The SEM and the public procurement of Consumer choice of medical goods across borders

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Abstract. Consumer choice in medical goods is examined in relation to the potentially relevant areas of pharmaceuticals, therapeutic appliances and dentures. Potentially, the impact of European legislation and jurisdiction on the Member States is very high, but in reality the outcome has been minimal. Four major factors account for this gap between impact and outcome: i) the restrictive handling of the pre-authorisation procedure, ii) differences in the health care baskets across Europe, iii) the "unusual" distribution systems of medical goods, and iv) the lack of the cost-reimbursement provisions.

1. Introduction

In this chapter, an attempt is made to analyse intention, impact and outcomes of both the TEC and secondary European legislation in regard to consumer choice for medical goods.

To analyse the impact of Community policy and ECJ rulings on consumer choice in medical goods, using the German situation as an illustration, a) the relevant European and domestic legal sources were analysed (see Table 1), b) medical goods were divided into three important sub-categories, c) structured telephone interviews were conducted, and d) secondary literature was used when appropriate.

Table 1: Major juridical sources in regard to consumer choice of medical goods

Legal source	Articles, paragraphs or rulings of relevance
European level	
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
Secondary legislation	EEC 1408/71 (Art. 13, 19, 22), modified/ extended especially by EEC 1390/81 [self-employed], 2791/81 [modification following the Pierik cases], 3095/95 [other insured], 1606/98 [special schemes for civil servants] and 307/99 [special schemes for students]
	EEC 574/72
ECJ	C-120/95 "Nicolas Decker"
	other ECJ cases (see next chapter)
German level	
Social Code Book V (SGB V)	§ 16 (1) 1, suspension of eligibility while abroad
	§ 17, provision for employed abroad
	§ 18, cost-coverage for treatment abroad

Germany was chosen as the analytical lead country for the topic of cross-border consumer choice in prescribed medical goods. The rationale for this choice is grounded not only in the fact that Germany has long and relatively densely populated borders to six other Member States (Denmark, the Netherlands, Belgium, Luxembourg, France and Austria) but also, more importantly, because for a brief period in 1998 cross-border consumer choice in prescribed medical goods was in principle possible – and took place.

2. Background

The subject of this section combines the topic of cross-border consumer choice for both medical goods and healthcare services (the latter are analysed in the next chapter).

2.1 Consumerism and patient sovereignty in healthcare

To conceptualise users of health services not only as patients, beneficiaries or insurees but also as consumers is a relatively new approach for most health services in the Member States. In market terms, the patient confronts suppliers of health care (physicians, hospitals etc.) with individual demands and preferences – which have to be distinguished from needs. It is assumed that the consumer is endowed with the power to make or influence decisions which would otherwise have been made exclusively either by the physician or the competent institution. Yet most health services only provide limited opportunities for patients to make choices in relation to prevention, diagnostics, therapy, or medical goods (Schwartz & Wismar 1998). Moreover, even if there is the chance to choose between different options, patients and consumers are faced with a severe lack of useful and valid information to make informed choices.

In terms of healthcare financing, consumer choice in goods seems at first sight a minor issue for health services, but this is not the case for the patient or consumer. Most health services have introduced user charges, reference prices or fixed lump sums for various goods such as glasses, pharmaceuticals, aids and dentures, leaving the patient to top up a considerable portion of the price. Differences in pricing between Member States can therefore serve as an incentive to acquire goods in another country. In addition, tourism and the tendency of pensioners to spend long periods in southern European countries make cross-border consumer choice in goods even more relevant even if not entirely necessary. Last but not least, frontier workers or people residing along densely populated European borders may choose to acquire prescribed medical goods across the border just for reasons of convenience.

2.2 International dimension in social protection

Cross-border provision of social services or international welfare-state arrangements are - in principle - not new, having developed before, parallel and independently from European integration. There are a variety of bi-lateral agreements on cross-border welfare state provision and some of them can even be traced back to the time before the First World War. For example, in 1912, Germany and Italy agreed on the co-ordination of pension schemes for frontier workers (Leder 1995). Similar activities took place between Belgium and France. Currently, Ireland and Northern Ireland are implementing measures for cross-border provision of services (McKee 1999). Germany has concluded Social Security Agreements with a wide range of countries which guarantee necessary treatments in case of

emergency or illness abroad[1]. The attempt to co-ordinate health services by introducing minimal standards in regard to the equal treatment of nationals and foreigners is in line with these developments. The International Labour Organisation (ILO), founded in 1919, and the Council of Europe have been active in this area (Leder 1995).

2.3 Co-ordination of social protection systems in the European Economic Community and the European Community

In this context, the co-ordination of social protection systems in the European Union has to be analysed. The necessity to co-ordinate social protection across the Member States of the EEA[2] can be best explained in terms of an example. In Denmark, all inhabitants – whether nationals or foreigners – are automatically covered by social provision. The welfare state is largely financed from taxation. In contrast to the welfare-state in Denmark, the German pension, health care, long-term care, unemployment and occupational accident schemes are statutory insurance systems financed jointly out of employers' and employees' contributions[3]. As a result the membership of the social insurance scheme is primarily workplace-related. A Danish citizen living in Denmark and working abroad in Germany would have to pay taxes both in Denmark for social protection and contributions in Germany for statutory insurance schemes. Vice versa, a German worker resident in Germany but employed in Denmark would neither pay contributions nor taxes for social provision. In terms of eligibility, the German worker would neither have access to the German or to the Danish health service while the Dane could enjoy the benefits of both.

To avoid such overlapping and excluding competencies, a common co-ordination of the social services was required, which is established in the TEC[4]. It was introduced immediately after the Treaty of Rome was signed – the third regulation ever to come in force in the EEC. In its latest version it is known as Regulation EEC 1408/7.

