Part II

Single European Market legislation and jurisdiction

Analysis of SEM legislation and jurisdiction

Matthias WISMAR and Reinhard BUSSE

Abstract. The creation of the European dimension in the health service started immediately after on the formation of the EEC. In total, a substantial number of 233 Single European Market interventions with at least potential effects on the health systems of the Member States could be identified. About two thirds originate from Community policy and one third from the European Court of Justice. These interventions are usually based on highly effective instruments, particularly directives and requests for preliminary rulings. The regulation density is particularly high as regards the free movement of persons and goods, especially in the area of pharmaceuticals. On the whole, the supply side is affected by more interventions than the demand side.

1. Europe is regulating – the scope of the regulatory measures

Over a period of more than 40 years (1958 to June 1998), 233 legal documents which met the inclusion criteria – i.e. referring both to health services and the SEM – were identified (Table 1). When allocating them to the categories defined for each of the four freedoms, it was necessary to make multiple citations. Comprehensive documents, in particular, such as Regulation 1408/71, had to be allocated to several categories. A total of 17 interventions were allocated several times.[1] Thus the total number of interventions with potential effects on the individual categories amounts to 260 data records.[2] An analysis revealed that the ECJ represented 35 % of interventions, clearly playing an important role in terms of the number of interventions.

Table 1: Single Market legislation and judicial decisions of the Community institutions with potential health service effects in the Member States 1958-30.6.1998

	Number of interventions identified	Total number of interventions allocated	Total number of interventions (%)
Community policy		168	65 %
ECJ		92	35 %
Total	233	260	100 %

[1] Regulation 1408/71 was allocated six times, Regulation 2001/83 five times, Regulation 1290/97 four times and Regulation 1390/81 three times. All other multiple cited interventions were allocated only twice.

[2] This second figure represents the total number of interventions for all calculations and statements unless otherwise stated.

2. The dynamism of the regulatory process

The total number of interventions already indicates that the interventions of Community institutions with potential effects on the health systems of the Member States are not just a recent phenomenon. The analysis of the time series (Figure 1) demonstrates that, from the very inception of European integration, Community institutions were at least co-regulating aspects relating to the regulation, financing or delivery of health services.

As early as in 1958, shortly after the formation of the EEC, "Regulation No. 3 on the Social Security of Migrant Workers" regulated the social security status of persons moving across national borders.

After sporadic interventions in the sixties, the beginning of the seventies saw regular regulation on the part of the Community institutions. Although this was subject to fluctuation, it is evident that there was an increase in the frequency of interventions until at least the mid-90s.

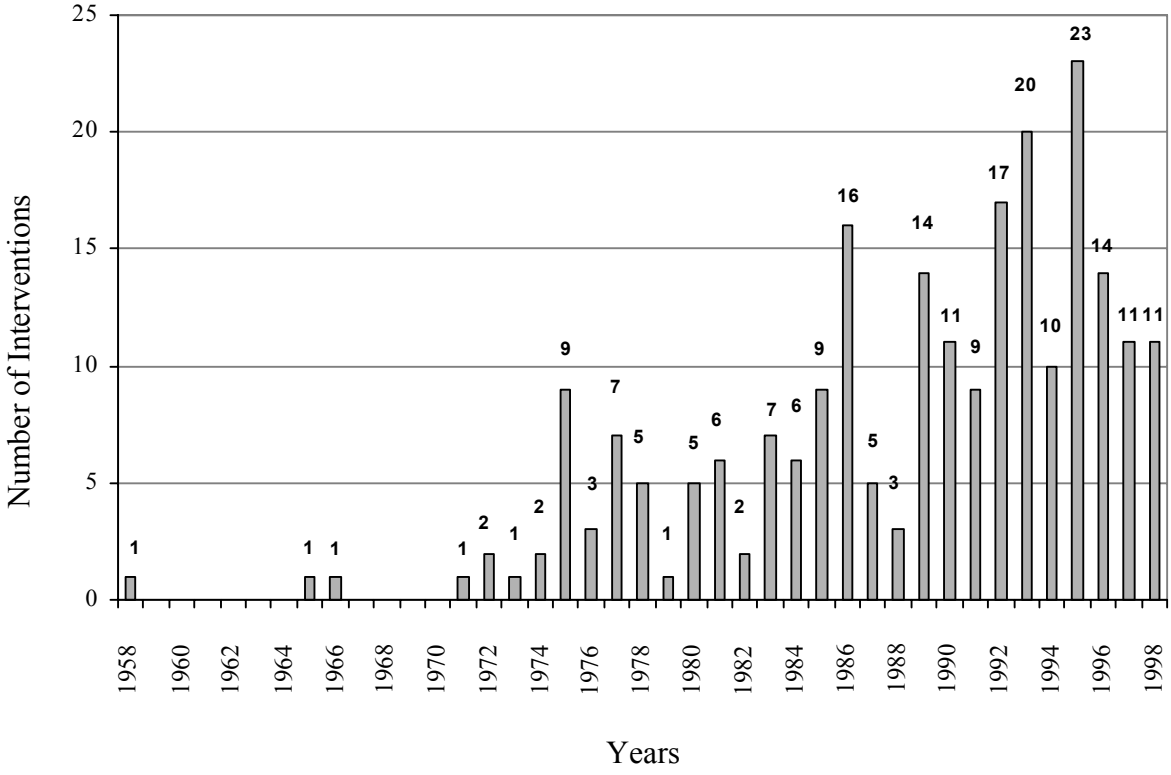

Fig. 1: Dynamism of SEM legislation and judicial decisions with potential health service effects in the Member States 1958 to 30.6.1998

3. Regulation according to categories

An initial assessment indicates the particular frequency of interventions for the interfaces of the free movement of persons and goods with the health system. In total they combine 248 interventions. This corresponds to 95 % of the total number of interventions found (Table 2). If the total number of interventions is broken down according to interventions on the supply side and interventions on the demand side, the regulation of the supply side prevails (Table 3).

Table 2: Allocation of the interventions according to the "four freedoms"

	The free movement of persons	The free movement of goods	The free movement of services	The free movement of capital	Total of the four freedoms
Number	128	120	12	0	260
Percentage	49 %	46 %	5 %	0 %	100 %

Table 3: Allocation of the interventions to supply side vs. demand side

	Supply side	Demand side	Total
Number	175	85	260
Percentage	67 %	33 %	100 %

While this allocation of interventions in relation both to the "four freedoms" and to the supply side and the demand side already reveals a certain imbalance, the picture can be further clarified by an analysis of the allocation of the interventions to the individual categories, i.e. "intervention density" which, in terms of quantity, focuses on the particularly active interfaces between Single Market integration and health services.

For the free movement of persons (Figure 2, white columns 1-5) it is evident that "short-term stay" and "Data exchange and protection", with 11 and 3 interventions respectively, have a considerably lower intervention density than the other categories.

