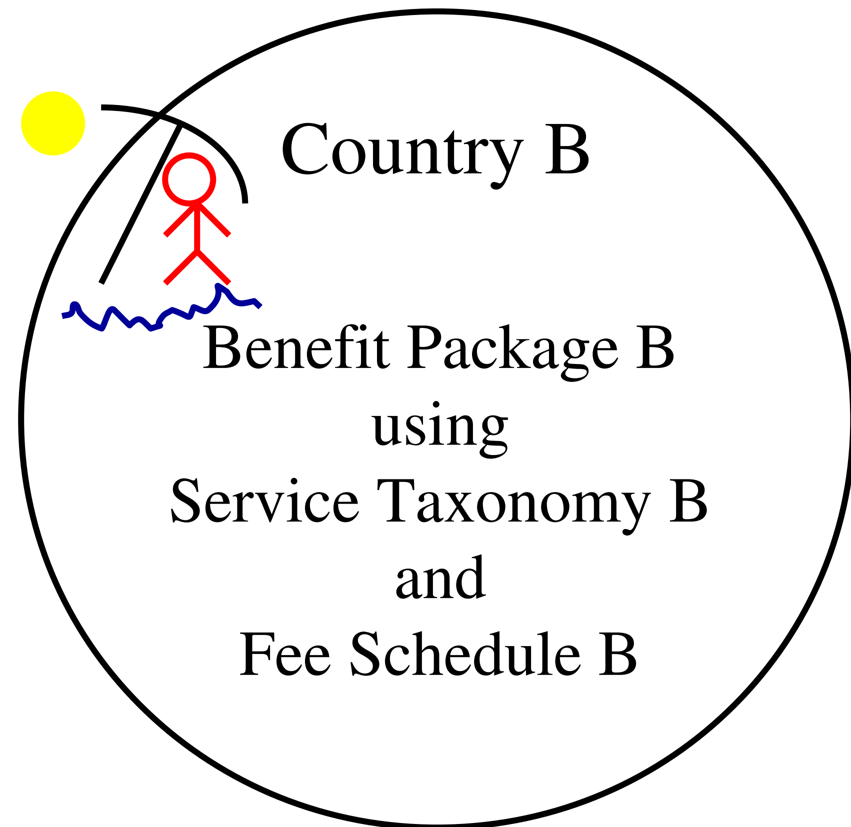


Solution: Form E112

- Patient applies to his/her sickness fund in Country A for authorization to get treatment in Country B
- E112 entitles to specific service in Country B (coverage and copayments as in Country A)
- Sickness fund in A will reimburse provider in Country B based on fee schedule in Country B

New Situation 1: Retired person from Country A wants to live in Country B (including receiving health care there).



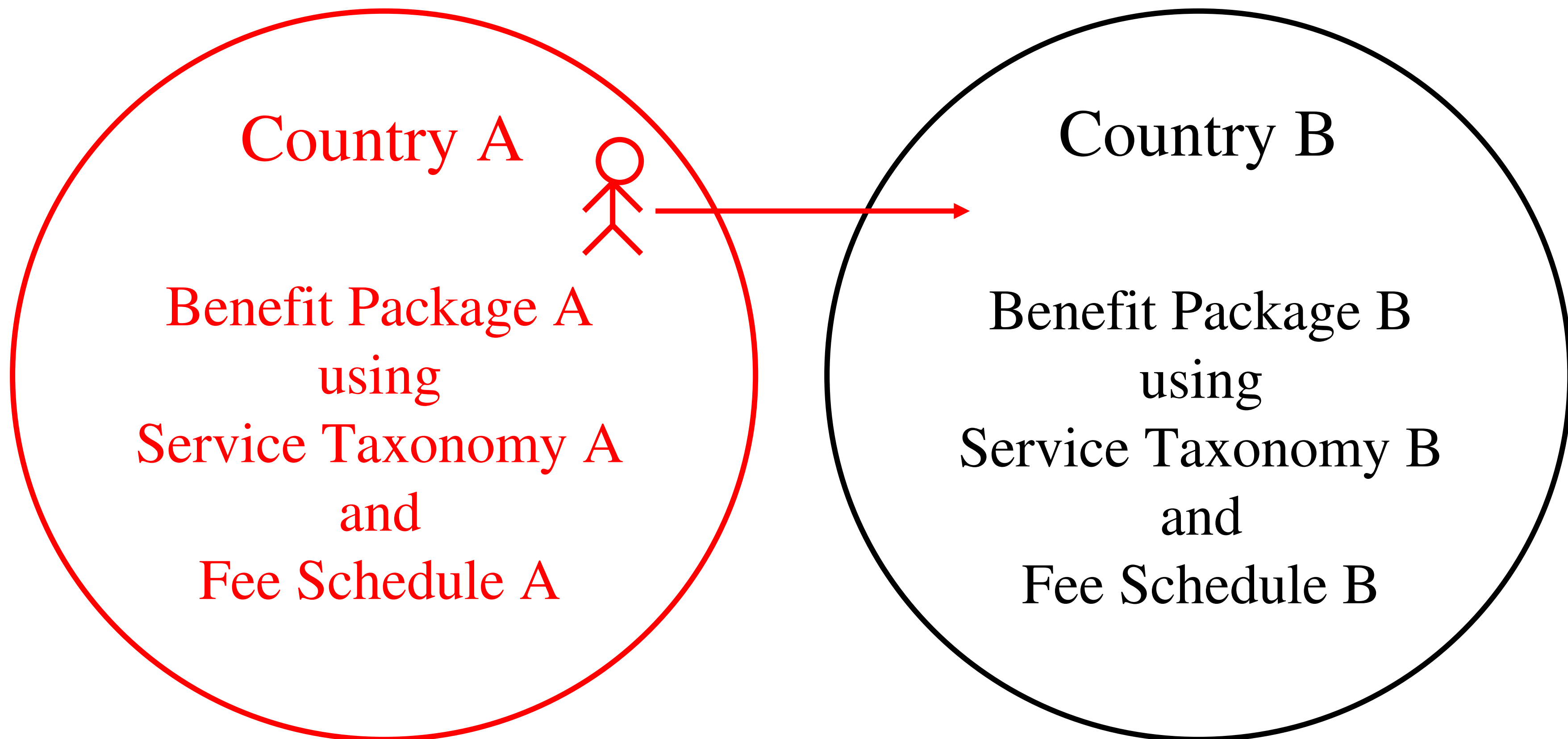


Solution: Extension of Form E111

- Retired people receive all medically necessary benefits covered in Country B (not only those immediately necessary; under Reg. 883/2004 extended to all persons)
- Sickness fund in A will reimburse country B (via national offices) – if there is no waiver agreement
- CAVE: Country B may be more generous than Country A (e.g. no co-payments for elderly in Spain)

European Health Insurance Card replaces E111

New situation 2: Patient from Country A *wants* go to Country B for treatment – to bypass waiting lists in A, because of perceived higher quality ...



