II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 8 May 2001

relating to a proceeding pursuant to Article 81 of the EC Treaty

Cases: IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 EAEPC (complaint)

(notified under document number C (2001) 1202)

(Only the English text is authentic)

(Text with EEA relevance)

(2001/791/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation No 17 of 6 February 1962 first Regulation implementing Articles 85 and 86 of the Treaty [1], as last amended by Regulation (EC) No 1216/1999 [2], in particular Articles 3 and 6 thereof,

Having regard to the Commission of 13 July 1999 to initiate proceedings in this case,

Having given the undertaking concerned the opportunity to make known its views on the objections raised by the Commission pursuant to Article 19(1) of Regulation No 17 and Article 2 of Commission Regulation (EC) No 2842/98 of 22 December 1998 on the hearing of parties in certain proceedings under Articles 85 and 86 of the EC Treaty [3],

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

WHEREAS:

I. FACTS

A. *INTRODUCTION*

(1) This decision concerns the compatibility with Article 81 of the EC Treaty [4] of Glaxo Wellcome SA's sales conditions regarding pharmaceutical products supplied to Spanish wholesalers. Pursuant to clause 4 of these sales conditions, Glaxo Wellcome SA operates a distinction between, on the one hand, the prices charged to wholesalers reselling its products to Spanish pharmacies or hospitals for (reimbursable) end-use in Spain and, on the other hand, prices charged to wholesalers exporting the products. The latter prices are higher than those applied in case of domestic resales.

B. *PROCEDURE*

(2) On 6 March 1998, Glaxo Wellcome SA (hereinafter 'GW SA') notified new sales conditions (hereinafter the 'new sales conditions') with a view to obtaining a negative clearance pursuant to Article 2 of Regulation

[1] OJ 13, 21.2.1962, p. 204/62.
[2] OJ L 148, 15.6.1999, p. 5.
[3] OJ L 354, 30.12.1998, p. 18.

[4] In the text of this decision, references to 'Article 81 of the Treaty' refer to the EC Treaty. This Article was formerly known as Article 85.

No 17 or, alternatively, an exemption pursuant to Article 4 of Regulation No 17. On 30 June 1998, GW SA informed the Commission of slight modifications concerning in particular the calculation of the export price for older products. It also provided the Commission with a new list of 'Spanish' prices valid as of 29 June 1998. On 28 July 1998, GW SA's parent company, Glaxo Wellcome plc (hereinafter GW plc) transmitted a supplementary notification drawing the Commission's attention 'to factors that are not specific to Glaxo Wellcome's business in Spain, but that affect the business of Glaxo Wellcome and its subsidiaries throughout the EU'.

(3) Subsequently, a number of wholesalers and wholesaler associations lodged complaints with the Commission pursuant to Article 3(2) of Regulation No 17. All complaints argue that GW SA's sales conditions infringe Article 81 of the Treaty, while some of them add that these conditions also violate Article 82 of the Treaty. Complaints were received from the following undertakings or associations of undertakings:

(a) Aseprofar ('Associación de Exportadores Españoles de Productos Farmacéuticos') which is a Spanish professional organisation consisting of five pharmaceutical wholesalers: Centro Farmacéutico Asturiano SA, Unyexport Medicamentos SA, Euroserv SA, Galénica SA Farmacéutica Aragonesa and Centro Farmacéutico Nacional SA. Aseprofar's objective is the defence of freedom of exportation and interstate circulation of pharmaceutical goods, pursuant to the rules of the European Union [5]. The total turnover of the five wholesalers for 1997 was around EUR 1,35 billion (ESP 225 billion). Another Spanish professional organisation comprising two associations each of eight wholesalers called Fedifar ('Federación Nacional de Asociaciones de Mayoristas Distribuidores de Especialidades Farmacéuticas y Productos Parafarmacéuticos') intervened to support Aseprofar's complaint;

(b) Spain Pharma SA, an individual Spanish wholesaler of pharmaceutical products. In 1997 it achieved a turnover of EUR 10,8 million (ESP 1,8 billion), three quarters of which is derived from exports to other Member States;

(c) Bundesvervand der Arzneimittel-Importeure (BAI), an association of German importers of pharmaceutical products;

(d) European Association of Euro Pharmaceutical Companies (EAEPC) representing the interests of national associations of importers and exporters of pharmaceutical products located in Germany (BAI), Spain (Aseprofar), United Kingdom, Denmark, the Netherlands, Norway and Sweden.

(4) On 10 September 1998, the Commission sent GW plc a warning letter pointing out that the new sales conditions appeared to infringe Article 81 of the Treaty. On 29 September 1998, GW plc submitted a memorandum entitled 'Response of GW plc to the legal arguments in the Commission's letter of 10 September 1998' (hereinafter referred to as: 'GW memorandum'). Subsequently, it submitted two economic studies analysing the effects of parallel imports entitled 'GW's Spanish pricing system: the need for a new approach to parallel imports' (hereinafter referred to as: 'London Economics study') and 'The adverse effects of parallel imports on consumer welfare' (hereinafter referred to as: 'Prof. Rey study I').

(5) On 13 July 1999, the Commission adopted a statement of objections to which GW plc replied on 15 November 1999 (hereinafter referred to as: 'the reply to the SO'). The reply to the SO contained another study on pharmaceutical pricing (hereinafter referred to as: 'Frontier Economic study I').

(6) GW was given the opportunity to make known its views in an oral hearing which took place on 8 and 9 December 1999. The complaints Aseprofar, Spain Pharma and EAEPC participated in the hearing. The European Federation of Pharmaceutical Industries and Associations (EFPIA) also participated in support of GW plc.

(7) On 22 December 1999, the Commission sent a formal request for information to GW plc concerning a number of issues discussed at the oral hearing. GW plc replied on 14 February 2000. A week later, it also submitted its comments regarding two studies submitted by Aseprofar regarding 'The effects of parallel imports on social welfare' undertaken by Professors Corchón and Marín (hereinafter referred to as: 'Prof. Corchon and Marin study'). GW plc's comments on these studies are embodied in two more studies: one produced by Frontier Economics (hereinafter referred to as: 'Frontier Economics study II') and another one prepared by Professor Rey (hereinafter referred to as: 'Prof. Rey study II').

(8) EAEPC submitted a written version of its intervention at the oral hearing as well as documentation entitled 'Parallel trade of pharmaceutical' on which GW plc commented on 23 February 2000.

[5] Article 2 of the statutes of Aseprofar (free translation into English).

C. *PARTIES TO GW NEW SALES CONDITIONS FOR SPAIN*

1. GLAXO WELLCOME SA

(9) As stated above (recital 2), GW SA is the Spanish subsidiary of GW plc. Its main activity is the creation and discovery, development, manufacture and marketing of medicines in Spain. The company operates directly as well as through its subsidiaries Wellcome Farmacéuticas SA, Allen Farmacéutica SA and Duncan Farmacéutica SA with which it forms an economic unit. Total turnover was EUR 306 million in 1996 (ESP 50,9 billion).

(10) GW SA forms part of the Glaxo Wellcome group which is a major global player manufacturing pharmaceutical products in 33 countries and selling them in 57 countries. In 1996, GW plc had a turnover of GBP 7,9 billion (EUR 11,2 billion). In 2000, GW plc merged with the pharmaceutical company Smithkline Beecham to form the new entity GlaxoSmithkline plc. The merger was cleared by the Commission on 8 May 2000 ([6]).