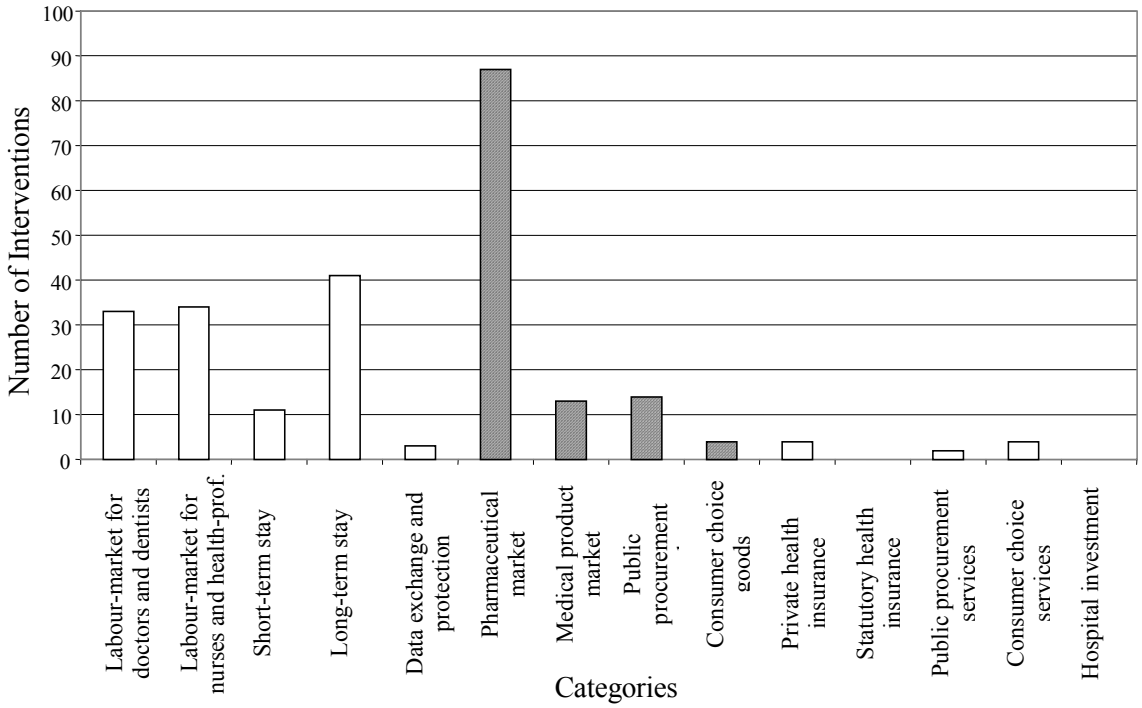

Fig. 2: Intervention density according to categories

A different picture results from the analysis of the categories for the free movement of goods (Figure 2, black columns 6-9): One category – "Pharmaceuticals market" – quite

clearly predominates and, with 87 interventions, reaches the highest regulation density of all categories.

For the categories of the free movement of services (Figure 2, white columns 10-13) the regulation density is considerably lower in comparison with the previous freedoms, although more equally distributed. It is strikingly apparent that no intervention for "statutory health insurance" – in the sense of offering insurance – could be identified.

For the category "hospital investment" (Figure 2, column 14), which falls within the sphere of the free movement of capital, it was not possible to identify any intervention.

4. The "penetration power" of the instruments of the Community institutions

The previous stages of the analysis have shown that there is a large body of legislation and judicial decisions at the interface between Single Market integration and health services, that this is a dynamic development and that it is of particular quantitative significance for certain categories.

In order the gauge the qualitative significance, a further analysis examined the instruments with which the institutions of the EU intervene. This analysis provides information concerning the addressees, the effects, the contents and the form of the interventions. In this way conclusions can be reached concerning the potential significance of the instruments. This is referred to as "penetration power" (i.e. how effectively they penetrate national legislation and regulation).

Table 4: Instruments of Community policy

	Instrument				
	Regulation	Directive	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

Community policy has five instruments (Table 4) – regulations, directives, decisions, recommendations and other resolutions – of which the weakest instrument is "recommen-dations". Recommendations are generally addressed to all Member States and thus have a universal character, but they are not binding in any way. The instrument "Other resolutions" are binding, but are exclusively addressed to the institutions and the administration of the EC. These resolutions have no potential direct effect on health services. However if the institutions of the EU are reformed by resolutions in such a way

that this results in institutions whose organisational objective has potential effects on the health systems of the Member States, these are included in our survey. “Decisions” have a universal character and are binding. However they regulate individual cases and not general matters. (For example, new pharmaceuticals approved by the European Agency for the Evaluation of Medicinal Products are licensed via a directive; this type of directives has, however, been omitted here in order to avoid distorting the numbers.)

The instruments which are particularly relevant and which have a binding, general and universal character are, without any doubt, “directives” and “regulations”. A directive defines an objective which all Member States need to achieve. The means employed to achieve the objective are, however, a matter for the Member States. A regulation harmonises not only the political objectives, but also the means and can thus be regarded as the most powerful instrument in Community policy.

In the section of Community policy under investigation considerable use is made of powerful political instruments (Figure 3). Regulations and directives together account for 124 interventions, which corresponds to a proportion of almost 80 % of all interventions of Community policy. Directives alone account for 81 interventions – or 75 if double allocations are omitted. To put this number into perspective, the total number of SEM directives in force in May 1999 was 1405 (Single Market Score Board No. 7 [November 2000]), i.e. 5 % of them have at least potential effects on health services.

In addition to Community policy, the ECJ plays an important role in the field (see Table 1). Of the six instruments of the ECJ, four are only of minor significance for the area of health services (Table 5). Proceedings for annulment, proceedings for failure to act and actions for damages always relate to the actions of the Community institutions or to their failure to act and are not directly relevant to the Member States. The same applies to appeals heard by the ECJ, the so-called remedies.