Not included in Regulation 1408/71!

Two major developments:

1. Extension of network of contracted providers across borders, especially in EuRegios – patients are treated as if inside their country.
2. Patient-enforced flexibility – starting with Kohll and Decker going from Luxembourg to Belgium and Germany and claiming reimbursement afterwards which the sickness fund refused but the ECJ granted (at fee rate in Luxembourg).

Three rulings that changed our perception of the "Free Movement of Patients"

Decker (C-120/95)

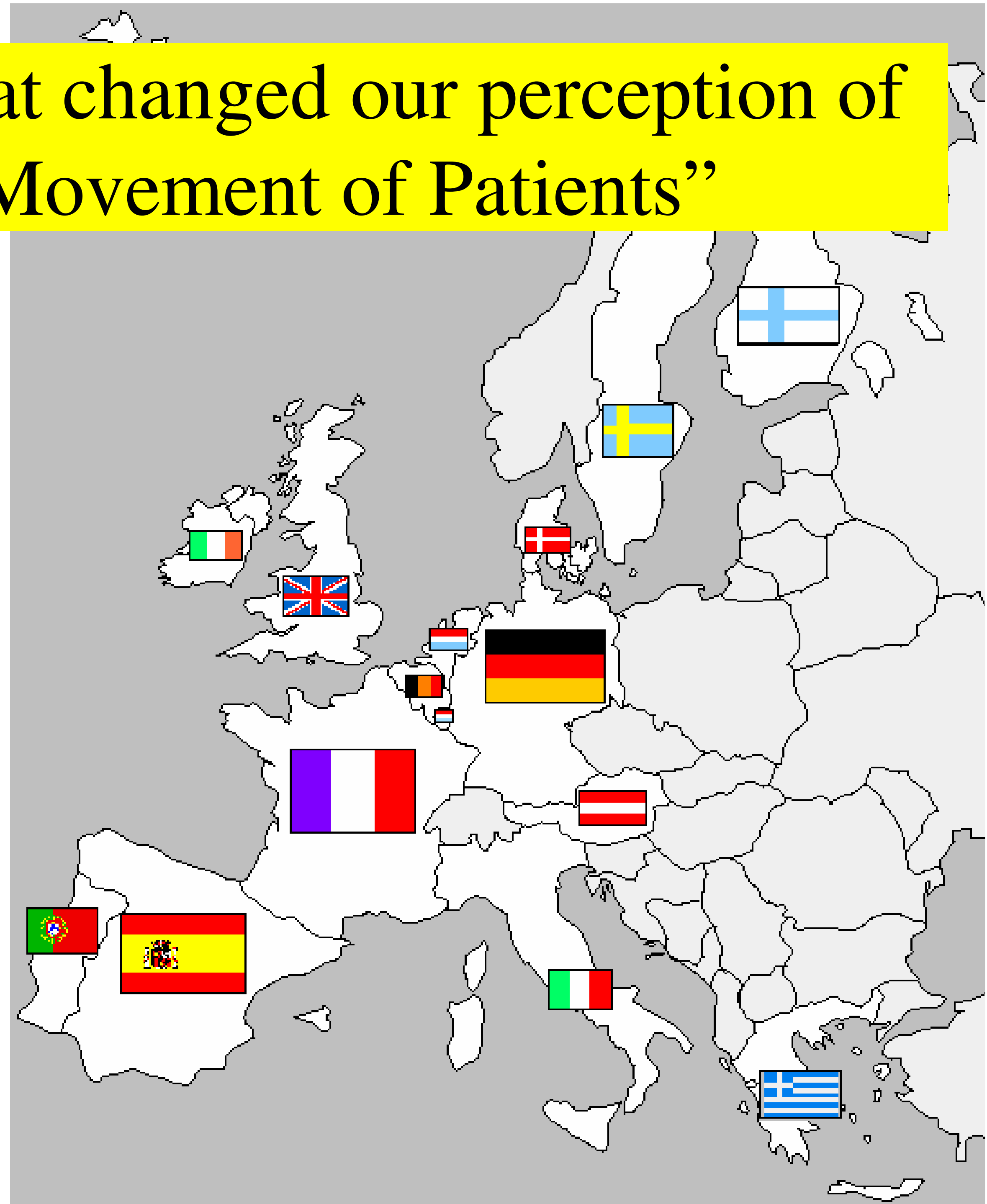
free movement of goods

Kohll (C-158/95)

free movement of services

Molenaar (C-160/96)