2.4 The Decker ruling

Meanwhile, the development of European legislation in respect to the issue of cross-border purchase of prescribed medical goods goes beyond Regulation EEC 1408/71 through the impetus of the preliminary ruling of the ECJ in regard to the "Decker case" (C-120/95). Nicolas Decker, a Luxembourg citizen went abroad to purchase a pair of glasses, prescribed by a Luxembourg ophthalmologist. He bought a pair of glasses in Arlon, Belgium. When he returned to Luxembourg he claimed the cost incurred abroad for the glasses from his sickness fund. This was denied on the ground that he had not gone through the normal pre-authorisation procedure. According to Regulation EEC 1408/71, patients who travel to

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1 Social protection arrangements are in force (January 2000) with Bosnia-Herzegovina, Bulgaria (pensions only), Yougoslavia, Macedonia, Croatia, Poland, Switzerland, Slovenia, Turkey, and outside Europe Chile (pensions only), Israel, Canada (pensions only), Marocco, and the USA (pensions only).

2 Iceland, Liechtenstein and Norway as parts of the European Economic Area are part of the co-ordination of social protection in the European Union.

3 Among the five statutory insurance pillars of the German welfare state, only the occupational accident insurance is payed exclusively by employer contributions.

4 TEC Art. 42 (ex-Art. 51): "The Council shall, acting in accordance with the procedure referred to in Article 251, adopt such measures in the field of social security as are necessary to provide freedom of movement for workers; to this end, it shall make arrangements to secure for migrant workers and their dependants: (a) aggregation, for the purpose of acquiring and retaining the right to benefit and of calculating the amount of benefit, of all periods taken into account under the laws of the several countries; (b) payment of benefits to persons resident in the territories of Member States. The Council shall act unanimously throughout the procedure referred to in Article 251."

another Member State with the express intention of purchasing medical goods at the expense of the competent institution have to meet this requirement. Otherwise, their costs are not covered. Decker took his case to a Luxembourg court, referring to the free movement of goods established by the TEC. In turn, the competent Luxembourg court asked the ECJ to clarify the interpretation of the TEC through a preliminary ruling. The base line of the interpretation was that the free movement of goods is in principle applicable to health services, as long as neither the financial stability of the service nor the public's health is in danger (Wismar & Busse 1998). Yet, the Decker case is not the end of the story. Many questions arising from this and subsequent rulings remain unresolved or disputed.

3. Medical goods relevant for consumer choice

Medical goods for the purpose of this chapter are:

- pharmaceuticals,
- therapeutic appliances and
- dentures.

The potential impact could be very high since, as the German social health insurance (SHI) expenditure data show (Table 2), 19% of all SHI expenditure are for medical goods – a sum of almost € 24.5 billion (not including patient co-payments and direct purchases).

Table 2: Expenditure on medical goods in German SHI (1998) = theoretical impact

Goods	Expenditure in billions of Euro	Percentage of SHI total
Pharmaceuticals	17.06	13.4%
Appliances	4.38	3.5%
Dentures	3.02	2.4%
Sum of goods	24.47	19.3%
SHI total	126.89	100.0%

3.1 Pharmaceuticals

According to the German Pharmaceutical Act (*Arzneimittelgesetz*), pharmaceuticals are substances or manufactured substances which cure, soften, prevent or diagnose illness, sufferings or impairments in humans and animals.

According to § 31 of the SGB V, patients in Germany have a right to obtain pharmacy-only drugs at the expense of the SHI. The German pharmaceutical market contains several, partially overlapping segments:

- Pharmacy-only drugs: Pharmaceuticals which are only allowed to be sold in pharmacies (market data are only available for these drugs).
- Prescription-only drugs: Within the pharmacy-only drugs, prescription-only drugs form the largest segment. These are only allowed to be sold with a prescription and in a pharmacy.
- Prescription possible: Pharmaceuticals which may be prescribed at the expense of the SHI funds. These drugs may also be bought over-the-counter in a pharmacy but a prescription is needed if a SHI fund is to cover the costs.

– Non-prescription drugs: These drugs can be purchased without a prescription in a pharmacy and they cannot be obtained to the expense of SHI funds. The patient has to pay for these drugs in all cases.

Figure 1 visualises the various market segments by expenditure volume.