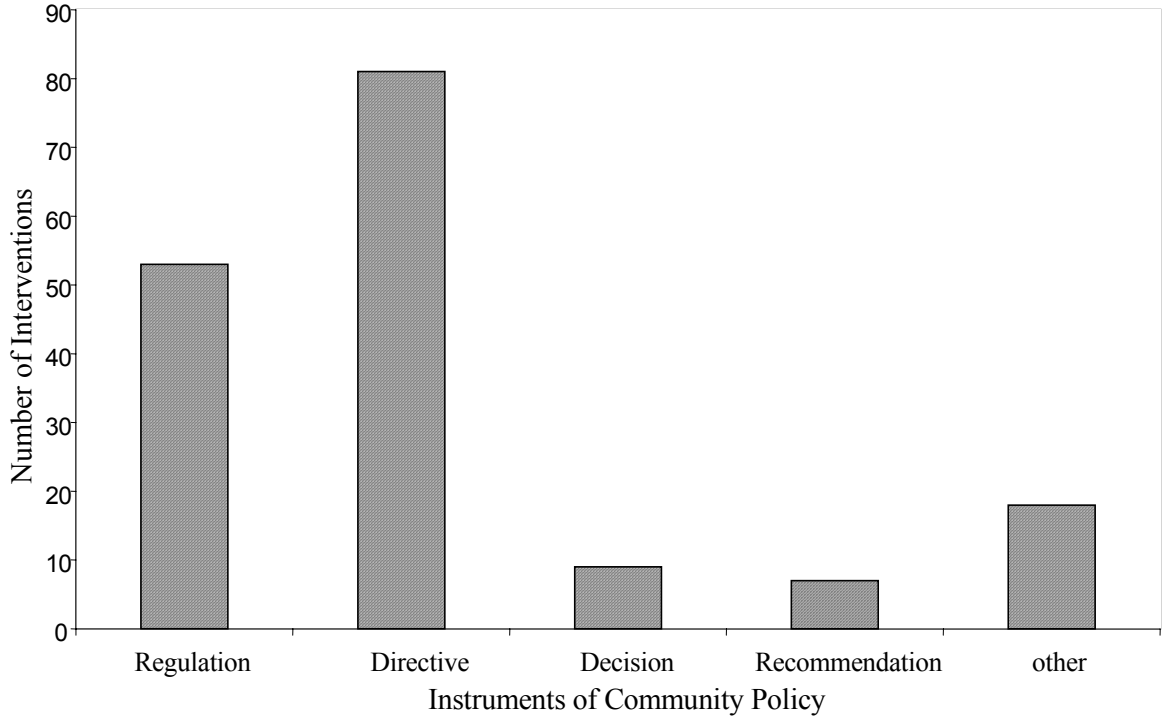

Fig. 3: Instruments of Community policy according to the number of interventions

The instruments of the ECJ which are relevant to the analysis are the request for a preliminary ruling and proceedings for failure to fulfil Treaty obligations. Both types of

proceedings are engines of European integration. One is aimed at bringing about a harmonisation of interpretation and application of Community law and the other at enforcing its implementation in the Member States.

Table 5: Instruments of European jurisdiction

	Instruments					
	Proceedings for failure to fulfil Treaty obligations	Proceedings for annulment	Proceedings for failure to act	Actions of damages	Remedies	Requests for preliminary rulings
Objective	Examination as to whether Member States have complied with their obligations under the EC Treaty	Examination of the legality of the actions of Community institutions	Examination of the legality or the failure to act of a Community institution	Clarification of the Community's liability outside the Treaty obligations	Clarification of legal questions	Harmonisation of the interpretation and application of EC law
Defendant	Member State	Community institutions	Community institutions	Community institutions or their employees	Court of first instance	
Plaintiff	Commission; Member States (seldom)	Member States; Council; Commission; Parliament (under certain circumstances); individual persons affected	Court of Justice	All natural persons or legal entities	Parties to the proceedings	All courts can, and in the last instance must, request a preliminary ruling in as far as the matter concerns EC law
Sanctions	Payment of a lump sum or a fine	Declaration of annulment pertaining to legal acts of the Community or parts of such acts	Formal complaint			

The most common type of proceedings are requests for a preliminary ruling, which account for 73 % of all types of ECJ interventions with at least potential effects on health services (see Figure 4). This type of proceedings also has particular significance outside the health care area. The 1997 statistics on the rulings of the ECJ show that requests for preliminary rulings accounted for 66 % of all proceedings in which judgements were announced. This type of proceedings has the objective of bringing about a consistent interpretation and application of EC law throughout the whole of the Community. Only courts of the Member States may request a preliminary ruling from the ECJ. This will be the case if the outcome in a national case is largely dependent on Community law. The ECJ decides how European law should be interpreted with binding effect. The ruling on interpretation is returned to the national court which then has to apply the law as it has been interpreted by the ECJ. The request for a preliminary ruling is therefore a very important hinge between EC law and the national courts. This hinge function is intended to make national courts “guardians of Community law”.

The much-discussed cases of Kohll and Decker were preliminary rulings. The idea that the ECJ, with its rulings on the Luxembourg disputes, judged merely on individual cases that have no import outside Luxembourg and are without general application cannot be sustained in view of the significance of Community law, the function of the ECJ, the effect of this type of proceedings and the close interrelationship between the ECJ and the national courts.

The second most common form of proceedings are proceedings for failure to fulfil Treaty obligations. This type of proceedings accounts for 21 % of all types of ECJ interventions identified. They enable the ECJ to ascertain whether the Member States are honouring their obligations under the Treaty. This type of proceedings can be brought by the Commission and also by the Member States. The ECJ pronounces its judgement at the end of a staged procedure. If the Commission is of the opinion that a Member State is in breach of its obligations under the Treaty, it first sends a formal notice and then a reasoned opinion (as laid out in Article 226 of the Treaty). Member States are required to respond to such infringement letters within a certain deadline. If the Member State allows the time limit for submitting such a statement to lapse or if the Commission regards such a statement as being inadequate, it may then initiate the next stage of the proceedings by bringing the case before the ECJ. The ECJ will then ascertain whether the Commission is justified in its view. If the Commission is of the opinion that the Member State has failed to comply with the ruling of the ECJ within a certain time limit, it will initiate the final stage of the proceedings. Now the ECJ has to find whether the Member State in question has failed to comply with its obligations. The ECJ may impose the payment of a lump sum or a fine.

With a total of 86 interventions (or a proportion of 93 % of all interventions on the part of the ECJ) proceedings for a preliminary ruling and proceedings for failure to fulfil Treaty obligations are the major instruments applied. For both cases one can safely assume a considerable penetration power.