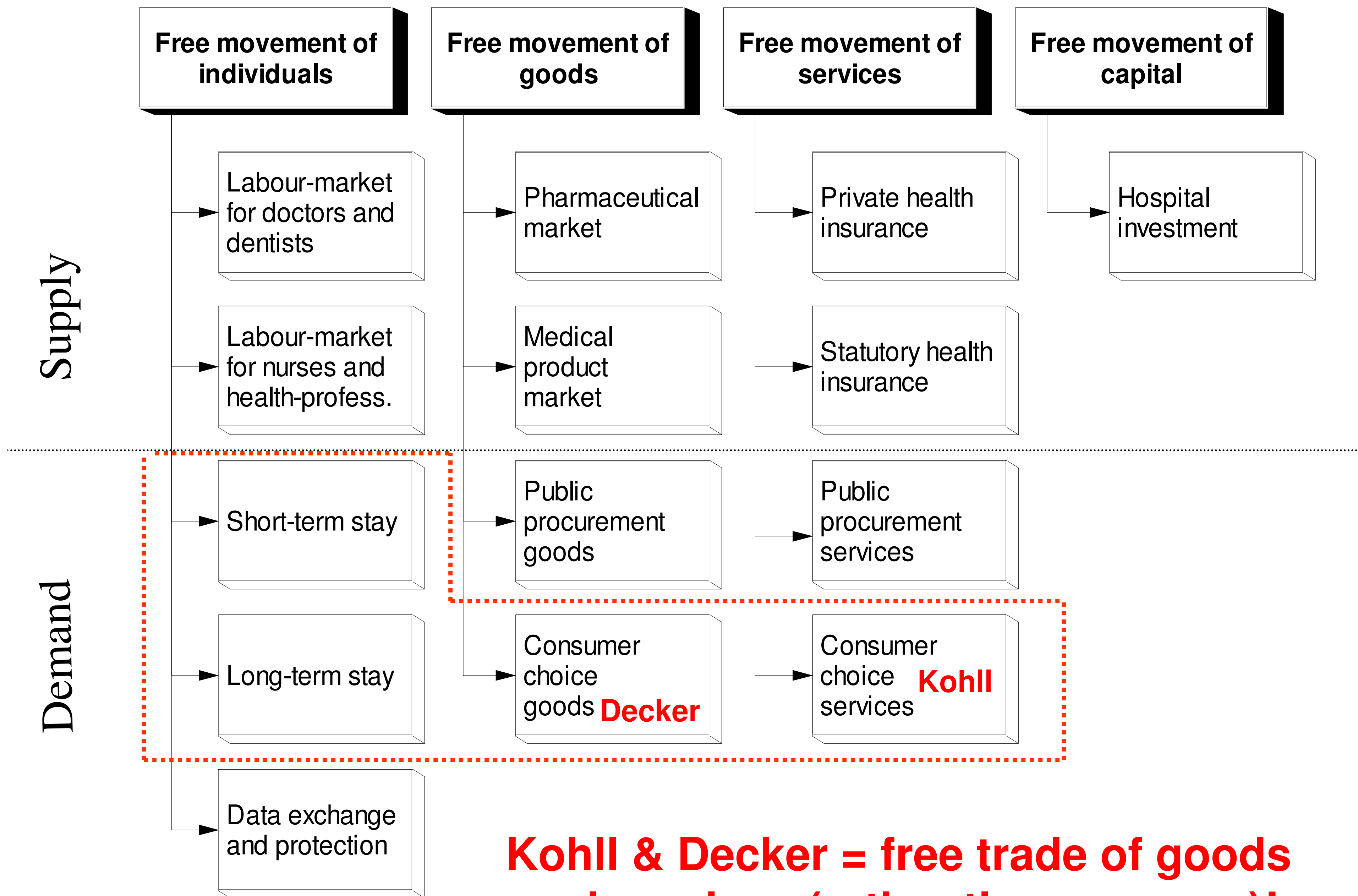
free movement of service-equivalent cash-benefits; definition of what belongs to health service and what not



Kohll ruling

"The fact that national **rules** fall **within the sphere of social security** **cannot exclude the application of Art. 59 and 60** of the Treaty. While Community law does not detract from the powers of the Member States to organise their social security systems, they must nevertheless comply with Community law when exercising those powers, i.e. the fact that a national measure may be consistent with a provision of secondary legislation, in this case Art. 22 of **Regulation No 1408/71**, does not have the effect of removing that measure from the scope of the provisions of the Treaty."

Legal source	Articles, paragraphs or rulings of relevance
TEC	• Art. 23 (ex-Art. 9), Free movement of goods • Art. 28-30 (ex-Art. 30, 34, 36), Prohibition of quantitative restrictions between Member States • Art. 49-50 (ex-Art. 59-60), Free movement of services
Secondary legislation	• EEC 1408/71 (Art. 13, 19, 22), modified/ extended by EEC 1390/81 [self-employed], 2791/81 [modification following the Pierik cases] and 1606/98 [civil servants] • EEC 574/72
ECJ	• C-117/77 & C-182/78 Pierik I & II • C-120/95 Decker & C-158/96 Kohll • other cases currently pending at the ECJ: C-368/98 Vanbraekel; C-385/99-1 Müller-Fauré/ van Riet; C-157/99 Geraets-Smits/ Peerbooms



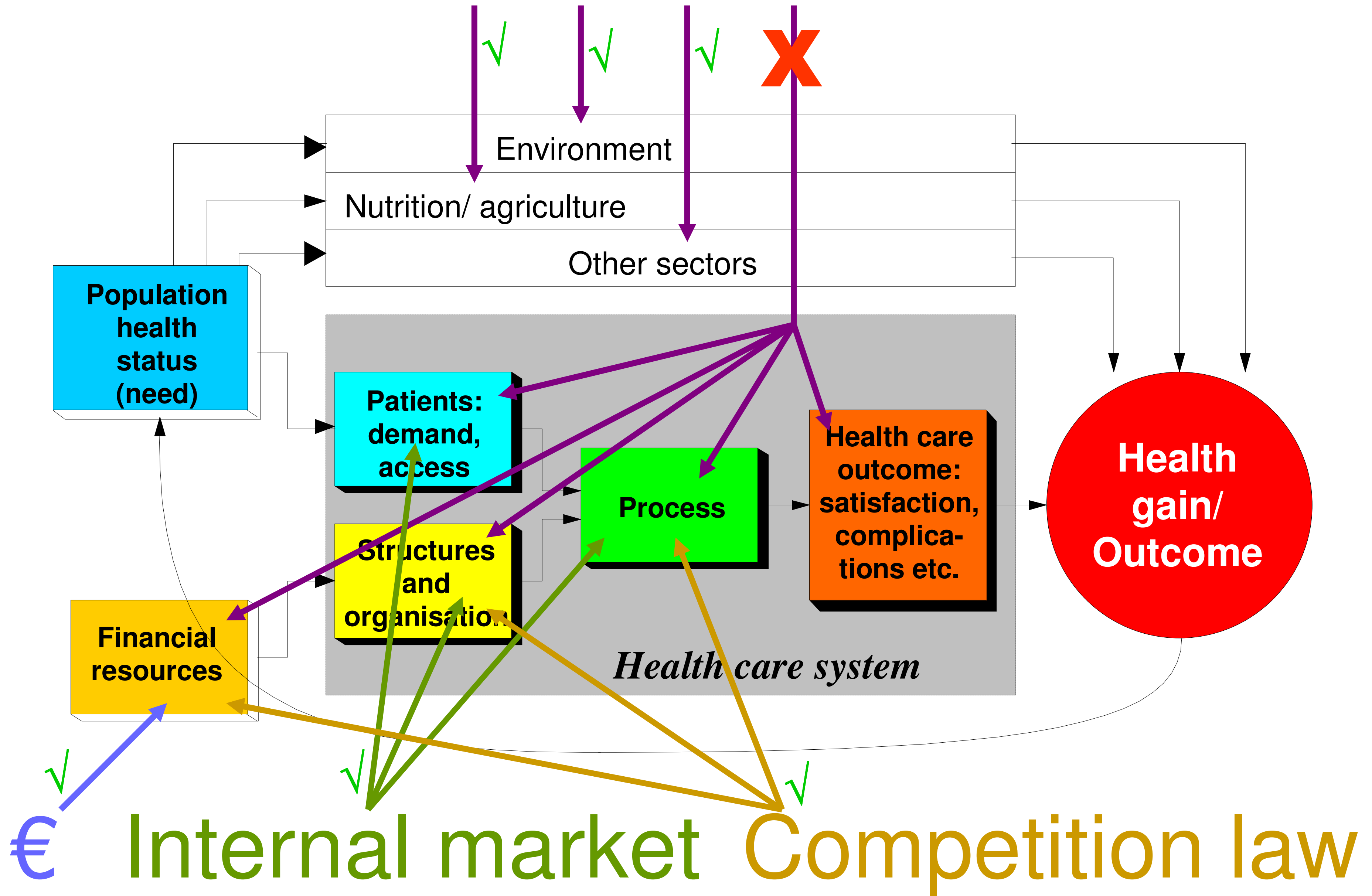
Kohll & Decker = free trade of goods and services (rather than persons)!