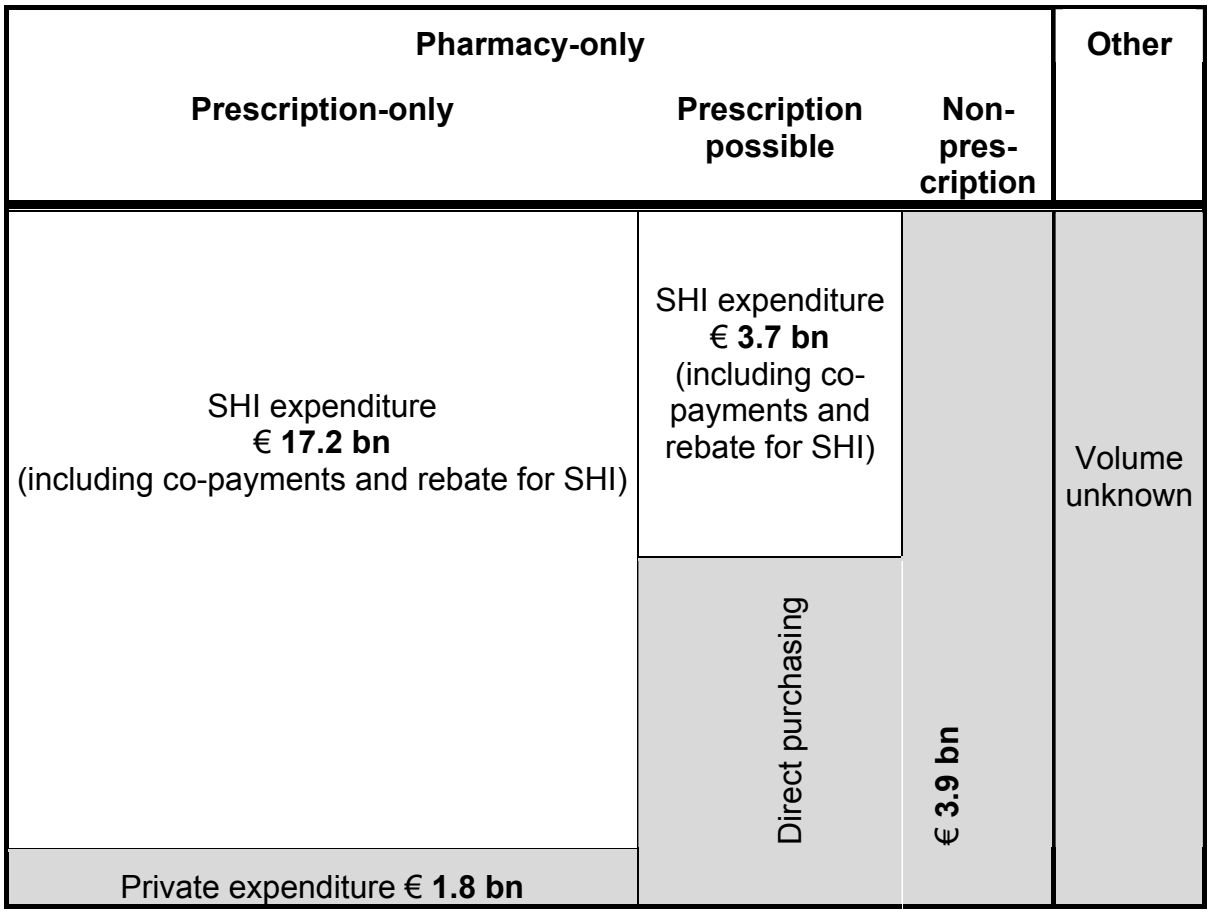

Fig. 1: The German pharmaceutical market according to segments and market volume in Euro (1998); areas in white indicate the SHI-covered market, areas in grey unrestricted consumer choice

Most pharmacy-only drugs may be prescribed to the expense of the sickness funds. However, there are a few but important exceptions – which even include prescription-only drugs – and these are gaining increasing attention (Busse 2000):

– Since 1983 drugs for certain conditions (common colds, drugs for the oral cavity with the exception of antifungal drugs, laxatives and drugs for motion sickness) are legally excluded from the benefits' package for insured people over 18 years old (§ 34(1) SGB V).
– The Social Code Book allows the Minister of Health to exclude "inefficient" drugs (i.e. they are not effective (for the desired purpose) or combine more than three drugs the effect of which cannot be evaluated with certainty (§§ 2, 12, 34(3) and 70 SGB V). The evaluation of these drugs takes into account the peculiarities of homeopathic, phytotherapeutic or anthroposophic drugs. A negative list according to these principles came into effect on 1 October 1991. It was revised in 1993 and contains about 2 200 drugs.

– Additionally, drugs for "trivial" diseases (such as common colds) which can usually be treated by treatments other than drugs may be excluded (§ 34(2) SGB V). A list of this type has not yet been worked out.

The coverage of drugs is also regulated in the pharmaceutical guidelines of the Federal Committee of Physicians and Sickness Funds and forms part of the contract between the two sides at the federal level. These guidelines, which are legally binding, attempt to steer the appropriate use of different groups of pharmaceuticals. They limit the prescription of certain drugs to certain indications (e.g. anabolics to cancer patients), specify that they may only be used after non-pharmaceutical treatments were unsuccessful (e.g. so-called chondroprotective drugs) or in a few cases, disallow any prescription by the sickness funds (e.g. drugs to quit smoking).

In mid-1998, the Federal Committee amended its pharmaceutical guidelines to exclude drugs for the treatment of erectile dysfunction and drugs to improve sexual potency such as Viagra. The committee argues that individually very different behaviour does not allow the determination of a standard of disease upon which to base economic considerations. In its opinion, the responsibility of the sickness funds ends where personal lifestyle is the primary motive for using a drug. The Federal Social Court disapproved of the general exclusion of drugs for the treatment of erectile dysfunction and instead demanded measures against their misuse.

3.2 Therapeutic appliances

Therapeutic appliances comprise devices such as prostheses, glasses, hearing aids, wheelchairs or inhalators. Insured persons are entitled to them, unless they are explicitly excluded from the benefit catalogue through a negative list issued by the relevant ministry (§§ 33 and 34 SGB V).[5] The regulations for the coverage of non-excluded therapeutic appliances are complex and therefore are only briefly described (for further details see Perleth et al. 1999).

The federal associations of the sickness funds publish a medical appliances catalogue, which contains among others:

– a legal account of who may be entitled to medical aids debited to the SHI,
– an alphabetical catalogue of all medical appliances,
– the medical appliances listing which can be provided for the account of the SHI.

The medical aids listing represents a positive list of services which can be provided at the expense of the statutory health insurance (Table 3). The decision to include medical aids lies exclusively with the federal sickness funds' associations. The definition of the medical aids listing is established by law (§§ 126-128 and 139 SGB V).

In the German SHI, the insured person has a right to contact lenses in exceptional cases only. And in these cases the SHI only grants a subsidy up to the costs of spectacles otherwise needed.

[5] The Federal Ministry of Labour and Social Affairs (the predecessor of the Ministry of Health) has explicitly excluded aids with small or disputed therapeutic benefit or low selling price (e.g., wrist belts, ear flaps etc.).

3.3 Dentures

Paragraph 30 SGB V subsumes dental prostheses, caps (crowns) and bridges as "dentures". Currently 55 different goods/procedures in the area of prosthesis and denture are listed in the Unified Value Scale-Dentist ("Bema – Bewertungsmaßstab Zahnärzte"). The Federal Committee of Dentists and Sickness Funds agrees on the services provided under SHI coverage and their value relation in so-called value points. Table 4 provides an overview on the prosthetic procedures that matter most in terms of reimbursement value.