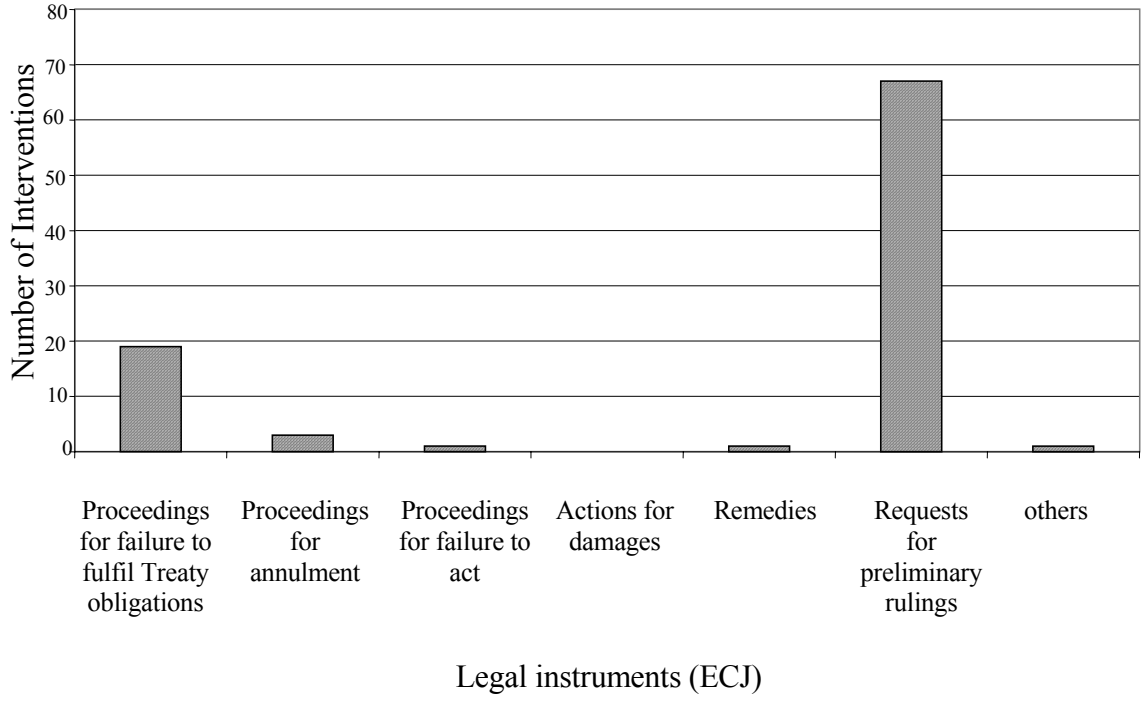

Fig. 4: Instruments of the ECJ according to the number of interventions

5. Summary and conclusions

This chapter has taken a closer look at the fictional separation between the SEM on the one hand and health services on the other in terms of both quality and quantity. It has assessed the interventions of Community policy and the European Court of Justice (in relation to the four Single Market freedoms) with at least potential effects on the health systems of the Member States in terms of the number of interventions, their frequency and timing, and the regulation density for various health service categories. The results can be summarised as follows:

- The creation of the European dimension in the health service did not first come about with the ECJ rulings of April 1998, which attracted such wide public attention, but was commenced directly on the formation of the EEC.
- Since the seventies the frequency of interventions has become more dynamic and peaked in the first half of the nineties.
- In total, a substantial number of some 250 interventions with at least potential effects on the health systems of the Member States could be identified. About two thirds originate from Community policy and one third from the European Court of Justice.
- The interventions which have potential effects on the health systems of the Member States are usually based on highly effective instruments, particularly directives and requests for preliminary rulings.
- The regulation density is particularly high as regards the free movement of persons and goods. The interventions affect the EU-wide labour market for physicians, dentists and other occupations in the healthcare sector on the one hand, and short-term and long-term visits by tourists, employees etc. on the other. The intervention density as regards the free movement of goods can mainly be explained on the basis of the markets for pharmaceutical products. On the whole, the supply side is affected by more interventions than the demand side.

Transposition of European directives into national legislation

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Abstract. This chapter concentrates on the transposition of SEM directives as they need to be formally implemented on the Member State level. In the case of the Federal Republic of Germany with its 16 Länder, sometimes several dozens of transposition measures such as laws or ordinances are necessary for full transposition, a process which often also takes considerable time. Similarily, the strong role of Swedish counties in healthcare leads to several transposition measures per directive while in Spain the number is lower. In comparison, a variety of transposition patterns emerge.

1. Instruments and transpositions

According to the analysis in the previous chapter, on a European level there are four principal instruments which have proved to be potentially powerful in their effect (Table 1). Of these four instruments, only directives can be subjected to any meaningful and feasible analysis of the incorporation of European legislation and court rulings into national legislation and regulations ("transposition").

Table 1: Relevant instruments of legislation and judicial decisions of the Community institutions and their mechanisms of implementation

	Community policy		**ECJ**	
Instrument	**Regulation**	**Directive**	**Proceedings for failure to fulfil Treaty obligations**	**Proceedings for a preliminary ruling**
Transposition	No transposition, no account needs to be given	Transposition; account needs to be given	ECJ examines transposition	"Transposition" is the decision of referring court
Result	No research possible	Research possible	Research is possible in principle but rare	Research is possible in principle but rare

The reason for this is that directives only specify the objectives, but not the measures themselves. Member States not only decide the appropriate measures to attain the objectives, but also the legislative means which are appropriate to the circumstances. Member States are under an obligation to ensure that directives are implemented in accordance with their objectives and to report to the Commission, within the prescribed time limits, that directives have been transposed into national law. This means that directives leave "traces" in national legislation. The measures that are selected in the various Member States, the means and the time needed for implementation can be researched and analysed. As a reminder: A total of 75 SEM directives were identified which refer to health services.

In the case of regulations, on the other hand, there is a close interrelationship between the European and the national level. Regulations come directly into force – or within the prescribed time limits – and apply to all EU citizens. They do not need to be transposed into national law and leave hardly any traces that can be researched on the national level (except possible administrative orders).

Proceedings for failure to fulfil Treaty obligations are usually initiated if the transposition of a directive is not communicated in time, or is communicated incompletely, or if the Commission criticises the transposition as not being appropriate to the objectives. In principle, it is possible to find such proceedings. However, as the ECJ is now in a position to impose substantial lump sum payments and fines, most Member States make efforts to avoid such proceedings.

Preliminary ruling proceedings, which in terms of their quantitative and qualitative aspects represent a particularly effective type of proceedings in our investigation, take effect in two ways. First through the judgement of the relevant court which has clarified questions on the interpretation and application of Community law in the preliminary ruling proceedings. Here it can be expected that the court in question will abide by the interpretation. Second, the courts in subsequent judgements can refer to judgements that have already been pronounced. In principle it is possible to search for at least some of the subsequent judgements in databases. However, due to the disproportionate relationship between research effort and results, this was not done in this project. Although it is quite possible that a large number of the preliminary rulings that are relevant can be found in the databases concerned, they would also be cited if the judgement is of only marginal relevance or does not fulfil both criteria for inclusion. The qualitative analysis that would then be necessary would go beyond the scope of the research project, without necessarily enabling any additional insights.

2. Transposition in Germany

2.1 Methodological remarks

In theory, there should be two ways to analyse the transpositions of European directives, either through the body in Germany that is responsible for reporting back to the Commission or through the recipient of that information at the Commission. In practice both methods are only feasible to a limited extent.

On the German side there is a collection office which reports all transposition measures to the Commission. This collection point is at the Federal Ministry for Industry and Technology. From there contact is cultivated with the relevant liaison offices in the individual Ministries and with the Commission. Department 4 at the Federal Ministry for Health (consumer protection, veterinary medicine) collects all transpositions that the Ministry has initiated. This is handled in a similar way in the other Ministries. The Federal Ministry for Industry and Technology then reports the transpositions to the Commission.

Unfortunately, the database at the Federal Ministry for Industry and Technology proved to be unsuitable for the purposes of the study. First, the data it contains only goes back as far as 1980 and secondly it contains sensitive information which could give rise to problems under the data protection laws.[1]

[1] At this point the authors would like to offer their most grateful thanks to the officials of the Federal Ministry for Industry and Technology who were a great help to in every respect, despite the data protection rules.