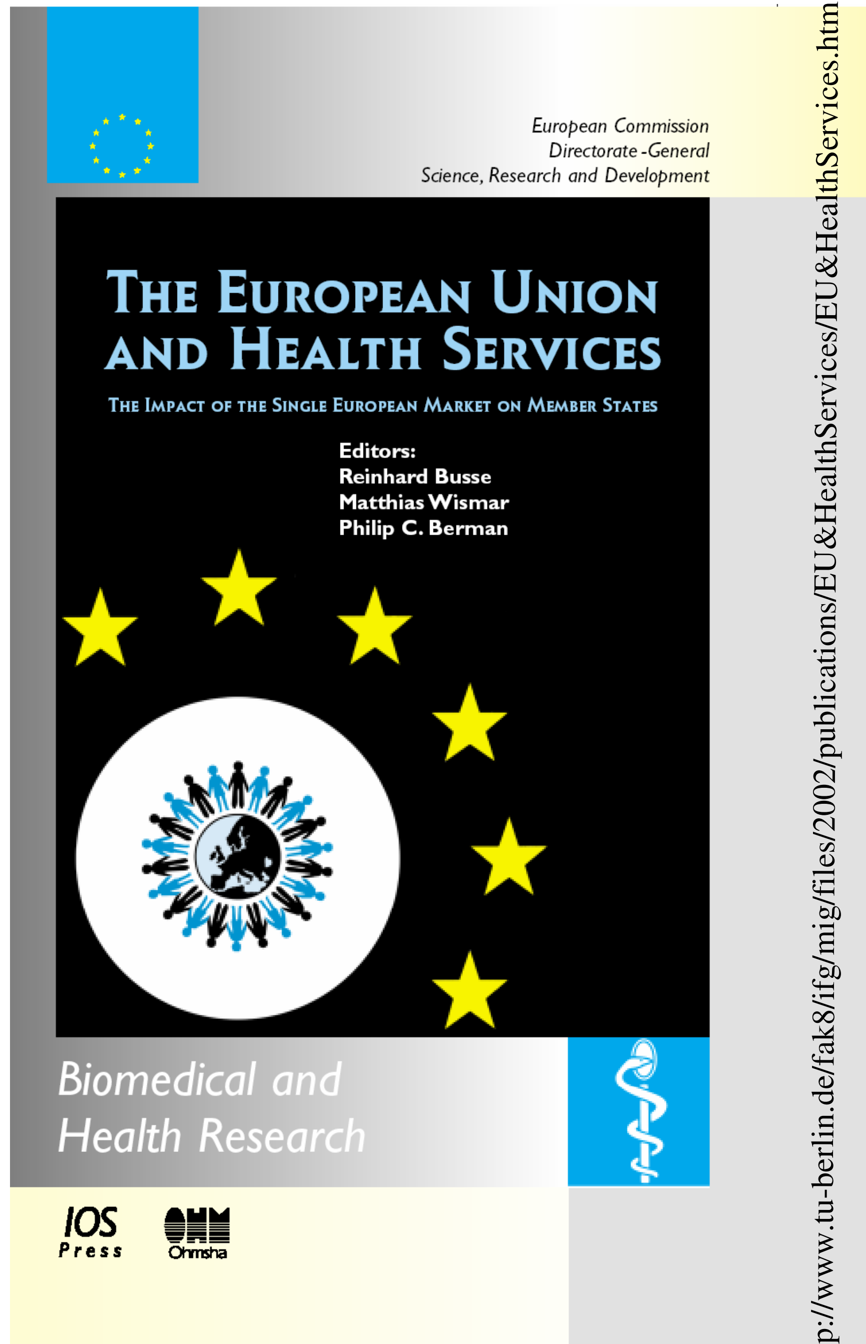
- Regulation 1408/71: free movement of persons (esp. workers)

ECJ rulings:

- 1998 Kohll & Decker: free movement of goods and services also applies in health care (only in ambulatory sector?, only in cost-reimbursement systems?)
- 2001 Peerbooms & Smits-Geraets:
  exclusion of benefits need to be evidence-based
  (in the medium run = EU benefits catalogue?!);
  pre-authorisation may not be refused in cases of unduly waiting times or capacity shortages
- 2003 Müller-Fauré & Van Riet: general entitlement for reimbursement of ambulatory services;
  for hospital services, this may be limited, but the criteria must be clearly defined (*but:* what is ambulatory? what services must be planned?)

EU health policy





“At European level, health services have to adapt to market rules, while at national level, health services are seen as part of a social model.

To overcome this situation and to ensure the social status of health services, we need – possibly paradoxically – to develop a European health policy.“

If we accept that conclusion, the question is:

Should European health policy be based mainly on the “regular” instruments (regulations, directives etc.) or on the “open method of coordination” (OMC)?

What is the OMC?

- Member States define – supported by the Commission – objectives and appropriate indicators for evaluation
- How to reach objectives is entirely up to Member States
- Member States have to regurarly provide data on progress; the worse should learn from the better („best practice“); non-achievement of objectives needs to be justified

How could the open method of coordination be applied to health care?

Objectives in Commission Communication 4/04:

- **Accessibility of care** for all, based on fairness and solidarity, taking into account the needs and difficulties of the most disadvantaged groups and individuals, as well as those requiring costly, long-term care;
- **High-quality care** for the population, which keeps up with medical advances and the emerging needs associated with ageing and is based on an assessment of their health benefits;
- Measures to ensure the long-term **financial sustainability** of this care and aiming to make the system as efficient as possible.