Table 3: Listing of therapeutic appliances according to § 128 SGB V by number of category

01	Vacuum devices	13	Hearing aids	25	visual aids
02	Adaptation aids	14	Inhalation devices and devices for breathing therapy	26	Sitting aids
03	Instruments and devices for the application of medicines	15	Aids for incontinence	27	Speaking aids
04	Bathing aids	16	Aids for communication	28	Standing aids
05	Bandages	17	Aids for compression therapy	29	Stoma-items
06	Radiation devices	18	Vehicles for sick persons	30	Splints
07	Aids for the blind	19	Nursing care items	31	Shoes
08	Orthopaedic insoles	20	Storage aids	32	Therapeutic movement devices
09	Devices for electrostimulation	21	Measuring instruments for status and function of the body	33	Toilet aids
10	Walking aids	22	Mobility aids	99	various items
11	Therapeutic appliances against decubitus (bedsore)	23	Orthotics		
12	Aids for patients with removed larynx	24	Prothetics		

Source Hilfsmittelkatalog einschließlich Hilfsmittelverzeichnis, 1.11.1996

Table 4: The ten prosthetic procedures/goods with the highest cumulative reimbursement value and the their frequency 1995 (western part of Germany only)

Bema-No.	Rank	Prosthetic procedure/good	No. of procedures in thousands
91b	1	full porcelain bonded bridge	4,039
20b	2	porcelain bonded crown on tooth	3,996
19b	3	provisional crown	12,609
91d	4	telescopic crown	881
20c	5	jacket or partial crown	670
97a	6	total upper jaw	481
96c	7	partial prosthesis (more than 8 teeth missing)	649
92a	8	bridge element	1,559
100b	9	restoring prosthesis	1,668
24c	10	removal and fixing of provisional crown/bridge	9,536

Source: Kassenzahnärztliche Vereinigung 1996

4. Consumer choice across borders in European legislation and jurisdiction

The surprising finding of this section is that even Regulation EEC 1408/71 contains in principle a far-reaching provision to facilitate cross-border consumer choice for prescribed medical goods.

4.1 Elements of consumer choice in EEC 1408/71: Population covered and rules and principles

Originally, Regulation EEC 1408/71[6] only covered workers. But from the early 1980s onwards, Regulation EEC 1408/71 gradually extended its scope in terms of groups covered. Regulation EEC 1390/81, which came into force on 1st July 1982, included the self-employed. The Regulation also covers members of workers' and self-employed persons' families and their dependants, as well as stateless persons and refugees. In 1991, the Commission submitted a proposal to extend the scope of the Regulation to include all insured persons, particularly students and others not in gainful employment. This proposal has been incorporated into Regulation 1408/71 through Council Regulations EC 3095/95 and EC 307/99.

Council Regulation EC 1606/98 extended the scope of Regulation 1408/71 in order to put civil servants on an equal basis with general statutory pension rights prevailing in the Member States. As a rule, the provisions of the Regulation cannot be invoked by nationals of third countries working in the Union. After pressure from the European Parliament, the Commission in 1997 presented a proposal for a Regulation amending Regulation 1408/71 as regards its extension to nationals of third countries (COM(97)0561).

Although complicated in detail (and terminology) Regulation EEC 1408/71 and the accompanying provisions of Regulation EEC 574/72 rest on two simple sets of rules and four main principles. The two sets of rules are:

1. It defines the competent state as the state in which the beneficiary is employed and has to contribute to social protection schemes either by contribution or by taxes[7].
2. It defines the competent institution as the one from which the beneficiary receives social provision. In case the beneficiary receives social provision outside the competent state the medical care offered is not in accordance with the medical care standards of the competent state but with the standards of the state the patient receives the care[8].

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[6] Benefits covered by Regulation EEC 1408/71 encompass: sickness and maternity benefits; invalidity benefits, including those intended for the maintenance or improvement of earning capacity; old-age benefits; survivors benefits; benefits in respect of accidents at work and occupational diseases; unemployment benefits; family benefits.

[7] Regulation EEC 1408/71 Art. 13, Paragraph 2, Letter (a): A person employed in the territory of one Member State shall be subject to the legislation of that State even if he resides in the territory of another Member State or if the registered office or place of business of the undertaking or individual employing him is situated in the territory of another Member State.

[8] Regulation EEC 1408/71 Art. 19: Residence in a Member State other than the competent State - General Rules: 1. An employed or self employed person residing in the territory of a Member State other than the competent State, who satisfies the conditions of the legislation of the competent State for entitlement to benefits, (taking account where appropriate of the provisions of Article 18) shall receive in the State in which he is resident: benefits in kind provided on behalf of the competent institution by the institution of the place of residence in accordance with the provisions of the legislation administered by that institution as though he were insured by it.

The four main principles are:

1. Equal treatment. workers and self-employed persons from other Member States must have the same rights as the competent State's own nationals. In other words, a Member State may not confine social security benefits to its own nationals. The right to equal treatment applies unconditionally to any worker or self-employed person from another Member State having resided for a certain period of time.
2. Aggregation. The aggregation principle means that the competent Member State must take account of periods of insurance and employment completed under another Member State's legislation in deciding whether a worker satisfies the requirement regarding the duration of the period of insurance or employment. The right to membership of sickness funds, for example, can be transferred directly from a fund in one Member State to a fund in another Member State.
3. Prevention of overlapping benefits.
4. Exportability. Benefits can be paid throughout the EU and Member States are prohibited from reserving the payment of benefits to people resident in the country[9].

Regulation EEC 1408/71 is not specific about medical goods. Nevertheless, it does contain some provision allowing cross-border consumer choice in prescribed medical goods, which would otherwise not be granted. The most obvious case are frontier workers. They may obtain health care in both the country of the competent state and the competent institution[10].