An attempt to gain access to a database of the Commission containing the transpositions as reported by the Member States also failed – surprisingly, such a database apparently does not exist.[2]

As a way out of the dilemma, it was decided to examine the Juris database which was searched for legislation transposing European legislation on the national level. The Juris database proved useful as a way out of this situation. The Commission reports the implementation reports it receives to Juris. These are entered into the database and are available for a search. The interpretation of the database search commissioned, must be made subject to a number of reservations, however:

- If no report has been received regarding implementation, this can, but does not necessarily have to mean that the directive in question has not been implemented. It is possible that Germany has failed to report the implementation measure or that the Commission has not (yet) passed on the report.
- The report regarding the implementation measure is forwarded over a lengthy route: from the implementing office, via the collection office in the Ministry in question, via the contact point at the Ministry for Industry and Technology, then to the Commission and finally to Juris. Some of the information can get lost along the way (passive postal effect) and this makes it difficult to retrieve when conducting the search.
- In accordance with the federal structure, statutes are published in so many different publication media that it was hardly possible to obtain a clear picture of them and no search can be carried out for them, so that, in some cases, only the report concerning the source was available for analysis.

2.2 The implementation of directives in Germany

A total of 202 transpositions were identified implementing 54 European directives (Table 2), and thus there were no results for 21 out of the total of 75 directives identified during the first stage of the project.[3] As the majority of these directives were issued in the nineties it is quite likely that they are still either at the reporting or the implementation stage.

Table 2: The total number of transpositions in Germany

Total number of directives (without double allocations)	Directives for which no search could be made	Directives with transpositions	Transpositions for those 54 directives
75	21	54	202

If the 202 transpositions are allocated to the categories (Figure 1), it can be seen that once again in terms of quantity, the free movement of persons (columns 1-5) and the free movement of goods (columns 6-9) represent the main interfaces between health services and the SEM. However, the weighting of the intervention density for the individual categories differs from the weighting at both the European level and that found in Spain and Sweden. Thus "Public procurement goods" is regulated by more transpositions than the "Pharmaceuticals market" in Germany, even though the latter has more than twice as many EU directives.

[2] The authors would like to thank Mr Paul Belcher, Head of EHMA's Brussels Office for the research activities in Brussels.

[3] Directives 66/454, 73/240, 76/764, 77/65, 83/189, 83/570, 90/366, 92/25, 92/28, 93/4, 93/36, 93/37, 93/42, 93/93, 94/38, 95/43, 95/46, 96/6, 96/71 and 98/21.

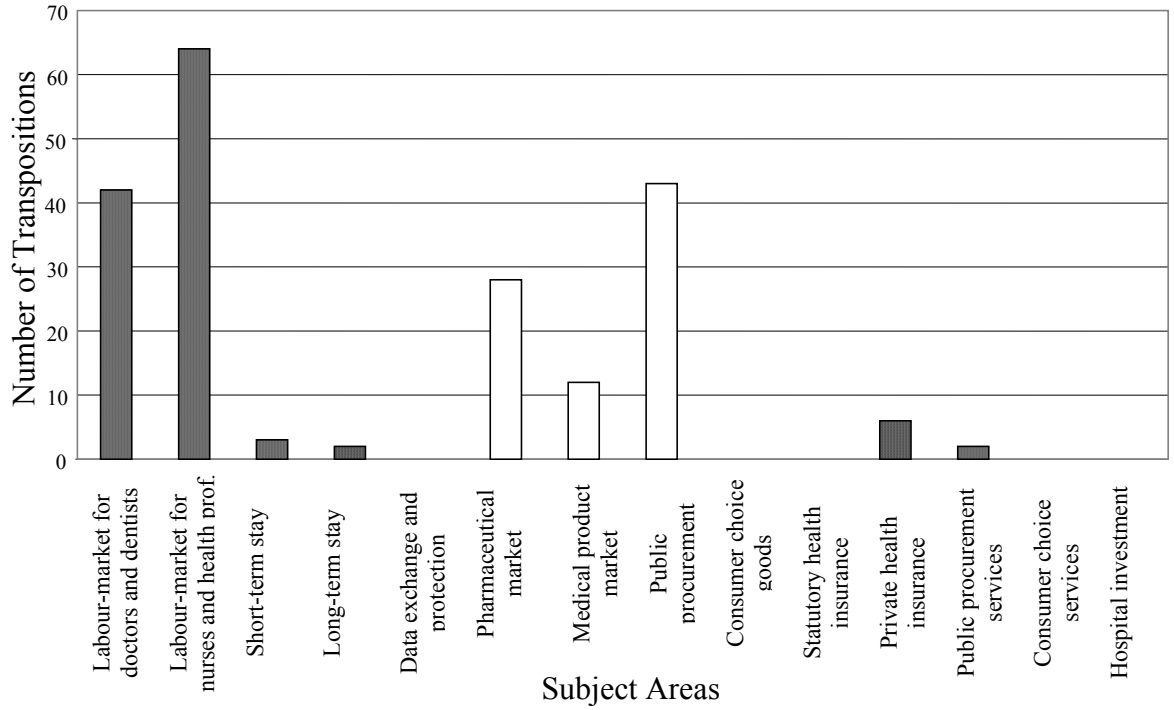

Fig. 1: Number of transpositions in Germany according to categories in the four freedoms

As there are on average almost four transpositions for each European directive; shifts between the subject areas can partly result from the very unbalanced allocation of the transpositions (Figure 2).