Which objectives are really relevant?

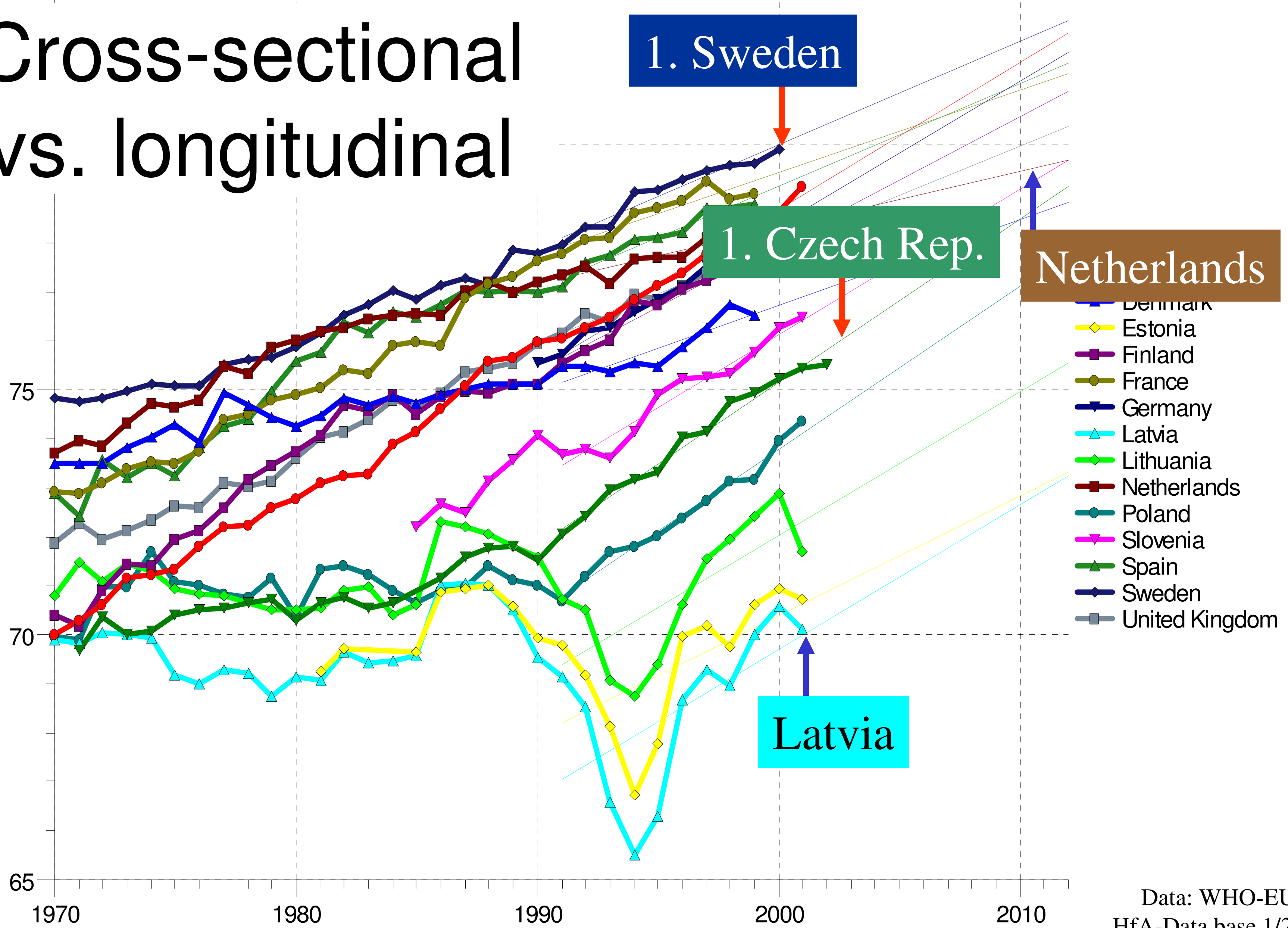
- to achieve a high population health status for the entire population (healthy life expectancy),
- to ensure access to needs-based and effective health technologies,
- to design health systems and make them function according to justified population health needs and expectations,
- assuring a fair *and* sustainable financing of health care.

What needs to be considered methodologically?