Regulation EEC 1408/71 also provides a legal basis for different ways of intentional cross-border care and therefore for consumer choice. The first procedure, outlined in Article 22(1)(a), was originally intended for health care during a temporary stay abroad, during which insurance with the competent institution is certified through an E111 form. Only certain groups of persons may receive healthcare services regardless of whether their condition is urgent. These are:

– pensioners and their families;
– unemployed persons and their families who go to another Member State to seek employment;
– employed or self-employed persons exercising their professional activity in another Member State;
– frontier workers (although their families must obtain prior authorisation for non urgent treatment if there is no agreement between the countries concerned);
– students and those undertaking professional training and their families.

All other persons are only entitled to receive goods and services if their condition urgently requires it, i.e. it is not the intention of Regulation 1408/71 to facilitate the crossing of borders to receive goods or services.

The second procedure, regulated in Article 22(1)(c), is outlining an option for al these “other” persons. It requires, however, pre-authorisation by the competent institution, which is certified through an E112 form[11]. According to the Regulation, only under certain

[9] This principle does not apply to all social security benefits. There are special rules for the unemployed.

[10] Regulation EEC 1408/71 Art. 20: A frontier worker may also obtain benefits in the territory of the competent State. Such benefits shall be provided by the competent institution in accordance with the provisions of the legislation of that State, as though the person concerned were resident in that State.

[11] Regulation EEC 1408/71 Art. 22: An employed or self-employed person who satisfies the condition of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and: [...] who is authorised by the competent institution to go to the territory of

circumstances and on very specific grounds in regard to the health status of the patient can this pre-authorisation be denied[12]. A denial of the pre-authorisation is categorically ruled out if the patient has to wait an unacceptable time for treatment[13].

The pre-authorisation procedure – although not intentionally designed for the purchase of goods – does not seem to preclude cross-border consumer choice. As a matter of fact, if the wording of Regulation EEC 1408/71 is strictly applied, the competent institution has no right to deny pre-authorisation for the purchase of a pair of glasses in another Member State. Despite the bureaucratic procedure, Regulation EEC 1408/71 already facilitates consumer choice[14].

4.2 Elements of consumer choice in the "Decker ruling"[15]

In principle, the Decker ruling is on consumer choice. But three restrictions have to be made. First of all, it applies explicitly only to the ambulatory sector. Although the Attorney General referred to the hospitals sector in his opinion, the ECJ did not follow the argument because the Decker case did not apply to it.

The ECJ did not only scrutinise the case according to the Articles 28 (ex 30) and 30 (ex 36) of the Treaty of the European Communities, which deal with the free movement of goods, but also according to the Council Regulation (EEC) 1408/71 in its amended and updated version by Council Regulation (EC) 118/97. The main question was if a national rule which demands a prior authorisation by a social security institution of a Member State as pre-condition for a reimbursement of a good purchased by an optician established in another Member State is compatible with the Articles 28[16] and 30[17] of the TEC.

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another Member State to receive there the treatment appropriate to his condition, shall be entitled: to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provision of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State; to cash benefits provided by the institution in accordance with the provision of the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the provisions of the legislation of the competent State.

[12] Regulation EEC 1408/71 Art. 22: The authorisation required under Paragraph 1 (b) may be refused only if it is established that movement of the person concerned would be prejudicial to his state of health or the receipt of medical treatment.

[13] The authorisation required under Paragraph 1 (c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

[14] The gap - or better gulf - between theory and practice of regulation EEC 1408/71 will be analysed below.

[15] The question of the Luxembourg legal backgrounds will not be discussed here, but instead the focus will be directed at the aspects which are relevant for the health systems throughout Europe.

[16] TEC Article 28 (ex-Article 30): Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

[17] TEC Article 30 (ex-Article 36): The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

First of all, the ECJ questioned the applicability of Art. 30 in regard to social provision and came to the clear conclusion that social security cannot exclude the application of the principle of free movement of goods[18].

In regard to the limits of 1408/71, the ECJ concluded that although 1408/71 regulates reimbursement procedures in case of prior authorisation, it does not apply to cross-border provision of services and goods without prior authorisation (par. 27-29).

In regard to the assumed conflict between the pre-authorisation procedure and the free movement of goods, the ECJ endorsed the view of Nicolas Decker. The Court held the opinion (par. 34-36) that the rules at issue encourage persons insured under the Luxembourg social security scheme to purchase their medical goods in Luxembourg and not abroad[19]. This was regarded to be a barrier to the free movement of goods.

In Article 36 of the Treaty of the European Communities some exceptions to the free movement of goods are permitted, for example if the financial balance of the social security system is endangered. A reimbursement at a flat-rate would have – according to the ruling (par. 38-40) – no effect on the financing or the balance of the social security system.

According to the opinion of the court (par. 43), an equal quality of goods purchased in another Member State is guaranteed due to the system for the recognition of professional education and training. Furthermore, the Court pointed out (par. 44) that the protection of public health was guaranteed because the spectacles were purchased using a prescription from an ophthalmologist.

In conclusion, the European Court of Justice ruled:

> ”Articles 30 and 36 of the Treaty of the European Communities preclude national rules under which a social security institution of a Member State refuses to reimburse to an insured person on a flat-rate basis the costs of a pair of spectacles with corrective lenses purchased from an optician established in another Member State, on the ground that prior authorisation is required for the purpose of any medical product abroad.”

5. Impact on national legislation

Unlike European directives, regulations such as EEC 1408/71 and preliminary rulings (like the Decker ruling) do not require a formal process of transposition. Regulations are addressed towards EU citizens, and they are generally and immediately in force.

Two reactions are possible: 1. Actors in the health policy arena may feel obliged to comply with the regulation or ruling instantly, even if the government is inactive. 2. The regulations and their contents are not generally known by citizens or other actors involved because they do not have to be transposed into national legislation through a process which, depending on the subject, will bring many details to light (as it is the case with directives).