(11) In section 3.1 of its supplementary notification, GW plc specified that 'because Glaxo Wellcome has effective ownership and control of Glaxo Wellcome SA, the two firms constitute a single undertaking for purposes of Community law'. It emerges from section 1.1 of that notification that 'Glaxo Wellcome' refers to Glaxo Wellcome plc. The present Decision will refer to Glaxo Wellcome (GW) as designating the entire group, except where it is necessary to make a specific reference to either GW SA or GW plc.

2. SPANISH WHOLESALERS

(12) The other parties are the Spanish wholesalers who subscribed to the new sales conditions. Over a hundred pharmaceutical wholesalers are active in Spain. GW SA transmitted its new sales conditions to 89 wholesalers ([7]). In total, 75 wholesalers, whose sales represent over 90 % of all GW SA sales in Spain ([8]), accepted these conditions. They include GW SA's five main clients: Cofares, Reguladora de Compras del Mediterráneo, Cecofar, Saga Galénica and Federació Farmacéutica. Safa Galenica raised a reservation concerning the legality of the new sales conditions, whereas Federació Farmacéutica stated that they would not be able to comply with the obligation of Clause 1B(c) of the new sales conditions according to which they would have to specify whether the products can be funded by social security or other public funds. Another wholesaler which subscribed to the sales conditions, but does not belong to GW SA's five main clients (Cofaran), also expressed doubts about the legality of these conditions ([9]).

D. *PRODUCTS CONCERNED*

(13) GW SA points out that the new sales conditions apply in total to 82 pharmaceutical products. In its reply to the SO, GW specifies that all these products are prescription drugs. For a complete list of these products, see Annex 1 to this Decision. The total number takes account of the fact that several drugs are sold in different dosages and packages forms (for example, Lamictal 25 mg/56 tablets, 50 mg/56 tablets, 100 mg/56 tablets and 200 mg/30 tablets) and/or that some drugs are administered in different ways (for example Ventolin inhalable or injectable).

(14) The relevant pharmaceutical products cover a variety of different fields, for example, drugs functioning in the respiratory system (bronchodilators/A-Asthma, nasal preparations and antihistamines), drugs used for the treatment of infections, preparations for nausea and ulcers, dermatological products, immunomodulating agents, anti-malaria drugs, hormonal preparations, cardiac drugs, preparations for the central nervous system or musculo-skeletal system, otologicals and products for herpes and migraine.

(15) In its supplementary notification of 28 July 1998, GW plc submitted a list of eight products which it considers to be the prime candidates for parallel trade between Spain and the United Kingdom: Becotide, Beconase, Becloforte, Flixotide, Imigran, Lamictal, Serevent and Ventolin ([10]). This number (eight) does not take account of the fact that these drugs are sold in different dosages and package forms or are administered in different ways. Their total number is 15 if this fact is taken into account.

([6]) Commission decision in Case IV/M.1846 — Glaxo Wellcome Smithkline (OJ C 170, 20.6.2000, p. 6).

([7]) For a full list: see Annex to the original notification, Document No 1ter [82, 91 to 101]. Note: page numbers in brackets [] refer to a page in Commission file IV/36.957. Reference to the complaints files are indicated with case number and page number.

([8]) Response by GW of 6 May 1998 to information request of 15 April 1998, Annex 4 [678 to 687].

([9]) Response by GW of 6 May 1998, p. 8 and Annex 5 [642/689 to 706].

([10]) Supplementary notification by GW of 28 July 1998, annex 12 [910, 911].

(16) In its response of 14 December 1998 to a formal request for information, GW plc provided market shares between June 1996 and June 1998 in all Member States for the 82 products covered by the new sales conditions. GW plc calculated these market shares on the basis of data collected by the medical research company International Medical Statistics (IMS). The data relate to classes of drugs belonging either to the second or the third level of the 'Anatomical therapeutic classification' (ATC) drawn up by EphMRA (European Pharmaceutical Marketing Research Association). The ATC classification groups the pharmaceutical specialities into therapeutical classes. The second ATC level corresponds to therapeutical main groups whereas the third ATC level reflects therapeutical/pharmacological subgroups.

(17) The table in Annex 2 has been drawn up by the Commission. It focuses on six Member States and shows GW's market shares valid as at June 1998. Where the table does not give a market share, the product is not marketed or data are not available. Specific Spanish brand names are added between brackets. Figures reflect sales values expressed in GBP at constant exchange rates.

(18) It emerges from that table that GW's market shares for the eight products which it considers to be the prime candidates for parallel trade are substantial. Becotide, Becloforte, Flixotide, Serevent and Ventolin all belong to the second level R3 class bronchodilators/A-Asthma. For this class of drugs, GW holds a Community-wide share of [...] (*) % with a peak in the United Kingdom of [...] %. Its UK share for Beconase (which is part of the third level R1A class) amounts to [...] %. Lamictal (which is part of the second level N3 anti-epileptics class) gives GW a Community-wide share of [...] % and a UK share of [...] %. Finally, Imigran yields shares of [...] % in the Community and up to [...] % in the United Kingdom.

E. *GW SALES CONDITIONS FOR SPAIN: CONTENTS AND ENFORCEMENT*

1. CLAUSE 4 OF THE NEW SALES CONDITIONS

(19) The notified new sales conditions entered into force on 9 March 1998. Clause 4 deals with the prices charged by GW for its pharmaceutical specialities to its wholesalers (the 'industrial price') and reads as follows.

'A. Pursuant to the provisions of subsections 1 (first paragraph) and 2 of Article 100 of Law 25/1990 of 20 December 1990 concerning medicine, the price of pharmaceutical products of GW SA and its subsidiary companies shall, in no event, exceed the maximum industrial price, established by the Spanish health authorities when the two factors which allow for the application of the said legal rules are present, namely:

— that the aforementioned pharmaceutical products are financed by the funds of the Spanish social security or by Spanish public funds,

— that the acquired pharmaceutical products are subsequently marketed at a national level i.e. through pharmacies or Spanish hospitals.

B. In the absence of one of these two factors (i.e. in all case where Spanish law gives full freedom to the laboratories to set the prices of their pharmaceutical products themselves), GW SA and its subsidiaries will fix the price of their pharmaceutical products according to real, objective and non-discriminatory economic criteria and completely irrespective of the destination of the product determined by the purchasing warehouse. In particular, GW SA and its subsidiary companies will apply to their pharmaceutical products the price which, on the basis of their internal economic surveys, had been initially proposed to the Spanish health authorities and objectively updates taking account of the increase in the cost of living in accordance with the provisions of subsections 1 (first paragraph) and 2 of Article 100 of law 25/1990 of 20 December 1990 concerning medicine, and other prior Spanish legislation concerning setting of prices of medicines.'

(20) It follows from the terms of Clause 4A (in particular its second indent) that GW SA offers the Clause 4A price only to the Spanish wholesalers on the condition that they resell the drugs to an end-use destination (pharmacy or hospital) located in Spain. Hence, Clause 4A prevents Spanish wholesalers who export the drugs outside Spain from purchasing these drugs at this price. In the case of export, they have to pay the higher price provided for in Clause 4B (see Table 2).

(21) In its notification of 28 July 1998, GW plc states that the objective of Clause 4 is 'to allow consumers in Spain to obtain GW products without prejudicing the ability of GW to fund research and development in the Community and without distorting the ability of all GW distributors (including those based in Spain) to compete with each other on the basis of price, service and

(*) Parts of this text have been edited to ensure that confidential information/business secrets are not disclosed. Those parts are indicated by square brackets.

efficiency throughout the Community'. It submits that the Clause 'do[es] not block and [is] not intended to block sale by distributors established in Spain to countries outside Spain or to protect distributors established outside Spain, where Spanish distributors have an advantage due to superior efficiency or differences in exchanges rates' ([11]).