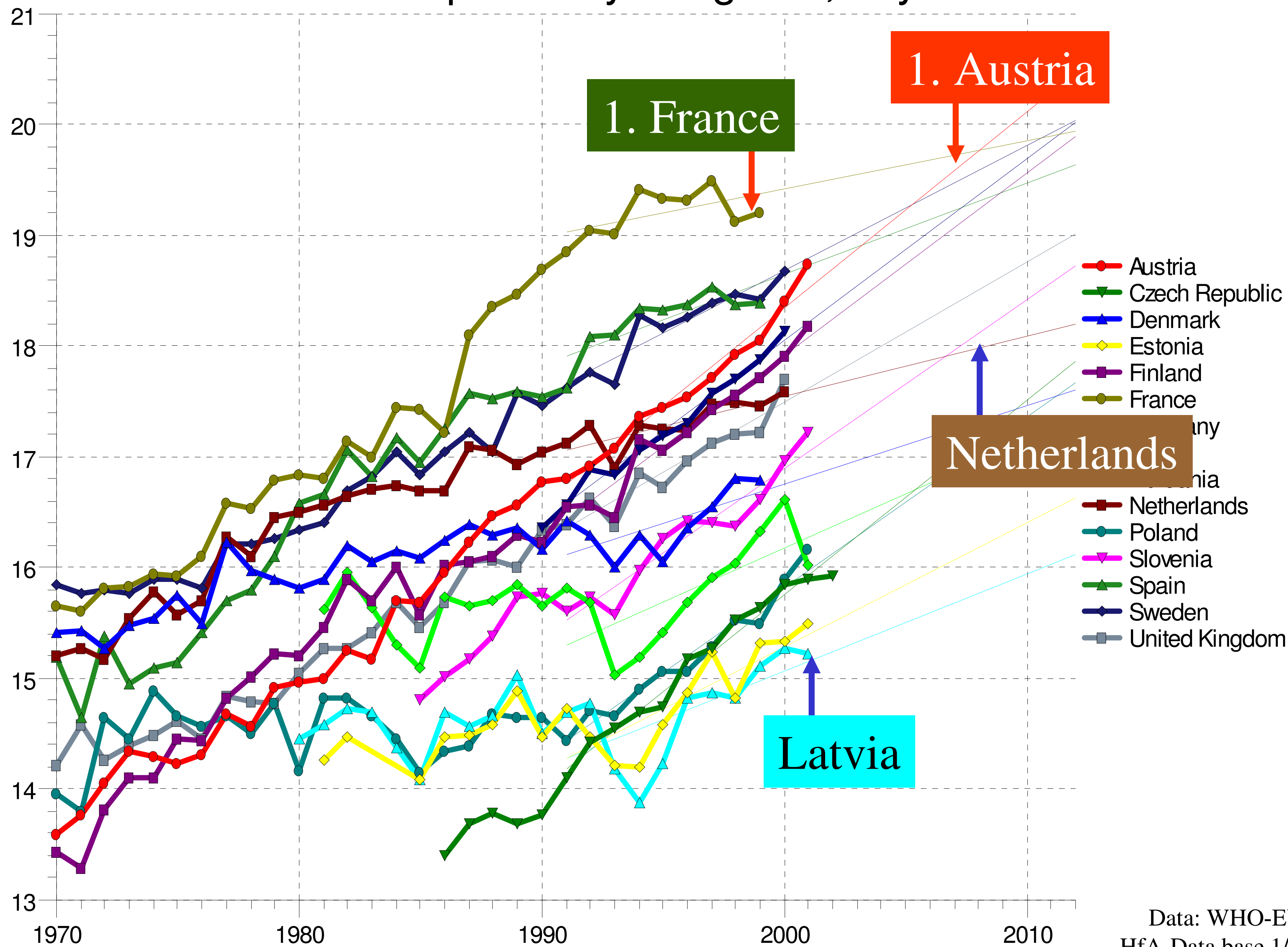
- Indicators need to be 1. based on data which – in all Member States – are collected *objectively*, are available in *good quality* and *timely*, and 2. *valid*.
- Data must *transnationally comparable*, which is not always the case (e.g. health expenditure as % of GDP).
- *Context* is relevant for interpretation, e.g.:
  Did expenditure only drop because certain services have been removed from the benefit catalogue?
- Emphasis on *health care outcomes* not inputs!
- *Indices* should *not* be used.

- to achieve a high population health status for the entire population (healthy life expectancy)

060101 +Life expectancy at birth, in years



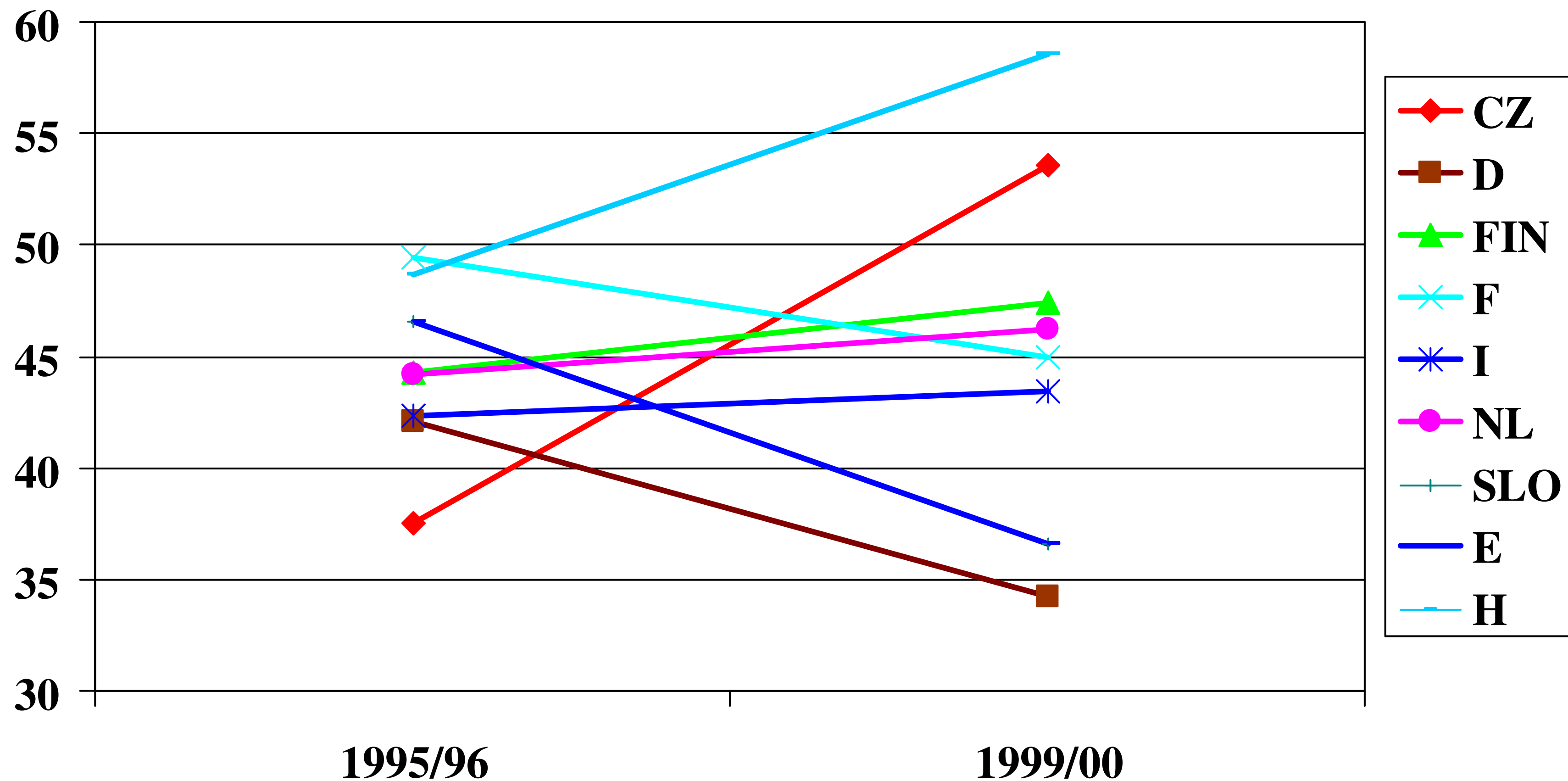
Data: WHO-EURO
HfA-Data base 1/2004



060204 +Life expectancy at age 65, in years
21
20
19
18
17
16
15
14
13
1970
1980
1990
2000
2010
1. France
1. Austria
Netherlands
Latvia
Austria
Czech Republic
Denmark
Estonia
Finland
France
Netherlands
Poland
Slovenia
Spain
Sweden
United Kingdom
Data: WHO-EURO
HfA-Data base 1/2004