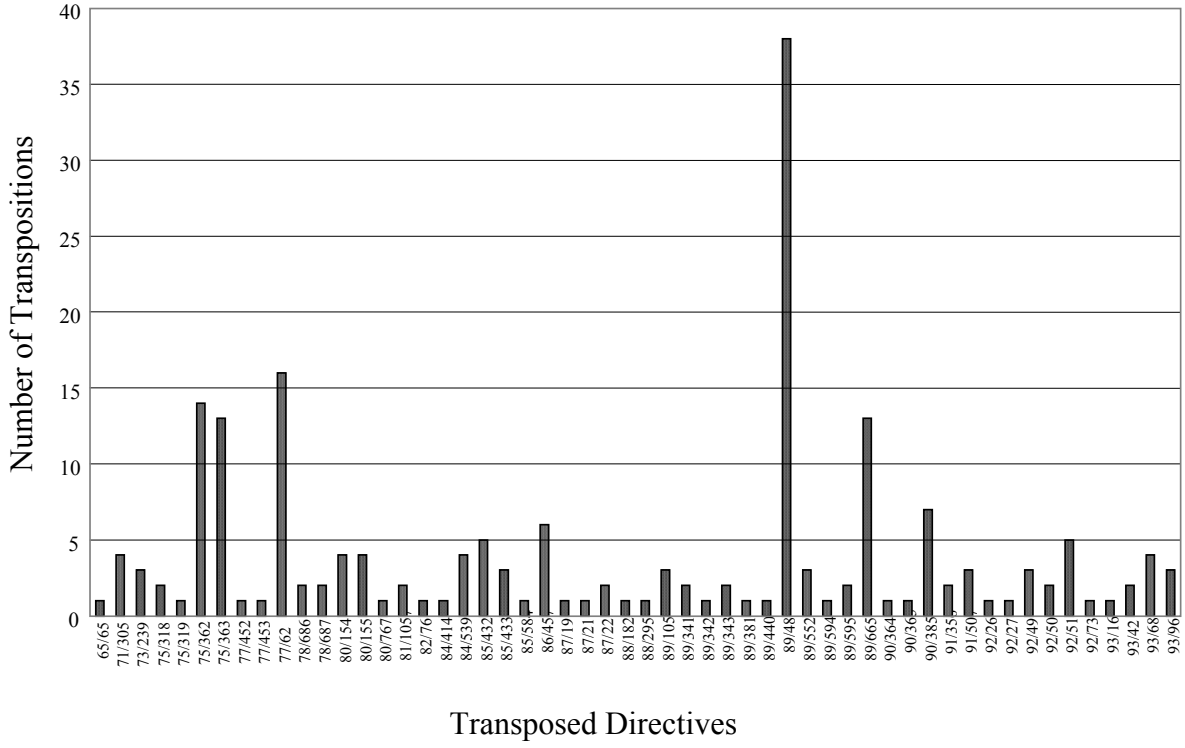

Fig. 2: Number of transpositions according to directives

As far as the implementation of European directives in Germany is concerned, the question of the regulatory strength and thus the type of instruments that are used for implementation must also be considered.

In the section of Community policy under investigation, European directives in Germany are mainly implemented by means of laws and decrees (Figure 3). These two instruments at the level of the Länder and the federal government together accounted for a total of 80 % of all transpositions. This means that the high penetration power of the instruments used, which could already be ascertained at the European level, continues on implementation in Germany.

Out of the 202 transpositions that were identified during the database search, 49 % were initiated at the federal level and 41 % at the level of the Länder. This relative balance of transpositions between the federal government and the Länder has to be interpreted carefully, though, because as soon as a transposition falls within the competence of the Länder, it is usually implemented by the majority of Länder using corresponding measures. The activities of the Länder are therefore counted several times. Thus, more directives at the interface between health services and the SEM are actually transposed at the federal level.

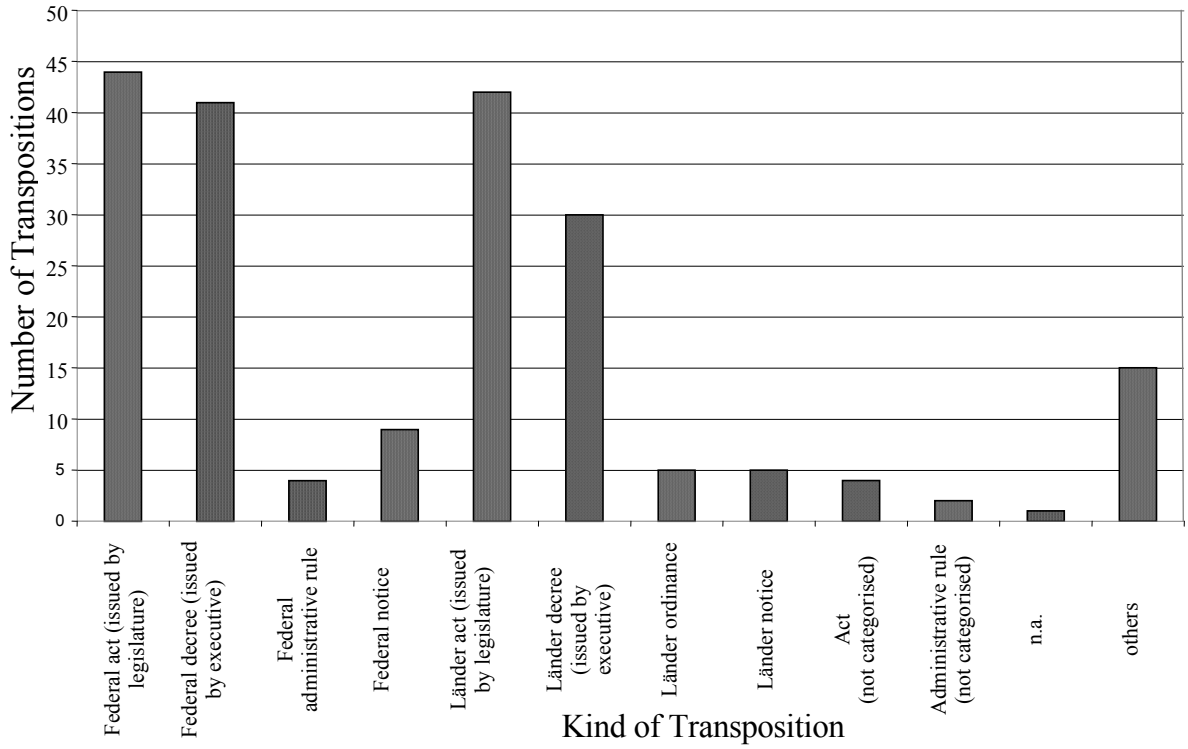

Fig. 3: Transposition measures according to instrument and level of politics

The time taken to transpose directives is of particular interest (Figure 4). Major delays or even the postponement of implementation would in effect suspend European legislation in Germany. While the danger is not the intentional failure to comply with the prescribed deadline for the implementation of the relevant European directive, there is, in a worst-case scenario, a danger of proceedings for failure to fulfil Treaty obligations if one Land does not transpose a directive, perhaps resulting in lump sum payments or punitive fines for Germany as a whole.

However it has proved difficult to determine the exact date of implementation. In Germany, a European directive can simultaneously be implemented through several transpositions and by several agencies, such as the federal government and the Länder, so that

the process can often be a lengthy one. There is also a methodical problem to be considered in interpreting the period required for implementation. Transpositions that have met with no objection over the years can suddenly be examined by the Commission as to whether the Member States implement the directive correctly. For this analysis, the European database was compared with the German one. Out of the 54 European directives for which German transpositions could be identified, 50 contained sufficient information concerning details such as implementation, the date of coming into force, the date that they were passed etc.

In some cases, a negative period of implementation can be noted in Figure 4. This is the case if existing German law complies with European directives that have recently come into force. When the measures were reported to the Commission therefore, the German authorities reported the laws or decrees that guarantee the implementation of the European directives, although some of these were enacted a long time ago. This is an interesting indicator for the fact that not all directives will actually impact upon national legislation.