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[18] Par. 24: ”[...] that measures adopted by Member States in social security matters which may affect the marketing of medical products and indirectly influence the possibilities of importing those products are subject to the Treaty rules on the free movement of goods; and that the fact that the national rules at issue in the main proceedings fall within the sphere of social security cannot exclude the application of Article 30 of the Treaty.”

[19] Par. 35: ”While the national rules at issue [...] do not deprive insured persons of the possibility of purchasing medical product in another Member State, they do nevertheless make reimbursement of the costs incurred in that Member State subject to prior authorisation. Costs incurred in the State of insurance are not subject to that authorisation.”

Nevertheless, governments can feel obliged to amend existing legislation in order to bring it into line with the regulation or preliminary ruling.

Not all Member States adopted a formal position in regard to the Decker ruling or documented one in the course of a preparatory meeting in November 1998 for the German Presidency (Gobrecht 1999).

5.1 Impact of the "Decker ruling" in Germany

In Germany, the Decker ruling caused a sharp political response (Wismar & Busse 1998). With the 2nd SHI Restructuring Act of 1997 (i.e. before "Decker"), the previous conservative-liberal parliamentary majority had expanded the choice between the customary benefit in kind principle and the cost-reimbursement procedure to all insurees while it had previously been restricted to voluntary members (i.e. those who have a choice between SHI and substitutional private health insurance). The earlier restriction was re-introduced with the Act to Strengthen Solidarity in SHI which was passed by Parliament late in 1998, i.e. after "Decker". The objective was to roll-back all those market mechanisms which were believed to cause social inequalities or to undermine solidarity. This restriction met the firm criticism especially of the liberal party which did repeat its opposition to the measure even a year later during the debate of the Reform Act of SHI 2000 (Deutscher Bundestag 1999).

In a draft version of that Reform Act of SHI 2000, clarification in regard to the Decker ruling was planned, but for unknown reasons it was finally abandoned. The original amendment stated that insurees, who are eligible for cost-reimbursement in the domestic territory, could submit claims from all EU Member States. Additionally, there were plans to allow those (mandatory) insurees who had chosen the option of cost-reimbursement previously to be granted this right again. This was in reaction to the protest especially by pensioners who live for longer periods in the south without giving up Germany as country of residence.

5.2 Impact on pharmaceuticals in Germany

These legal activities limiting consumer choice of medical goods across borders can be contrasted against legal provisions made in regard to pharmacies and parallel and re-imports of pharmaceuticals[20]. Parallel and re-import pharmaceuticals do play a role in regard to consumer choice in prescribed medical goods. Parallel imports are those which were produced abroad by companies linked to German producers but imported by an independent import company parallel to the distribution channel of the resident company. Re-imported pharmaceuticals are those which were produced by a domestic company and exported to markets abroad and then re-imported to the market of origin by an independent company. The incentive for both parallel imports and re-imports is the pricing differences of pharmaceutical goods across Member States.

The Health Care Reform Act of 29th December 1988, which came into force on 1st of January 1989, required through §129 SCB that all pharmacies have to hold stocks of cheap imported pharmaceuticals for consumers. This rule was abolished due to doubts that such a legal provision might not comply with the rules of a free market. Nevertheless, the federal associations of sickness funds and the German Pharmacists' Organization (*Deutscher*

[20]In the strict sense, re-imports and parallel imports do not fall in the scope of this chapter, because it is not the consumer that moves across the border but the good. Nevertheless, it is briefly dealt with to draw a more complete picture from the consumers' point of view.

Apothekerverband) agreed to have import pharmaceuticals in stock as long as they are at least DM 1 cheaper than the comparable product on the German market.

6. Outcome

6.1 The outcome of the "Decker ruling"

Despite the harsh reaction of the former German government in regard to the "Decker ruling", sickness funds felt obliged to comply with the new legal situation. The telephone interviews conducted in 1998[21] produced evidence on the cost-reimbursement of costs incurred abroad[22].

According to the sickness funds, prescriptions issued by a physician can generally be used in every Member State, provided that foreign pharmacies, opticians or medical suppliers accept the prescription. The application of an E-form or the pre-authorisation procedure is necessary neither for acquisition nor for reimbursement of medical goods. Therefore, the German liaison office for SHI ("Deutsche Verbindungsstelle Krankenversicherung Ausland") is not involved.

Cross-border purchases of medical goods require the cost-reimbursement procedure because the sickness funds do not have a direct link to pharmacies, opticians or in the medical suppliers abroad and are therefore unable to clear the bill directly in terms of the "benefit in kind" procedure.

Obviously there are variations in the handling of cost-reimbursement. The Kaufmännische Krankenkasse Hannover (KKH) asks the foreign health insurance before reimbursing the patient which costs would have been reimbursed there in the same case and uses this amount as a measure for its payment. The Barmer Ersatzkasse (BEK) reimburses the costs at the price of the most favourable contract provider after individual case examination only. If a therapeutic aid is purchased abroad, maintenance and guarantee from the side of the health insurance and at the expense of the health insurance are excluded.

In regard to pharmaceuticals the patient also receives the equivalent quality and the same active substance in the other Member States, in accordance with European licensing regulations, and in addition, if possible, the same volume. However, differences in package size and in the appearance of the package are possible[23]. The German SHI funds only reimburse the costs of pharmaceuticals according to German law, the pharmaceutical guidelines and in accordance with the German contracted rates, i.e. minus a rebate of 5% which German pharmacies have to give to sickness funds and minus the patient's co-payment. Additionally, the patient has to cover costs above the German reference price.

The case of therapeutic appliances appears more complicated than pharmaceuticals. In the case of eyeglasses purchased abroad, the insuree receives the fixed subsidy for the eyeglass lens according to German reimbursable prices. Frames of eye glasses are generally not reimbursed, however. Payment occurs at maximum up to that German price level, yet never more than the invoice amount. That means that the insured can never make a profit but may save money by purchasing pharmaceuticals or eyeglasses abroad.