(22) GW plc further states that Clause 4 could affect trade between Spain and all other Member States. It acknowledges that 'in practice, the principal immediate effect of [Clause 4] will be on trade between Spain and the UK, inasmuch as the greater part of Spanish-sourced parallel imports are sold on the market in the UK' ([12]).

2. ENFORCEMENT OF CLAUSE 4 OF THE NEW SALES CONDITIONS

(23) GW initially suspended supplies to the wholesalers who refused to subscribe to the new sales conditions which entered into force on 9 March 1998. Its stated reason for doing so was to avoid discrimination towards the 75 wholesalers who had accepted the new conditions ([13]). Spain Pharma SA confirmed that following its refusal to accept the new sales conditions, it was no longer supplied by GW SA ([14]). Three members of Aseprofar (Euroserv, Cefena and Cefasa) also indicated that supplies were reduced almost to zero for the same reason ([15]). GW further explains how it monitored the implementation of the sales conditions by those wholesalers who had actually subscribed to them. It stresses that it had no practical means of ensuring strict compliance with Clause 4 ([16]).

(24) In one case (Cofares), it was a competitor which informed GW SA of the exports. When questioned by GW SA, Cofares acknowledged the existence of these exports and declared they had taken place by mistake. GW SA then requested payment of a supplementary invoice covering the difference between the Clause 4A and 4B prices.

(25) In seven other cases (Cecofar, Reguladora de Compras del Mediterráneo, Nafarco, Molina Serrano, Cofex, Hefagra and Cofas), GW SA compared the volume of products acquired by the wholesalers at the Clause 4A price with the IMS data concerning these wholesalers' domestic sales. The actual sales in Spain appeared to be significantly lower than the supplies made to them at the Clause 4A price. GW SA requested the seven wholesalers to specify the amount of exported products acquired at the Clause 4A price in the period between 9 March 1998 (entry into force of the new sales conditions) and 16 October 1998 (entry into force of interim measures ordered by the Spanish competition authorities: see recital 26), with a view to sending them a supplementary invoice covering the difference between the Clause 4A and 4B prices. All wholesalers replied that they had not exported products after 9 March 1998. In reply to the Commission's information request of 30 October 1998, GW SA pointed out that there would be valid reasons for terminating commercial relations with a wholesaler who repeatedly infringed the new sales conditions and systematically refused to pay the supplementary invoices.

(26) On 26 October 1998, the Spanish competition defense tribunal ('Tribunal de Defensa de la Competencia') adopted interim measures ordering GW SA to suspend the application of Clause 4 for a period of six months. GW SA appealed to the 'Audiencia nacional' (national Spanish court) against the interim measures.

(27) Pending the appeal, GW SA supplied its products to wholesalers at the maximum wholesale Clause 4A price, whether or not they had signed the new sales conditions and irrespective of the destination (domestic or abroad) of the purchase products. According to GW, orders significantly exceeded GW SA's sales and production

([11]) Ibid., see p. 6 [838].
([12]) Ibid. see p. 7 [839].
([13]) Response by Glaxo of 6 May 1998, p/ 15 [649].
([14]) Response by Spain Pharma of 6 November 1998 to information request of 14 October 1998, p.3 (Case 37.121, p. 931).
([15]) Response by Aseprofar of 13 November 1998 to information request of 14 October 1998 (Case 36.997, pp. 1209 et seq.).
([16]) Response by GW of 14 December 1998 to information request of 30 October 1998, Annex 15 [1779-1784].

forecasts. On 5 January 1999, GW SA therefore decided no longer to supply the total quantities ordered by the wholesalers who had not signed the new sales conditions but rather to allocate to them volumes based on their historic ordering patterns. In this respect, GW indicated that 'since each wholesaler is supposed to carry out its activity in a more or less defined territory in Spain, this (i.e. high volume orders) would endanger the legitimate objective (and legal obligation) of GW SA to maintain an adequate and balanced supply of its products throughout Spain' ([17]). Aseprofar confirms that GW did not supply all the quantities requested by its members ([18]).

(28) Shortly before the expiry of the interim measures in July 1999, Aseprofar and Fedifar requested an extension of those measures. The 'Tribunal de Defensa de la Competencia' granted that request. However, the prolonged interim measures did not enter into force since the two wholesale associations failed to desposit a security. To date GW SA has nevertheless refrained from implementing the new sales conditions.

F. *PARALLEL TRADE IN PHARMACEUTICAL PRODUCTS WITHIN THE COMMUNITY — IMPACT OF NATIONAL REGULATORY FRAMEWORKS AND CURRENCY FLUCTUATIONS*

(29) Prices for pharmaceutical products vary between Member States. The price differences create opportunities for parallel trade. They are even the 'key drivers of parallel trade' ([19]). At the oral hearing, GW plc stated that intra-Community trade in prescription medicines is estimated to have increased over a period of 12 years (1985 ot 1997) from 0,5 % to 2 % of total sales ([20]).

(30) While price differences may be influenced by many factors, two main factors are highlighted in this section: the regulatory framework in the Member States and currency fluctuations.

([17]) Response by GW of 9 February 1999 to information request of 22 January 1999, pp. 1 and 2 [1063 to 1064].
([18]) Faxes from Aseprofar to the Commission of 26 February 1999, 5 March 1999, 29 March 1999, 14 April 1999 (Case 36.997, pp. 1338 to 1550 and pp. 1723 to 1790).
([19]) London Economics study, p. 16 [1020].
([20]) GW slide presentation at the oral hearing of 8 and 9 December 1999 [4241].

(31) The first factor is structural. In the absence of harmonisation at Community level, the national authorities of the Member States enact and enforce rules aimed at controlling, directly or indirectly, the sales prices charged by pharmaceutical companies and determining the purchasing cost for end-consumers and the State budget. In order to achieve cost savings, many Member States seeks to promote parallel trade (see recital 34).

(32) The second factor is, by its very nature, cyclical. When the currency of a country targeted by parallel traders because of its high price levels depreciates, parallel trade tends to decrease whereas it is likely to increase when that currency gains in value.

(33) GW has submitted the table below (Table 1) which gives a broad picture of the level of pharmaceutical prices in different countries (note: footnotes to this table reflect GW comments) ([21]). This table also indicates whether Member States have enacted measures to stimulate parallel trade. Finally it contains rough estimates of the magnitude of parallel trade in the Community. The degree of parallel imports appears to vary between the Member States. According to the table, parallel imports have higher market shares in the United Kingdom, in Denmark and in the Netherlands. For the United Kingdom, GW's estimate is between 4 % and 8 % (see recital 34). This percentage corresponds by and large to the National Health Service's estimate (see recital 49).

(34) **Table 1: Incentives, prices and parallel imports**

Country	Price	Incentives for parallel imports	Parallel imports market share ([1])
Belgium	Medium to low	Yes	2 %
Denmark	High to medium	Yes ([2])	9 %
Germany	High	No	2 %
Finland	High to medium	Yes	Low
France	Medium to low	Yes	Low
Greece	Low	Yes	0 %
Ireland	High to medium	No	Low
Italy	Low	Yes	0 %
Luxembourg	Medium	No	Low
Netherlands	High to medium	Yes ([3])	10 % (12 %)

([21]) The table features in the London Economics study, p. 18 [102].