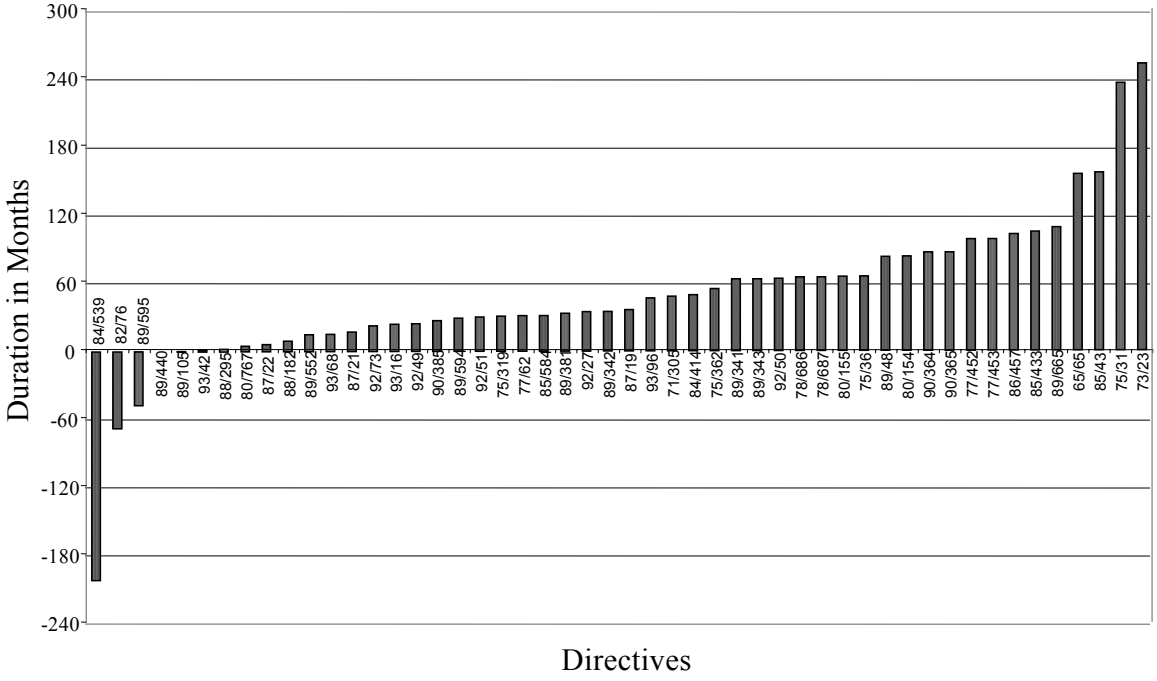

Fig. 4: Time required to implement directives in months

European directives which require no further implementation are, however, a marginal phenomenon. Roughly two fifths of all directives are implemented in Germany only after they have come into force AT a European level, i.e. after the set deadline. However, there are also outliers which required up to 20 years to be fully transposed.

Whether the transposition actually fulfils the requirements of the directive is another matter. For example, the first stage for initiating proceedings for failure to fulfil Treaty obligations in relation to the Third Directive concerning Indemnity Insurance (92/49/EEC) has been commenced with Germany as the defendant. The Commission was of the opinion that Germany, in putting the directive into effect, was in indirect breach of the provisions of this directive. This directive was intended to guarantee the free movement of services for private health insurance. Insurance companies that are domiciled in the Member States of the EU were to have access to the entire SEM. However, a clause was incorporated into the German Social Code Book V (SGB V) which made the eligibility of private health insurance for a premium subsidy by employers dependent on the separation of branches of industry. This meant that private health insurance companies could only offer their services in the field of health care, but not in other branches (SGB V, Article 257, paragraph 5). But

this excluded a number of potential competitors from the German market for private health insurance. In all probability, however, the conflict will be settled amicably. The offending clause is not of central importance.

2.3 Conclusions

The implementation of European legislation in Germany can generally be said to lack transparency. Although the Federal Ministry for Industry and Technology collects the transpositions for the implementation of directives so that they can be reported to the Commission, the data kept by the Commission, just like the data in the Juris database, suffers from the many different types of implementation and the many different implementation agencies involved. Although most directives are implemented at the federal level, there is an increasing number of acts and decrees on the level of the Länder, as it is often also necessary for directives to be implemented at this level. Whether and when implementation has actually occurred is often very difficult - and sometimes impossible - to ascertain under present circumstances. As regards the chronological dimension of transposition of directives into German law, it has been shown that it has usually taken about three years until final transposition was reported. In individual cases, however, it took more than ten years and Directive 65/65 has still not been transposed into German law to the satisfaction of the Commission. The traditionally weak German transposition record has improved however during the study, a fact which might not yet be reflected in the transpositions identified: While in November 1997, it was - together with Belgium – ranked second last failing to transpose 8.5 % of all SEM Directives, that rate had fallen to 2.4 % in May 1999 and 3.1 % in November 2000 – placing Germany at number 5 and 9, respectively (Single Market Score Board No. 7).

3. European Union law and British law

This brief section outlines the procedure for translating European law into British law. First, the UK is not a federal country – although a devolved parliament for Scotland and a devolved assembly for Wales may alter things somewhat. Second, Britain has a record of automatic implementation of EU law. This does not square with the perception of Britain as a "European laggard", but the paradox is that the UK "moans a lot and then obeys" whereas other countries may appear to be "good Europeans" but are then less likely to implement EU laws automatically. (Of course it is useful for British politicians – as for any politicians – to moan about Europe in order to "pass the buck" to Europe for laws which they are' at the end of the day, reasonably happy to translate into British law!) As recently as in November 1997, the UK was fourth after Denmark, the Netherlands and Finland in its transposition of SEM directives record Due to increased efforts in Sweden and Spain and the relatively slow transposition progress in the UK, its position had however decreased to the sixth place by November 2000 (Single Market Score Board No. 1 and No. 7).

It is the responsibility of Member States to "do as necessary" to translate directives into national law. One question (in the UK as elsewhere) is whether the transposition of the Directive requires a new law, a modification of existing law, or overturning of a law? In the UK, in normal circumstances, a strong executive and a compliant parliament with an overall majority of the government means that parliament acts as a rubber stamp. Most contentious issues have been dealt with at the level of the Council of Ministers (or, less likely, the Commission) and once the directive has been framed, the transposition in the UK is an automatic matter. There are, clearly some sensitive issues, but these normally resolved

by the permanent representatives in Brussels prior to the framing of directives. One example was the Directive concerning working hours – exemptions for junior doctors was heavily pushed by Britain.

European law is traditionally transposed into British law in late night sessions which are ill-attended. There is, of course, the well-known anecdote of Mrs Thatcher's Government signing more centralising European legislation than any other British Government in history. The conclusion for Britain is that the transposition of EU directives into British law is not really a matter of interest.