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[21] Telephone interviews were conducted in August 1998 with major SHI funds (Allgemeine Ortskrankenkasse, AOK; Techniker Krankenkasse, TK; Deutsche Angestellten Krankenkasse, DAK; Barmer Ersatzkasse, BEK; Innungskrankenkasse, IKK; Kaufmännische Krankenkasse Hannover, KKH; Gmünder Ersatzkasse, GEK). Local offices were chosen in order to get as close to operational business as possible.

[22] Question in the structured interview fell in four categories: pharmaceuticals, small appliances (eyeglasses), expensive appliances (wheel-chair), denture.

[23] This applies theoretically to eyeglasses and wheel-chairs, too, according to statements of sickness funds.

Most German SHI funds have a pool of therapeutic aids and appliances which need not be made up for each insured person individually (wheel-chairs, walking aids etc.). The patient only borrows the appliance from this pool, i.e. they do not pass into the possession of the patient. Generally, the permission of the sickness fund must be given first, as in Germany, before medically prescribed therapeutic aids or appliances can be purchased. The legal requirements for cost-reimbursement of therapeutic aids or appliances are laid out in the SGB V. According to § 13 and § 126, the dispensary supplying the therapeutic aids has to be a contracting party of the health insurance. Therefore, reimbursement of costs for therapeutic appliances acquired abroad might be possible merely in individual cases after precise examination.

All sickness funds interviewed would grant the fixed cost subsidy – which was used at that time but has since been abolished in favour of co-insurance – for dentures purchased abroad only under certain conditions which again vary from sickness fund to sickness fund. The Techniker Krankenkasse (TK) grants the fixed cost subsidy only if the denture was made in Member or in countries with which a Social Security agreement exists to regulate the terms of settling the account. The Allgemeine Ortskrankenkasse AOK demands a certification that the dentures correspond to German high-quality standards (expert opinion, equivalence certification). The BEK excludes guarantees in the case of foreign dentures purchased at its expense.

One of the reasons to expect (more) cross-border consumer choice are price differentials. Yet, knowledge on pricing of medical goods across Europe is limited. But both patients and the competent financing institution may have an incentive for cross-border consumer choice as Table 5 suggests for dentures

Table 5: Price indices (purchasing power parity / average hourly wage in manufacturing industry) for selected dental care procedures in 1999 (Germany = 100)

	CH	D	DK	F	GB	NL	H
crown	149/161	100/100	178/149	199/290	44/49	100/111	72/183
cast metal bridge	140/150	100/100	264/221	278/405	n.a.**	144/161	145/365
full porcelain bonded bridge	88/95*	100/100	158/132	177/258	35/39	81/90	60/150
metal cast denture (frame prosthesis)	91/98*	100/100	130/109	207/302	42/46	99/111	49/123
total prosthesis	132/141	100/100	139/117	251/365	28/31	77/86	63/159

* only dentist's honorarium; **is not part of the benefit package and only asked for seldomly by private patients

Source: Kaufhold & Schneider 2000

6.2 Pharmaceuticals: parallel and re-imports

It is estimated, that parallel trade within the European Union could reach annual growth rates of up to 5-12%. In 1995, the Federal Constitutional Court in Germany ruled that wholesalers have to take parallel imports and that pharmacies also have to stock the cheapest product. As a result, importers and wholesalers save money, but they also have to spend extra money on licences for the import and the re-labelling of the drugs as well as for instruction leaflets.

According to information of the Statutory Health Insurance and pharmaceutical importers, the total amount of turnover of parallel- and re-importing is about DM 700 million per year. This is equivalent to a rate of less than 2% of the total amount of prescribing turnover. A survey of the Federal Association of Pharmaceutical Manufacturers

(*Bundesfachverband der Arzneimittelhersteller*) – representing the non-prescription manufacturers – found that the most important countries of origin for parallel- and re-importing of pharmaceuticals are Greece and Portugal and then by a wide margin Belgium, Italy and Spain (cf. chapter on pharmaceutical market in Sweden). There has to be a minimum difference of 10% of the consumer price, for the importing to be profitable[24].

6.3 Unintended effects

At Community level, two basic intentions can be distinguished, one relating to secondary legislation and the other one to the TEC.

In regard to the former, Regulation EEC 1408/71's main intention was to ensure that EU citizens who are eligible for health care provision under a national health service or an insurance system can obtain access to the health care system of the state where they reside. EU citizens should not be deterred from exercising their free movement because of a possible loss of social security rights. In this respect the intention of Regulation EEC 1408/71 was to facilitate in the first place a European labour market. The objective was to link national social protection systems so that they interact or provide the migrant with a constant social protection (van der Mei 1998). Nevertheless, it was demonstrated, that the legal provision laid out in regulation EEC 1408/71 goes – at least in theory – beyond the mere European labour market perspective. From that point of view, the development towards an extended consumer choice in prescribed medical goods was not intended.

Approaching the issue from the TEC, the conclusion in regard to unintended effects is somewhat different. From the point of view of Community policy the attack on the "benefit in kind" principle is probably the most important unintended effect of the current developments. Although economists who favour market-like organisation of health services have always argued that the "benefits in kind" principle blurs the financial transparency of service provision – and is a source of inefficiency and waste and restricts the consumer sovereignty of patients – throughout the Member States the benefit in kind principle is still favoured. The argument go that the patient usually meets the provider of services under circumstances which are characterised by various asymmetries and, probably more importantly that, due to contractual arrangements, the "benefits in kind" principle allows better expenditure control.