- to ensure access to needs-based and effective health technologies

Sufficient blood pressure control 6 months after a CHD hospitalisation



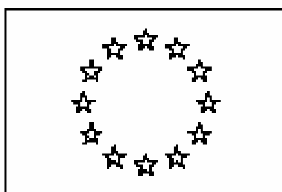
Daten: EUROASPIRE „Clinical reality of coronary prevention guidelines“, Lancet 2001; 357: 998

- assuring a fair *and* sustainable financing of health care

	Distribution: fairness in financial contribution (1.00 = max.)	Threshold	
		% of households with catastrophic payments (total expenditure)	% of households with catastrophic pay- ments (out of pocket)
Slovakia	**0.941**	**0.00**	**0.00**
United Kingdom	**0.921**	0.33	0.04
Denmark	**0.920**	0.38	0.07
Sweden	0.920	0.39	0.18
Germany	0.913	0.54	**0.03**
Hungary	0.905	0.96	0.20
Czech Republic	0.904	**0.01**	0.00
Belgium	0.903	**0.23**	0.09
Finland	0.901	1.36	0.44
Spain	0.899	0.89	0.48
Slovenia	0.890	1.88	0.06
France	0.889	0.68	**0.01**
Lituania	0.875	1.68	1.34
Estonia	0.872	2.47	1.30
Greece	**0.858**	**3.29**	**2.17**
Portugal	**0.845**	**4.01**	**2.71**
Latvia	**0.828**	**4.05**	**2.75**

Data: Murray & Evans „Health Systems Performance Assessment: Debates, Methods and Empiricism“, WHO 2003: 525-6

Current new developments

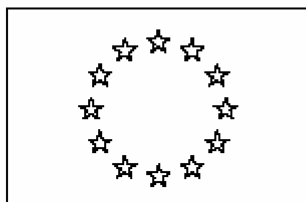


COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.4.2004
COM(2004) 304 final

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the "open method of coordination"



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.04.2004
COM(2004) 301 final

COMMUNICATION FROM THE COMMISSION

Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union

David BYRNE

European Commissioner for Health and Consumer Protection

Enabling Good Health for all

A reflection process for a new EU Health Strategy

15 July 2004

AREAS WHERE THE UNION MAY
TAKE COORDINATING,
COMPLEMENTARY OR SUPPORTING ACTION

The new Constitution

SECTION 1

PUBLIC HEALTH

Article III-278

1. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

Action by the Union, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover:

(a) the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education;

(b) monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drug-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article I-12(5) and Article I-17(a) and in accordance with Article I-14 (2)(k), European laws or framework laws shall contribute to the achievement of the objectives referred to in this Article by establishing the following measures in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use;

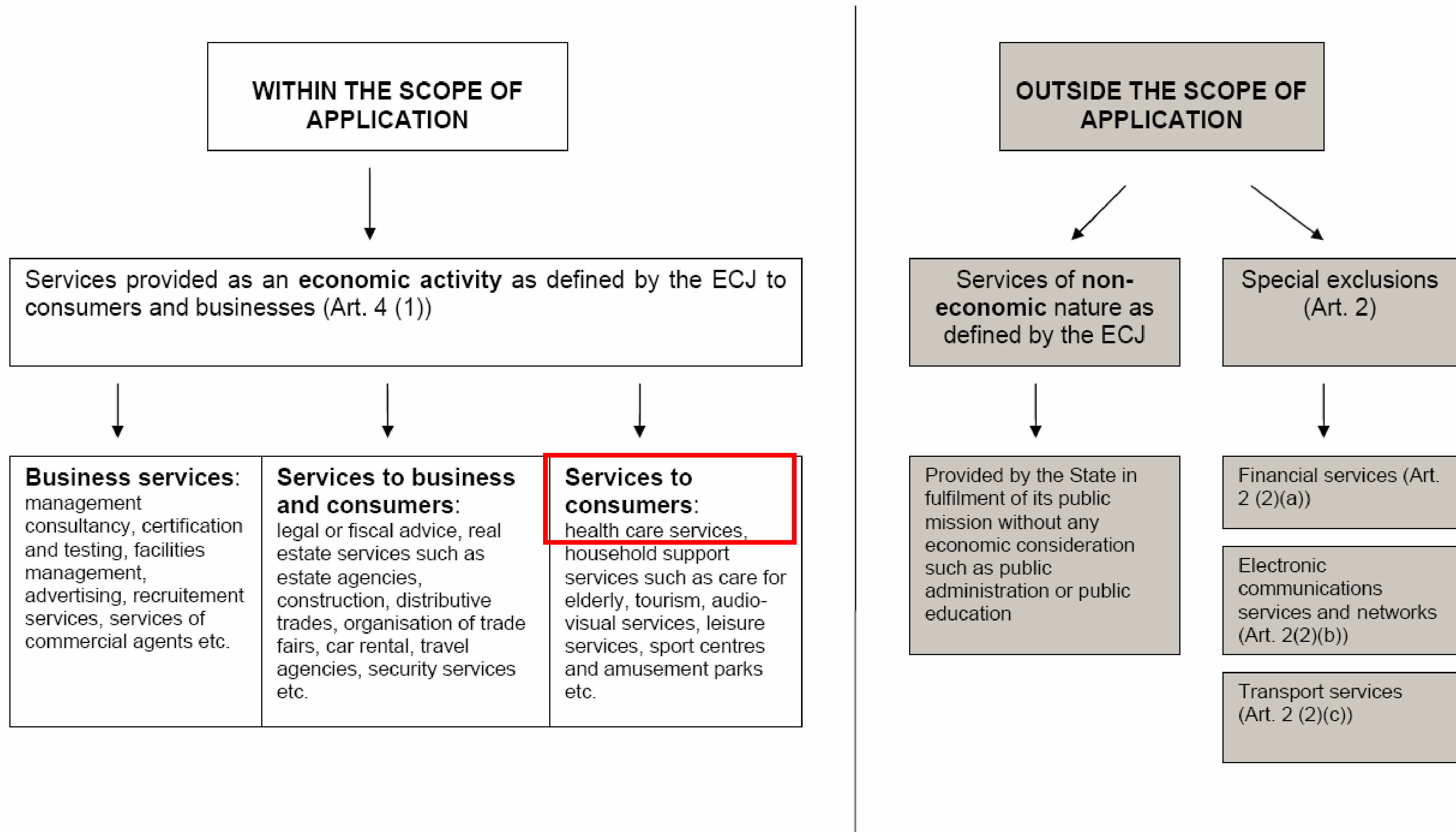
(d) measures concerning monitoring, early warning of and combating serious cross-border threats to health.