Country	Price	Incentives for parallel imports	Parallel imports market share (1)
Austria	High to medium	Yes	N/A
Portugal	Medium to low	Yes	0 %
Sweden	High to medium	No	1 %
Spain	Low	Yes	0 %
United Kingdom	Medium	Yes (4)	4 % (8 %)

(1) The figures in this column have been taken from Michael Burstall, Pricing and Reimbursement in Western Europe 1998, PPR Communications Ltd, 1998, figures in rackets indicate estimates from Datamonitor, 1997, where these diverge.
(2) Legal compulsion. In Denmark the pharmacists has a legal obligation to tell the customer about all the substitutes that are available in lieu of the prescribed drug, including parallel imports.
(3) Dutch pharmacists are paid the wholesaler's price plus a fixed fee. According to the Dutch health ministry, pharmacists may benefit from parallel imports if they buy a product at a lower price without informing the government; they would be reimbursed at the higher Dutch wholesale price.
(4) In the United Kingdom for every sale made, the pharmacist receives a fixed fee plus the manufacturer's list price minus the average wholesale discount on that medicine. Not only does such a system encourage parallel imports, it punishes pharmacists unable to obtain a wholesale discount.

(35) Since GW SA's new sales conditions are 'intended to remedy the adverse effects created by differences between the Spanish and UK systems of pharmaceutical price regulation by limiting the impact of the low prices mandated by the Spanish Government to Spain' (22), the description below (recitals 36 to 49) deals primarily with the regulatory framework in these two Member States. Nevertheless, it also contains some information about other Member States, in view of the fact that Clause 4B prices apply irrespective of the final destination of the exported products. Thereafter, some data on currency fluctuations are given

1. REGULATORY FRAMEWORK IN THE MEMBER STATES

(36) All Member States operate systems aimed at controlling — to varying degrees — prices for some or all categories of pharmaceuticals. Price control may be direct (for example, maximum sales prices) or indirect (for example, profit capping, maximum reimbursement levels). As Table 1 shows, most Member States have also enacted measures aimed at encouraging parallel trade. Hereafter (recitals 37 to 52) a short description is given of the regulatory framework in Spain and the United Kingdom as well as in the other Member States. The description focuses on price control *sensu stricto* and reimbursement schemes. Il also contains some information about incentives for parallel trade.

a) ***Spain***

(37) In Spain, maximum prices are fixed for reimbursable prescription drugs. The basic legislation is contained in Article 100 of Law 25/1990 (Ley del Medicamento), as modified successively in 1993, 1997 and 1998. Article 100(1) of Law 25/1990 provides generally that pharmaceutical prices must be set on the basis of objective and verifiable criteria. Article 100(2) of Law 25/1990 stipulates that the Ministry of Health and Consumers sets a maximum industrial price for each pharmaceutical product financed by the national social security system. As mentioned above (see recital 19), the industrial price is the price which a pharmaceutical company charges to wholesales. After GW hat notified the new sales conditions to the Commission, Law 55/1999 introduced further amendments to Article 100(1) and (2). These now explicitly specify that the maximum industrial price only applies to products dispensed in Spain and financed with social security funds or state funds related to health. The Ministry also sets the margins for commercialisation ['conceptos correspondientes a la comercialización', Article 100(3) of Law 25/1990]. These are the margins of wholesalers as well as of pharmacies. Hence, the Ministry also de facto sets the maximum retail price (that is to say, maximum industrial prices plus the wholesaler and pharmacy margins).

(38) The Ministry sets the maximum industrial price in accordance with a procedure set out in Royal Decree 271/1990. The price-setting procedure starts with a request from the pharmaceutical company. Pursuant to Article 3(2) of Royal Decree 271/1990, the company must submit the technical, accounting and financial documentation necessary for the preparation of an economic report. This report will be the basis for the determination of the price of the new pharmaceutical product. The company has to provide a very detailed study reflecting the real costs involved at the time of

(22) London Economics study, executive summary, p. v [1003].

the development of the pharmaceutical product ([23]). Article 3(3) of Royal Decree 271/1990 requires the national administration to take into account the 'complete cost, including the cost involved in research and development' when setting prices. It also provides that the administration must set the company's profit with reference to 'technical report on the economic and financial position of the company'.

(39) Independently from individual price applications, the general level of prices for pharmaceuticals in Spain has been discussed between the Ministry of Health and the pharmaceutical producers' association Farmindustria. However, in September 1999 Farmindustria decided to terminate its agreement with the Ministry of Health to contain pharmaceutical expenditure ([24]).

(40) Article 2(3) of Royal Decree 271/1990 enables pharmaceutical companies to apply for price increases when changes in the public health, technical, business or budgetary circumstances require [...such increases]. As GW plc acknowledges, GW SA has obtained price increases in this way on several occasions.

(41) In May 1997, the Spanish authorities agreed to price increases for Serevent, Imigran and Lamictal (in various dosages and package forms). Sometimes, the price increases were quite substantial (for example, Imigran, for which the maximum unit price rose from ESP 648,25 to ESP 750, or Lamictal 200 mg/30 tablets the authorised price for which went up to ESP 273,66 from a previous price of ESP 198,21 for the same product offered in packages of 56 tablets) ([25]).

(42) In July 1998 (after GW SA's notification), another substantial price increase was obtained for Ventolin Inh. 100 mg/200d. The authorised maximum price per unit rose from ESP 1,5 to ESP 2,1.

(43) It is worth noting that the abovementioned four products for which GW SA obtained price increases (Serevent, Imigran, Lamictal and Ventolin) all belong to the group of eight products which GW plc claim to be the main candidates for parallel export from Spain into the United Kingdom (see recital 15) ([26]).

([23]) Notification, p. 42 [42].
([24]) Reply to the SO, Annex 7, p. 3 [3765].
([25]) For further details on all price increases obtained by GW SA, see reply to the SO, Annex 9 [3795/6]. For Lamictal, the old package form (56 tablets) was replaced by the new package form (30 tablets): see GW response of 14 December 1998 [1698].
([26]) Supplementary notification by GW of 28 July 1998, Annex 12 [910, 911].

b) ***United Kingdom***

(44) Price control is governed by the pharmaceutical price regulation scheme (PPRS), which is agreed between manufacturers and the UK National Health Service (NHS). The scheme covers all licensed branded medicines sold to the NHS. The PPRS which was in force at the time of GW SA's notification ran from October 1993 to September 1998. The present PPRS covers the period from October 1999 to October 2004.

(45) Pharmaceutical companies set prices for their products freely, but their profits are capped by the PPRS if their total home sales of NHS medicines in the United Kingdom exceed GBP 25 million (20 million in the 1993 scheme). The PPRS caps profits by setting 'target' returns on capital employed on all sales. These target returns on capital ('ROC') are based on the historical average value of invested capital ([27]). There are two levels of ROC. The NHS uses a general ROC of 21 % in determining a company's liability to repay excess profits. A lower ROC of 17 % will be used to decide price increase application. Companies are allowed to deduct a percentage of their sales revenue from 'gross' profits as a reward for their R & D investments. For GW, this discount amounts to [...] %.

(46) When a manufacturer's profits exceed the target ROC, one or more of the following measures may be taken:

a) price reduction;

b) restriction or suspension of price increases requested by the manufacturer;

c) repayment of excessive profits.