Although the previous German government had strong views in regard to the Decker ruling and the influence of European legislation and jurisdiction, the current coalition government in Germany was far more moderate – if not tentative in its conclusion. Its first Minister of Health, Andrea Fischer pointed out that the accelerating economic integration inevitably has a growing influence on the structures and contents of health care systems (Fischer 1999). In this respect, restriction of free choice between the benefit-in-kind and the cost-reimbursement principle with the Act to Strengthen Solidarity in SHI was not so much a reaction to the assumed growing influence of Brussels on the German health service. It was far more an attempt to roll-back policies introduced by her predecessor, such as the increase in co-payments, the exclusion of services covered by SHI etc. (Busse & Wismar 1997). The idea was to eliminate elements of health care legislation with market character in so far as they were suspected of undermining solidarity.

[24] Arzneimittel für Europa, published by Arzneimittel Zeitung, 11th Edition, 1998: 24-8.

7. Comparison – Spain, Sweden and the UK

The outcome of the Decker ruling on the German health service was quiet unique compared to other countries for various reasons.

7.1 Cost-reimbursement

Among the Member States analysed in this project, Germany was the only one which endowed its insurees – at least for a certain span of time – with the universal right to cost-reimbursement. Therefore, the Decker ruling was directly relevant to Germany but to the other countries with NHS-type systems delivering medical goods in kind (or not at all).

In Spain, a 1967 Royal Decree permitted the reimbursement of costs in case of emergency and of unjustified refusal to provide health care. Today, the Spanish Royal Decree 63/1995 limits reimbursement to "cases of urgent, immediate and crucial health care for patients that have received care outside the National Health System. In these cases costs are reimbursed, once it has been proven that the National Health Services could not be used appropriately and that it is not an abuse or deviation of this exception".

From Sweden rather anecdotal evidence is reported from the handling of cost-reimbursement issues in regard to both 1408/71 and the Decker ruling. First of all, medically necessary treatment beyond the scope of E 111 (short term stay) seems to be ruled out. That implies that regulation EEC 1408/71 and especially the pre-authorisation procedure is handled very restrictively. In turn, cross-border consumer choice in prescribed medical goods is allegedly not taking place. According to information from the National Social Insurance Board, the Decker ruling was not regarded as providing a precedence. It was suggested rather that, if a patient should refer to the Decker case, this should be treated on an individual basis. Planned medical treatment, except in special cases – e.g. for dialysis or oxygen treatment – was more or less ruled out. However, an excessive waiting period for treatment could qualify for medical treatment abroad with cost reimbursement. Nevertheless, no reports on such cases were found.

In the UK cost reimbursement is literally unknown. At least until recently, the NHS lacked institutional, organisational and technical facilities to organise cost-reimbursement.

7.2 Benefit packages

A pre-condition for consumer choice of prescribed medical goods under 1408/71 is that the competent state and the Member State of the competent institution both have the desired item in their benefit packages. Yet, very little is known about what is in the benefit packages across Member States.

In Spain, the Royal Decree 63/1995 establishes a common frame for medical goods and services covered by the National Health System. In regard to dental care as specified in this catalogue, primary dental health care comprises: a) information and education regarding dental hygiene and health, b) preventive and care measures: administration of topical fluoride, obturations, seal of fissures with topical fluoride and other measures for children, according to the funding and the special dental programmes each year, c) acute orthodontic care including teeth extraction, d) preventive mouth exploration for pregnant women. On the basis of this catalogue, most dentures and prosthetics seem to be excluded from the benefit package (with the exception of the Basque Country where a more generous dental benefits' basket exists).

Dentures are, in principle, covered in the Swedish health service. Although, due to the decentralised organisation of the service, there seem to be some variation in access and user charges.

Table 6 shows that in many European countries dentures are not part of the benefit package, i.e. result in 100% user charges.

Table 6: User charges* in selected dental care procedures/goods (in per cent in 1999)

	CH	D	DK	F	GB	NL	H
crown	100 %	100 %	42-55%**	93 %	80 %	100 %	100 %
cast metal bridge	100 %	47-59 %	100 %	92 %	n.a.	100 %	100 %
full porcelain bonded bridge	100 %	78-84%**	100 %	93 %**	80 %	100 %	100 %
metal cast denture (frame prosthesis)	100 %	35-50 %	100 %	86 %	80 %	100 %	100 %
total prosthesis	100 %	35-50 %	100 %	89 %**	80 %	25 %	100 %

* without private complementary insurance; ** calculated per-cent

Source: Kaufhold & Schneider 2000

7.3 Distribution of prescribed medical goods

A further reason for the limitation of free consumer choice in prescribed medical goods is the specificity of the goods themselves. They are either only available in special shops, they do not always pass into possession of the patient or they need a national certificate to prove its quality.

In Germany, patients cannot buy their own dentures. The order for the denture is sent directly from the dentist to the dental laboratory which is accredited to the SHI. The dentist invoices the patient (for the co-insurance part) and the Regional Association of SHI Dentists (*Kassenzahnärztliche Vereinigung*) which in turn has contracts with the sickness funds. The cross-border purchase for denture or prosthetic parts by a German patient for his treatment in Germany is therefore impossible.

Therapeutic appliances may only be delivered to insured persons by authorised service providers. Authorisation is granted to service providers who guarantee a sufficient, expedient, functional and economical production, delivery and adaptation of therapeutic appliances and who recognise the declarations valid for supply to the insured (§ 126 SGB V). The federal associations of sickness funds are jointly drawing up a list of therapeutic appliances. In this register all therapeutic aids which must be provided by the SHI are listed and the intended reference prices are to be indicated (§128 SGB V). Only the products recorded in this list of therapeutic appliances can be prescribed at the cost of the SHI.

Quite similar distribution channels exist in Sweden. According to the Health and Medical Services Act appliances are tested individually. Most of the appliances do not pass into the possession of the consumer, but are owned by the county council. More than 90 per cent of all the appliances in Sweden are tested by a special institute. This institute also gives recommendations to the county councils which appliances should be used. But it is always the physician or the expert who helps the consumer to choose the appliances. Therefore, it is almost impossible to choose appliances across borders.

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