Such European laws or framework laws shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.

5. European laws or framework laws may also establish incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, as well as measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States. They shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.

6. For the purposes of this Article, the Council, on a proposal from the Commission, may also adopt recommendations.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.


DIRECTIVE ON SERVICES IN THE INTERNAL MARKET
WITHIN THE SCOPE OF APPLICATION
Services provided as an economic activity as defined by the ECJ to consumers and businesses (Art. 4 (1))
Business services: management consultancy, certification and testing, facilities management, advertising, recruitement services, services of commercial agents etc.
Services to business and consumers: legal or fiscal advice, real estate services such as estate agencies, construction, distributive trades, organisation of trade fairs, car rental, travel agencies, security services etc.
Services to consumers: health care services, household support services such as care for elderly, tourism, audio-visual services, leisure services, sport centres and amusement parks etc.
OUTSIDE THE SCOPE OF APPLICATION
Services of non-economic nature as defined by the ECJ
Special exclusions (Art. 2)
Provided by the State in fulfilment of its public mission without any economic consideration such as public administration or public education
Financial services (Art. 2 (2)(a))
Electronic communications services and networks (Art. 2(2)(b))
Transport services (Art. 2 (2)(c))

HOW DOES THE SERVICES DIRECTIVE AFFECT HEALTH AND SOCIAL SERVICES?

Health services are services under the Treaty and should benefit from an Internal Market framework.

Services Directive seeks to remove unjustifiable and in particular discriminatory barriers on freedom of establishment and freedom to provide services in those areas which are open to competition.

- It does **not require** MS to liberalise or privatise health or social services which are currently provided at national, regional or local level by the public sector or public entities.
- It does **not aim** to harmonise MS' regulation or modes of delivery of health or social services.
- It does **not interfere** with the way MS organise or finance their health and social systems.

Freedom of establishment

- Authorisation schemes for private operators would have to be non-discriminatory, objective and transparent
- Specific requirements listed in the Directive such as quantitative restrictions would be submitted to the mutual evaluation.
- In health and social services these types of requirements are justified if they are non-discriminatory, objective and transparent.

Free provision of services

- Derogation from the country of origin principle for recognition of professional qualifications
- Derogations for reasons related to public health (e.g. prohibition of certain treatments, respect of health and safety standards linked to the characteristic of the place)
- Information and transparency requirements on services providers, obligatory indemnity insurance
- Information/assistance to patients
- Administrative co-operation

Right for reimbursement

- Does not create new rights for patients
- Clarification of conditions for reimbursement on the basis of the case law of the ECJ
- complementary to Regulation 1408/71
- abolishes prior authorisation for non-hospital care
- for hospital care authorisation can be kept
- distinction between hospital and non-hospital care
- level of costs limited to the level of costs in the MS of affiliation

http://europa.eu.int/comm/internal_market/services/docs/strategy/2004-propdir/health_en.pdf

WHEN DOES THE COUNTRY OF ORIGIN PRINCIPLE APPLY AND WHAT DOES IT MEAN?

- The country of origin principle **applies only in the case of cross-border provision** of services without establishment. (If a service provider has a fixed infrastructure e.g. chemical laboratory, he is entirely subject to the law of that country.)
- It means that when a service provider wants to provide his services into another Member States without a permanent presence there, he **has to comply only with the administrative and legal requirements of his country of establishment**.
- It is **combined with a number of derogations**. A service provider will have the certainty that outside the derogations he has to comply only with his own law. This will be the case for many business to business activities.

DEROGATIONS CONCERN IN PARTICULAR:

Posting of workers Directive (96/71/EC). All matters covered by that Directive (such as minimum wages, working time, safety, hygiene and safety standards…) are excluded from the country of origin principle. This concerns working conditions laid down both by law and by collective agreements. Service providers must thus respect working conditions in the MS where they post workers and the authorities of that MS must control the compliance with those. (Art. 17(5), 24(1)).

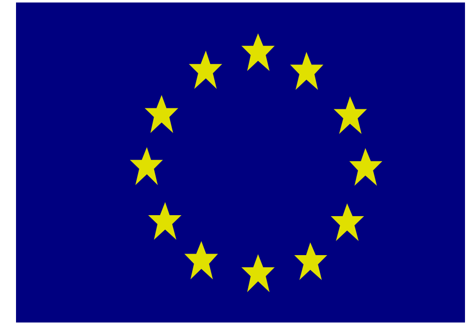
Professional qualifications. The provisions of the proposed Directive of professional qualifications dealing with freedom to provide services (title II, subject to the outcome of second reading) will be excluded from the country of origin principle of the Services Directive. (Art. 17(8))

Consumer contracts. Pending complete harmonisation of rules on consumer contracts, the law applicable to consumer contracts will be governed by the Rome Convention. (Art. 17(21))

Specific requirements linked to the characteristic of the place. Specific requirements which are inextricably linked to the particular characteristics of the place where the service is provided and which are necessary to maintain public policy, public health or the protection of environment (e.g. safety of buildings). Art. 17(17)).

Case-by case derogations. Derogations from the country of origin principle can be applied in individual cases against service providers creating a particular risk. MS may take measures relating to, for example, safety of services including aspects related to public health or the exercise of health professions. Such measures are subject to a Community procedure. (Art. 19)

How could the application of such developments influence European health systems? (1)



Initially probably not directly, but

- *Comparability* of services, their access and quality *will increase*,

and thereby contribute to the *Europeanisation of health care systems*, already on the way through

- mobility of short- and long-term tourists,
- cross-border contracts/ Euregios,
- ECJ rulings on Kohll/ Decker, Peerbooms etc.,
- the EU-health insurance card.

How could the application of such developments influence European health systems? (2)

This will in the medium-term probably lead to

- a European *benefit catalogue* (but not equal prices),
- Europe-wide rules/ standards for *accreditation* and *quality assurance*,
- Europe-wide diagnosis/ treatment *guidelines*.

This could make *Europe more concrete for its citizens* and help to *remove the conflict between markets and the social model.*

Technische Universität Berlin

This presentation and more material can be found on my department‘s website

http://mig.tu-berlin.de