(47) In October 1999, the PPRS introduced a general price cut of 4,5 % for all reimbursable drugs and all pharmaceutical producers. Pharmaceutical companies have two options to meet this price cut: either reduce all their prices by 4,5 % or modulate their prices by reducing the price for some drugs more substantially. Prices remain unchanged at the level of the cut for a period of 15 months until 1 January 2001 ([28]), except where a subsequent modulation is agreed. However, such a price modulation has to be cost-neutral. This means that any price change of a product must be implemented in such a way that the 4,5 % cut is still respected.

([27]) See reply the SO, Annex 4 [3674 to 3680].
([28]) Reply to the SO, Annex 4, p. 5 [3679] and response of 14 December 1998 [1709].

(48) Under the United Kingdom's reimbursement scheme, patients pay a uniform flat fee of GBP 6 per prescription drug purchased, except for prescription contraceptive medicines which are free. Certain categories of patients (for example those over 60 or under 18 years old, the poor and the chronically sick) are exempt from this payment ([29]).

(49) For every sale made, UK pharmacists receive a fixed reimbursement fee from the NHS. This fee is set by reference to the manufacturer's list price. This means that the pharmacist receives the same fee irrespective of the actual purchase costs incurred. Parallel imports of cheaper products thus yield the same fee as domestic purchases at the manufacturer's list price. The NHS operates a 'claw back' mechanism vis-à-vis pharmacists to take into account parallel trade. The NHS automatically deducts from the manufacturer's list price a discount (the 'claw back') in the range of 4 % to 5 %. This deduction is based on the assumption that it corresponds to the savings which all UK pharmacists together achieve each year by placing orders with parallel traders ([30]). Every pharmacist faces this 4 % to 5 % claw back, irrespective of whether or not he actually dispenses parallel traded products or, if he does, whether or not his savings correspond to the 4 % to 5 % figure. This claw back mechanism aims at ensuring that these savings are at least partially transferred to the NHS (and therefore to taxpayers). Although this mechanism might aim primarily at avoiding unjust enrichment by intermediaries and pharmacists, it also encourages them to increase parallel trade. If they purchase drugs via parallel trade in excess of the 4 % to 5 % used as a reference point in the claw back mechanism, they are indeed better off than competitors whose purchase of parallel-traded drugs are below that level or who even buy all their requirements domestically. The London Economics study submitted by GW explicitly states that the claw back system penalises traders who do not engage in a certain level of parallel trade ([31]).

In April 1999, the NHS set up the National Institute for Clinical Excellence (NICE). This institute makes recommendations to the NHS, patients and doctors on the use of medicines, medical equipment and clinical procedures. In this context, it also examines the cost-effectiveness of medical treatments and medicines.

c) ***Other Member States*** ([32])

(50) Like Spain, most other Member States operate direct price-control systems. These systems may cover all medicines (Belgium) or they may be confined to prescription drugs (the Netherlands) or to reimbursable drugs (Denmark, France, Italy and Sweden). In some countries, maximum prices are set on the basis of a wide variety of parameters, including actual or average price levels in other Member States (Belgium, Finland, Italy Sweden and the Netherlands) or on the basis of a more general reasonableness test (Denmark). In other countries, prices are fixed (France). The pharmaceutical companies are usually involved in the regulatory process together with other market players. Two countries allow, in principle, free pricing for all medicines (the United Kingdom and Germany). However, as explained above (recital 45), the United Kingdom caps profits for all branded drugs sold to the NHS. Germany — as indeed all other Member States mentioned above — exerts indirect price control via a reimbursement scheme.

(51) Reimbursement schemes can take various forms. Some countries operate a reference price system (for example, Germany, the Netherlands, Sweden and Denmark). This means that the national authorities reimburse the drugs which are authorised for reimbursement up to an amount equal to the reference price set by them. In some countries (Denmark and Sweden) the reference price is calculated on the basis of the price of the cheapest product(s) within the group. If the product is sold at a higher price, the patient pays the excess. The scope of the reference price system may vary. In Germany it does not cover patented drugs. In other Member States, patients may receive reimbursements expressed as a certain percentage of the sales price — sometimes up to 100 % (for example, France). In other countries, patients will pay a flat fee, regardless of the type of drugs, and the remaining amount is borne by the national health system (for example, the United Kingdom). A combination of both mechanisms can also occur. In these cases, patients in principle receive a reimbursement expressed as a percentage of the sales price but, in order to avoid the amount paid being excessive, the national authorities require no more than the payment of a modest flat fee (Belgium, Finland and Italy). There are often special regimes for the benefit of certain social groups (pensioners, invalids, widows and so forth). Further, in some countries (Denmark and Sweden), patients are not reimbursed if their annual expenses for drugs stay below a certain level.

([29]) Information taken from a working document featuring as Annex 6 to EFPIA's comments on Case IV/36957 of 22. November 1999.

([30]) London Economics study, p. 19 [1023]. GW's presentation in the oral hearing mentions 4 % to 5 % [4274].

([31]) London Economics study, p. 41 [1045].

([32]) Information taken from a working document featuring as Annex 6 to EFPIA's comments on Case IV/36957 of 22 November 1999.

(52) As Table 1 shows, most Member States also operate measures to encourage parallel trade. In the Netherlands, pharmacists are paid the domestic wholesale price plus a fixed fee (like in the United Kingdom). Pharmacists who find cheaper products via parallel imports do not have to inform the Dutch health ministry and will receive the same fee ([33]). This increases their profit margin and thus gives them an incentive to engage in parallel trade. There is no claw back mechanism to adjust these profits. In Denmark, which according to GW has a parallel trade penetration of 9 % ([34]), pharmacists have a legal obligation to inform the patient ordering a particular drug prescribed by his doctor about all available cheaper substitutes, including parallel traded products. Also in two other Member States (Germany and Sweden) where — according to Table 1 — no incentives for parallel imports exist, pharmacists are encouraged to use parallel imported goods. According to a 1999 report by the Swedish competition authority, counties recommend that pharmacies sell the cheapest medicine, including parallel products ([35]). In Germany, pursuant to amended paragraph 129 of the Social Security Act (Sozialgesetzbuch), pharmacists are also obliged to sell cheap imported pharmaceutical products in circumstances which will have to be spelled out in a contract between the pharmacies and the health insurance companies 'Krankenkassen' ('Re-Import Förderklausel', re-importation promotion clause) ([36]). According to the Ministry of Health, this clause should stimulate price competition and ultimately lead to savings for the health insurance schemes ([37]). These savings indirectly benefit the patient who finances these schemes through his monthly obligatory health insurance contribution ([38]).

2. CURRENCY FLUCTUATIONS

(53) The impact of currency fluctuations on parallel trade is universally acknowledged. Such fluctuations disappeared on 1 January 1999 between Member States belonging to the Euro-zone of the economic and monetary union. The United Kingdom, Denmark and Sweden are, however, still exposed to currency fluctuations. A 1998 study on 'parallel importing strategies' states the following:

'In the past, exchange risks have been a major complicating factor as exchange-rate movements can quickly erode, sometimes even eliminate, price differentials. Consequently, many importers have attempted to limit the risk by at least buying forward their major currency requirements. For the last few years, however, currencies among the code EC Member States have been very steady; the main exception is sterling in the UK. The strength of sterling in recent months has had a major positive impact on the profit ratios of importers in the UK.' ([39]).