4. The transposition of SEM directives in Spain

4.1 Implementation of EU legislation in Spain

The right to healthcare protection, which is recognised by the Constitution, is looked after at varying levels of public administration. According to the Spanish Constitution, Article 149.1.16, the State has sole responsibility healthcare issues across the Spanish borders, access and entitlements to as well as general co-ordination of healthcare, along with the legislation on pharmaceutical products. The regional governments are widely responsible regarding healthcare, above all in the management and planning of health services, along with further developing legislation within the rules set by the national level. Local councils also have responsibilities in this area, though subsequent to the General Law on Healthcare their resources are included within that of the region. Thus, the range of the norms transposed differs according to the body in charge and whether it is of a fundamental nature or not.

Another factor to be taken into account is the configuration of the national health system in Spain in which, unlike other Member States, and excluding certain regions such as Catalonia or Navarra, the provision of health services is a public service and healthcare is mainly carried out in the public sector.

Alongside transposition control, there needs to be application control. This is one of the major problems posed from a legal point of view, since a norm may be technically transposed but, afterwards, the various practices of the operators or Member States make it inapplicable.

4.2 Methods and results

Spanish ordinances that are affected by and also stem from previously identified legislation were located by means of a systematic search using IBERLEX-UE, a legislative database that provides the national transposition of Community directives.

The number of Spanish transpositions increased gradually over the years and 65 % of the identified 32 Spanish transpositions, mainly in the area of legislation, were passed during the years 1992 to 1994. This rhythm of transposition dropped from 1995 onwards.

As with SEM directives, Spanish legislation on transpositions concentrates on the transposition of directives that regulate the free movement of persons and goods (Table 3). In transpositions concerning the free movement of persons, the most predominant area is that which regulates the job market for nurses and other health professionals (57 % of those found). Legislation transposition regarding the regulation of the pharmaceutical market is predominant among those transpositions identified within the free movement of goods (66 % of those identified).

Table 3: Transpositions in Spain and Sweden – free movement of persons and goods

Free movement of persons					
	Labour market doctors	Labour market nurses	Short-term stay	Long-term stay	Data protection
SEM directives	21		3	3	2
Transpositions in Spain	3	8	1	2	0
Transpositions in Sweden	49		16	10	9
Free movement of goods					
	Pharmaceutical market	Medical devices market	Public procurement goods	Consumer choice goods	
SEM directives	23	10	8	0	
Transpositions in Spain	12	3	3	0	
Transpositions in Sweden	83	22	29	0	

5. The transposition of SEM directives in Sweden

5.1 Implementation of EU legislation in Sweden

As with other Member States in the EU, Sweden is obliged to implement and follow EU law. This obligation is, among other ways, communicated by the principle of loyalty according to Article 5 of the EC Treaty. The principle means that, for example, Sweden is obliged to take all actions that can be regarded as appropriate to ensure that the obligations are fulfilled under the treaty or other Community measures.

The Swedish government is responsible for Sweden implementing and abiding by EU legislation and is thus responsible for ensuring that the authorities instructions agree with the requirements stated in EU legislation. It is not required that EU legal acts are implemented in Member States by means of formal laws. The Member States can implement EU legal acts by means of national statutes based on their own legal systems. In Sweden the legal acts are implemented in accordance with the distribution of norm-establishing powers between the parliament, the government and the administrative authorities. The way an EU legal act is implemented in Sweden depends on how the issue has previously been dealt with within Swedish legislation.

The implementation process starts with a proposal for new Swedish act or regulation being studied and worked out by order of the Government. Subsequently the Government can present a bill for a new law, which will then be dealt with by the parliament. The implementation of EU legal acts in Sweden often means that the Government works out regulations and/or that authorities issue instructions. Coordination between the Government and the authorities is required in the latter regard. The authorities are therefore obliged to inform the ministry in question of the implementation of EU legal acts with instructions. The ministries inform the EU Commission of the Swedish implementation of the EU legal act and subsequently the Commission scrutinises the statute text (Agency for Administrative Development 1998).

Swedish authorities can implement EU directives in various ways. The main rule is that the text of the directive should be rewritten into a public authority instruction, but it could

also be reproduced verbatim. A third alternative is that an instruction could refer to the text of the directive.

The Agency for Administrative Development (1998) has conducted a study on the adaptation of Swedish regulations to the EU body of regulations, which shows that authorities in several cases have introduced regulations in EU-related directions that are more far-reaching than the requirements in the underlying EU legal acts. The same study shows that authorities, generally speaking, meet the EU legal requirements when implementing EU directives and completing EU regulations and instructions but that there is usually no control or follow-up of the authorities' instruction work. The lack of control is explained by the fact that public authorities' instructions due to EU legal acts mostly concern detailed, specific matters that require special competence. The Cabinet Office and the Ministries lack such competence.

5.2 Methods and results

For the Swedish transposition data, the National Board of Trade in Sweden has provided information. The database on the Official Journal of Community Legislation in Force and Others Acts of the Community Institutions (Volume I, Analytical Register) has also been used in the analysis. In addition, the Internet has also been used as a research tool and searches of relevant web sites have been made.

Regarding the free movement of individuals in the health sector, the overwhelming number of Swedish transpositions concern the labour market for doctors, nurses and other health personal. It further shows that the relatively few SEM directives within the category of short-term stay have necessitated quite a number of transpositions. Possibly even more surprising is the number of transpositions in the category of data protection.

Regarding the free movement of goods and services in the health sector, the overwhelming number of transpositions (62 %) are concerned with the pharmaceutical market, i.e. a situation similar to that in Spain but different to that in Germany. Further, it can be seen that there are also a number of transpositions within the categories of medical devices and public procurement of goods and services.

5.3 Conclusions

In the results scoreboard "Single Market Scoreboard No. 7" issued by the EU, it is maintained that "transpositions of Internal Market directives has considerably improved in most Member States. Denmark, Finland and Sweden have successfully kept their transposition deficit to below 1.5 %. … The 'fragmentation factor', the percentage of directives not yet implemented across all Member States remains high (12.8 %). One in eight Internal Market directives has not been transposed in every Member State. … Three years since the first launch of the Scoreboard it has become clear that administrations can achieve a significant reduction in the implementation deficit of Internal Market legislation only if intense administrative activity is coupled with political support at the highest levels. Internal Market legislation involves important reforms that can only be successfully implemented if there is adequate political backing. … Denmark, Sweden, Finland and Spain have done best in coming to grip with the transpositions process, and though they face some delays, they are well on course for eliminating their transpositions backlog." According to these statistics, Sweden ranked second in the EU when it came to implementing SEM directives in November 2000 – a drastic improvement in comparison to November 1997 when it ranked only eighth.

In Sweden it is commonly thought that the country is relatively conscientious concerning the transposition of those directives from the EU to national law. However, tendencies towards over-regulation have also been identified. Directives are usually implemented within the EU time-frame and reports are made to the Commission after the directives have been implemented. Perhaps this efficiency can be traced to the fact that Sweden is a relatively new member of the EU.

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