(54) GW itself notes that 'the appreciation of the pound has caused UK prices to increase relative to those in other EU countries' ([40]). Between October 1996 and April 1998 the GBP/ESP exchange rate rose from 200,27 to 262,09 (see Annex 3 to the Decision). This reflects an appreciation of the British pound by almost 30 %. The October 1996 rate is taken as a reference point because it is from that month onwards that the exchange rate has steadily increased. It reached its peak in April 1998 (the month after GW SA notified its new sales conditions) and fell somewhat thereafter. If the exchange rate in January 1996 (188,65) is compared with the rate in December 1998 (240,09), the British pound appreciated by almost 27 %. This period is relevant because it is for these years that GW has provided data concerning parallel trade of its products (see recitals 64 to 71).

G. *PARALLEL TRADE IN GW PRODUCTS WITHIN THE COMMUNITY — IMPACT OF THE GW SALES CONDITIONS*

(55) As said (recital 13), GW SA's new sales conditions cover 82 products, but GW plc has indicated that only eight products are prime candidates for parallel trade (15 if the different dosages, modes of administration and package sizes are taken into account). For these eight products, GWC plc has provided data concerning their price level in all Member States except Luxembourg, submitting that the Spanish prices artificially low ([41]). GW plc has also given data concerning the volume of parallel trade for these products, focusing on exports from Spain and imports into the United Kingdom ([42]).

([33]) See recital 34 and die London School of Economics study, p. 18 [1022].
([34]) London Economics study, p. 18 [1022]. All the other percentages in this paragraph are also taken from the London Economics study.
([35]) SCA report 'Konkurrens vid försäljnig av läkemedel', pp. 15 and 16.
([36]) BGBI. 1999, Part 1, No 59, p. 2637.
([37]) Webpage Gesundheitsministerium, Dialog Gesundheit, 69 Questions.
([38]) This is particularly important for patented products which, according to German law, are freely priced (and not subject to the reimbursement cap according to which the health insurance schemes only pay a fixed price, whereas any excess price is borne by the patient 'Festbeträge').
([39]) 'Parallel importing strategies' (SCRIP reports, 20 April 1998), PJB publications Ltd, p. 32.
([40]) Frontier Economics study, p. 32 [3728].
([41]) Original notification [10, 72 and 73] and supplementary notification by GW of 28 July 1998, p. 8 [840].
([42]) See Annexes 3 and 4 to the notification of 28 July 1998 [885 to 888] and GW plc's response of 14 December 1998 to questions 2 and 3 of the Commission's formal request for information of 30 October 1998 [1612 to 1621].

(56) Although Clause 4 of the new sales conditions applies to all 82 products listed in Annex 1 to this Decision, the Commission examined the price levels for the eight products identified by GW plc as particularly interesting for parallel traders. These price levels, which were valid on 27 April 1998 are examined in section 1 below. This section also considers more specifically the domestic price levels for Spain and the United Kingdom, although Clause 4B prices apply irrespective of the final destination of the products exported from Spain.

(57) In section 2, an account is given of GW plc's information concerning the volume of parallel trade in the eight products for the period 1996 to 1998, that is, essentially prior to the introduction of the new sales conditions in Spain.

(58) Sections 3 and 4 describe the potential impact of the Clause 4A and 4B prices on parallel trade towards other Member States by comparing them with the prices prevailing in those Member States.

1. LEVEL OF PRICES FOR GW IN 1998

a) ***GW prices throughout the Community***

(59) Table 2A below gives an overview of GW prices for the eight products for which — according to GW plc — parallel trade was mot significant in the Community on 27 April 1998. Prices are unit prices expressed in ESP. The Clause 4A and 4B prices in Spain are those following the entry into force of the new conditions on 9 March 1998). The prices in other Member States are those valid on 27 April 1998 but converted into ESP at 9 March 1998 exchange rate (as supplied by GW).

(60) The prices for Ventolin and Becotide are shown in a separate Table 2B because their Clause 4A and/or Clause 4B prices changed after 9 March 1998. The prices in that table were valid on 29 June 1998 and are expressed in ESP at the conversion rate of that date.

Table 2A: Glaxo Wellcome's prices in the Community (except Luxembourg) as at 27 April 1999

Name of product	SP [4A)]	SP [4B)]	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,03	13,49	8,03	5,56	3,64	7,57	4,41	8,62	2,09	5,36	2,95	5,63	3,10	5,59	6,03
Becloforte Inh. 250 mcg × 180 d.	12,31	21,94	26,44	22,21	18,97	26,59	21,81	30,71	8,34	22,31	10,81	23,43	17,36	23,53	25,65
Beconase Sp. NA. 50 mcg × 200 d.	2,15	5,70	6,30	5,56	4,40	7,35	/	7,68	/	4,96	2,95	5,41	3,00	5,67	5,56
Flixotide 50 mcg Inh. × 120 d.	16,13	18,73	16,07	/	16,61	14,45	/	/	/	17,26	13,80	19,57	19,76	/	21,15
Flixotide 250 mcg Inh. × 120 d.	53,75	69,99	48,37	45,80	58,94	48,93	/	65,31	51,16	58,70	58,94	54,35	71,88	/	71,92
Flixotide 100 mcg Accuhaler × 60 (*)	32,25	37,46	34,50	/	33,51	28,90	/	/	31,22	/	/	22,91	/	55,12	47,38
Flixotide 500 mcg Accuhaler × 60 (*)	107,50	139,98	96,92	/	118,74	97,87	/	/	/	/	/	88,15	/	152,77	148,92
Imigran 50 mg (4 compr.)	750,00	825,00	828,99	739,71	868,38	896,07	/	749,32	420,39	/	591,67	884,58	741,60	916,66	1 099,61
Imigran 6 mg inject. (2 jeringas)	2 695,50	3 752,00	4 054,51	3 242,50	4 179,53	3 625,54	3 604,97	3 605,24	2 990,46	/	3 004,04	3 854,17	3 046,30	3 430,35	4 347,25
Lamictal 100 mg (56 compr.)	155,36	185,72	/	173,22	213,17	190,27	161,65	208,86	148,96	203,14	146,63	235,85	139,14	222,21	232,33
Lamictal 25 mg (56 compr.)	53,57	74,27	/	54,09	78,06	64,45	54,81	55,47	37,24	75,04	36,57	58,95	45,04	75,26	79,19
Lamictal 50 mg (56 compr.)	89,28	107,55	/	86,62	125,23	110,30	/	108,73	74,47	117,78	73,31	117,92	75,10	132,64	134,68
Lamictal 200 mg (30 compr.)	232,90	245,83	/	/	394,25	330,28	/	385,26	217,94	365,65	283,86	471,69	/	389,39	394,92
Serevent Inh. 25 mg (120 d.)	34,54	46,95	30,14	31,89	38,94	38,02	34,86	31,72	31,25	39,05	30,78	34,27	31,92	/	52,95
Ventolin Inh. 100 mg (200 d.)	1,50	10,00	3,62	2,68	1,86	3,73	2,71	3,80	1,52	2,53	2,03	2,85	2,06	2,14	2,55

(*) Flixotide MDPI Diskus Inhaler in all countries except SP.

Source: Calculations based on data supplied by Glaxo Wellcome, letter of 6 May 1998, Documents 2 and 20 [662 and 663, 782 and 811], reply to the SO, Frontier Economics study I, Annex 6, p. 14 [3710].

Table 2B: Glaxo Wellcome's prices in the Community (except Luxembourg), as at 29 June 1998

Name of product	SP [4A)]	SP [4B)]	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,03	6,50	8,04	5,56	3,64	7,56	4,41	8,63	1,96	5,42	2,95	5,64	3,10	5,57	6,08
Ventolin Inh. 100 mg (200 d.)	2,10	2,65	3,62	2,69	1,86	3,73	2,71	3,80	1,43	2,55	2,04	2,86	2,07	2,14	2,57

Source: calculations based on data supplied by Glaxo Wellcome, letter of 30 June 1998, Documents 1 and 2 [821 and 826, 827], letter of 6 May 1998, Document 20 [782 and 811], reply to the SO, Frontier Economics study I, Annex 6, p. 14 [3710].

b) ***GW prices in Spain and the United Kingdom as compared to the Community average***

(61) Table 3 compares the Clause A4 prices for domestic sales in Spain (the source country of parallel trade according to GW) with the GW prices in the United Kingdom (the target country of parallel trade according to GW) as well as the Community average prices. This table is of limited use for assessing concrete market opportunities for parallel traders wishing to export from Spain to the United Kingdom. However, the table does show that Spanish prices cannot all be said to be 'artificially low' as contended by GW plc and that the vast majority of UK prices exceed the Community average by more than 20 %.

Table 3

A) Prices on 9 March 1998

	(ESP per unit of product)			*(EU = 100)*		
Name of Product	SP [4A)]	UK	EU	SP [4A)]	UK	EU
1. Becotide Inh. 200 × 50 mcg	2,03	6,03	5,04	40,28	119,64	100
2. Becloforte Inh. 250 mcg × 180d.	12,31	25,65	20,75	59,33	123,61	100
3. Beconase Sp. NA. 50 mcg × 200 d.	2,15	5,56	5,08	42,32	109,45	100
4. Flixotide 50 mcg Inh. × 120 d.	16,12	21,15	17,20	93,72	122,97	100
5. Flixotide 250 mcg Inh. × 120 d.	53,75	71,92	57,34	93,74	125,43	100
6. Flixotide 100 mcg Accuhaler × 60 (*)	32,25	47,38	35,72	90,29	132,64	100
7. Flixotide 500 mcg Accuhaler × 60 (*)	107,50	148,92	115,84	92,08	128,56	100
8. Imigran 50 mg (4 compr.)	750,00	1 099,61	790,58	94,87	139,09	100
9. Imigran 6 mg inject. (2 jeringas)	2 695,50	4 347,25	3 513,87	76,71	123,72	100
10. Lamictal 100 mg (56 compr.)	155,36	232,33	186,98	83,09	124,25	100
11. Lamictal 25 mg (56 compr.)	53,57	79,19	59,06	90,07	134,08	100
12. Lamictal 50 mg (56 compr.)	89,28	134,68	103,84	85,98	129,07	100
13. Lamictal 200 mg (30 compr.)	232,90	394,92	346,61	67,19	113,94	100
14. Serevent Inh. 25 mg (120 d.)	34,54	52,95	35,41	97,54	149,53	100
15. Ventolin Inh. 100 mg (200 d.)	1,50	2,55	2,54	59,06	100,39	100

(*) Flixotide MDPI Diskus Inhale in all countries except SP.

B) Prices on 29 june 1998

	(ESP per unit of product)			*(EU = 100)*		
Name of Product	SP (4A)	UK	EU	SP (4A)	UK	EU
1. Becotide Inh. 200 × 50 mcg	2,03	6,50	5,04	40,28	128,97	100
2. Ventolin Inh. 100 mg (200 d.)	2,10	2,65	2,58	81,04	102,71	100

(62) As regards Spain, half of the Clause 4A prices are at least 90 % of the Community average with two other prices (Lamictal 50 mg/100 mg) around 85 % of that average. Among those considerably below the Community average (less than 60 % of the Community average), are Becotide, which is a relatively old product introduced to the market in 1976, and Ventolin, for which GW SA obtained a price increase which reduced the price difference with the Community average to under 20 % (see Table 3B).

(63) In the United Kingdom, prices for 12 of 15 products are at least 20 % higher than the Community average price. In four cases, the gap widens to over 30 %. It goes up to almost 50 % for Serevent Inh. 25 mg/120 d.). The gap is particularly visible for products launched in more recent years, from 1990 to 1993, i.e. Flixotide, Imigran, Lamictal and Serevent.

2. VOLUME OF PARALLEL TRADE IN GW PRODUCTS DURING THE PERIOD 1996 TO 1998

(64) On 28 July 1998, GW plc supplied estimates concerning the volume of parallel trade in its products for the years 1996 to 1998 and the loss of sales revenue that this parallel trade caused.

(65) The first set of figures concerned, *inter alia*, parallel imports in all GW products from all sources into the United Kingdom. These imports had an estimated value of GBP [...] million in 1996, GBP [...] million in 1997 and GBP [...] million in 1998 (representing respectively [...] %, [...] % and [...] % of all UK sales). Taking into account sales revenues earned outside the United Kingdom, GW estimates the corresponding net losses of revenue at GBP [...] million, GBP [...] million and GBP [...] million respectively ([43]).

(66) A second set of data relates to parallel imports in the eight GW products for which there was the highest volume of parallel imports from all sources into the United Kingdom. The value of these imports amounted to GBP [...] million in 1996, GBP [...] million in 1997 and GBP [...] million in 1998 (representing respectively [...] %, [...] % and [...] % of all GW UK sales of these products) ([44]).

(67) A third set of figures shows parallel imports of these eight leading products into the United Kingdom from Spain only. Their value amounted to GBP [...] million in 1996 ([...] % of total UK sales), GBP [...] million in 1997 ([...] % of total UK sales) and GBP [...] million in 1998 ([...] % of GW total UK sales) ([45]). When offset against the revenues gained from higher sales in Spain, GW estimates that the net loss of revenue resulting from these imports amount to GBP [...] million over the three years (and GBP [...] million for 1998 alone) ([46]).

(68) A comparison of the second and third sets of data shows that the share of imports into the United Kingdom from Spain as compared to imports from all sources by and large remained the same: in 1996 [...] % (GBP [...] million out of GBP [...] million), in 1997 [...] % (GBP [...] million out of GBP [...] million) and in 1998 GBP [...] million out of GBP [...] million ([...] %). In other words, although the absolute volume of Spanish-sourced imports increased over those three years, their share of all imports into the United Kingdom remained stable at around [...] %.

(69) On 30 October 1998 and 22 January 1999, the Commission asked GW to provide more detailed information about parallel trade in the eight most important products. The Commission requested precise data about (a) the value and volume of Spain-sourced parallel trade towards each Member State for each of the eight products, and (b) the value and volume of imports into the United Kingdom from all mother Member States, including Spain, for each of these products ([47]).

(70) In its first reply on 14 December 1998, GW provided estimates concerning parallel exports from Spain. It did not, however, specify countries of destination. Moreover, it stressed, that 'it had little confidence that these figures provide an accurate reflection of the volume and value of the products leaving Spain'. GW recalled, *inter alia*, that much parallel trade lies outside formally audited distribution channels and that there is no pan-European auditing of parallel trade. As to imports into the United Kingdom, again only estimates were given and no indication was given regarding the source countries. Estimates given in this reply did not relate exactly to the eight products in their various dosage/package forms. Some products were added ([48]) whereas others were omitted ([49]).

(71) In the second reply, dated 18 and 25 February 1999, GW plc stated that 'there is no basis upon which GW can further refine its estimates by value and volume' but that its experience leads it to conclude that 'the vast

([43]) Annex 3 to supplementary notification of 28 July 1998 [886].
([44]) Ibid. annex 4 [888].
([45]) Ibid. annex 10 [907].
([46]) Supplementary notification of 28 July 1998, p. 38 [870].
([47]) Request for information of 22 January 1999 [967].
([48]) These products are Flixotide Inhaler 125 mg × 120 doses, Imigran Injection 2 × 0,5 ml, Serevent accuhaler 50 mg × 60 doses.
([49]) These products are Flixotide 50 mcg Inhaler (120 doses), Flixotide 250 mcg Inhaler (120 doses), Flixotide 100 mcg Accuhaler × 60 doses, Flixotide 500 mcg Accuhaler × 60 doses.

majority (90 % or more) of parallel imports from Spain find their way to the UK with the remaining exports being divided between Germany, the Netherlands, Denmark and Sweden'. As regards parallel imports into the United Kingdom, GW estimates that between 20 % and 100 % of the imports originate in Spain. Here too, GW admits that 'the value data is not "real" but derived from a series of assumptions' and hence that 'there is no real empirical basis for these estimates'. Therefore it 'would caution that the data provided may not be reliable' ([50]).

3. IMPACT OF GW SA'S NEW SALES CONDITIONS ON PARALLEL TRADE IN ITS PRODUCTS

(72) Table 4-1 provides a reliable starting point for assessing the impact which the introduction of GW SA's Clause 4A and 4B prices has had on the ability of Spanish wholesalers to export GW's products. On 27 April 1998, the price prevailing in other Member States was lower than the Clause 4A price in 38 cases. This means that Spanish wholesalers did not have an economic case for exporting the products in these cases even if they were able to purchase the products at the Clause 4A price. Hence, the Clause 4B price had no impact at all on parallel trade in these cases. In 66 other cases, the price in other Member States, while situated above the Clause 4A price, was below the Clause 4B price. Here, the Clause 4B price deprived wholesalers of an opportunity to export the products. Parallel trade was thus excluded. In the remaining 57 cases, the price in the other Member States was above the Clause 4A price but also above the Clause 4B price. The latter price, while not rendering parallel trade impossible, did make exports economically less profitable. As a consequence, parallel trade was impeded in these cases.

(73) There is a short separate table for Becotide and Ventolin (Table 4-1 B). For Becotide, the Clause 4B price was reduced on 29 June 1998, whereas for Ventolin, the Clause 4A price was increased (see recitals 42 and 60) and the Clause 4B price was reduced on the same date. As a result, parallel trade in Becotide became in theory possible in three countries whereas the opportunities for parallel trade at the Clause 4B price in Ventolin improved.

(74) Table 4-1 does not take into account the fact that Spanish wholesalers incur costs which must be added to the prices at which they buy the drugs from the pharmaceutical companies. These costs cover services like packaging and transport. There are no reliable data concerning the magnitude of these costs. At the oral hearing, GW plc argued that for some products — namely successful blockbuster products — these costs do not exceed 5 % whereas the complainants state that their costs an amount to 15 % ([51]). On this basis, Tables 4-2 and 4-3 reproduce the figures appearing in Table 4-1 but add respectively 5 % and 15 % to the Spanish prices. It is assumed that the costs are not materially different between domestic sales and exports although this may underestimate the packaging and transport costs related to exports.

(75) The allowance for wholesaler costs doe not change the result dramatically. In the 5 % cost scenario, there are 68 cases in which parallel trade is excluded by the Clause 4B price and 45 cases in which such trade is impeded. In the 15 % cost scenario, parallel trade is excluded in 74 cases and impeded in 14 cases.

([50]) In its supplementary notification of 28 July 1998 (p. 10) [842], GW had estimated that 'parallel imports from Spain account for about 20 % of sales of parallel imports into the UK'. A comparison of figures in Tables 4 and 10 annexed to this notification suggests that they accounted for around 40 % in the period 1996 to 1998 (see recital 68 of this Decision).

([51]) Case 37.380, Response by EAEPC of 12 May 1999 to the Commission's information request of 8 March 1999 [48].

Table 4-1: The effect of Glaxo Wellcome's pricing system on parallel trade from Spain to other Member States (except Luxembourg)

Grey areas show exclusions of parallel trade (i.e. cases such that 4A < national price < 4B). Bold figures show products whose trade is made less profitable by GW's 4B price (i.e. cases such that 4A < 4B < national price). Slashes (/) indicate that the product is not available for comparison.

A. Prices at 9 March 1998

Prices for all other Member States at 27 April 1998, converted into ESP at 9 March 1998 exchange rates; prices in ESP per unit of product

Name of product	SP (4A)]	SP (4B)	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,03	13,49	8,03	5,56	3,64	7,57	4,41	8,62	2,09	5,36	2,95	5,63	3,10	5,59	6,03
Becloforte Inh. 250 mcg × 180 d.	12,31	21,94	**26,44**	**22,21**	18,97	**26,59**	21,81	**30,71**	8,34	**22,31**	10,81	**23,43**	17,36	**23,53**	**25,65**
Beconase Sp. NA. 50 mcg × 200 d.	2,15	5,70	**6,30**	5,56	4,40	**7,35**	/	**7,68**	/	4,96	2,95	5,41	3,00	5,67	5,56
Flixotide 50 mcg Inh. × 120 d.	16,12	18,73	16,07	/	16,61	14,45	/	/	/	17,26	13,80	**19,57**	**19,76**	/	**21,15**
Flixotide 250 mcg Inh. × 120 d.	53,75	69,99	48,37	45,80	58,94	48,93	/	65,31	51,16	58,70	58,94	54,35	**71,88**	/	**71,92**
Flixotide 100 mcg Accuhaler × 60 (*)	32,25	37,46	34,50	/	33,51	28,90	/	/	31,22	/	/	22,91	/	**55,12**	**47,38**
Flixotide 500 mcg Accuhaler × 60 (*)	107,50	139,98	96,92	/	118,74	97,87	/	/	/	/	/	88,15	/	**152,77**	**148,92**
Imigran 50 mg (4 compr.)	750,00	825,00	**828,99**	739,71	**868,38**	**896,07**	/	749,32	420,39	/	591,67	**884,58**	741,60	**916,66**	**1 099,61**
Imigran 6 mg inject. (2 jeringas)	2 695,50	3 752,00	**4 054,51**	3 242,50	**4 179,53**	3 625,54	3 604,97	3 605,24	2 990,46	/	3 004,04	**3 854,17**	3 046,30	3 430,35	**4 347,25**
Lamictal 100 mg (56 compr.)	155,36	185,72	/	173,22	**213,17**	**190,27**	161,65	**208,86**	148,96	**203,14**	146,63	**235,85**	139,14	**222,21**	**232,33**
Lamictal 25 mg (56 compr.)	53,57	74,27	/	54,09	**78,06**	64,45	54,81	55,47	37,24	**75,04**	36,57	58,95	45,04	**75,26**	**79,19**
Lamictal 50 mg (56 compr.)	89,28	107,55	/	86,62	**125,23**	**110,30**	/	**108,73**	74,47	**117,78**	73,31	**117,92**	75,10	**132,64**	**134,68**
Lamictal 200 mg (30 compr.)	232,90	245,83	/	/	**394,25**	**330,28**	/	**385,26**	217,94	**365,65**	**283,86**	**471,69**	/	**389,39**	**394,92**
Serevent Inh. 25 mg (120 d.)	34,54	46,95	30,14	31,89	38,94	38,02	34,86	31,72	31,25	39,05	30,78	34,27	31,92	/	**52,95**
Ventolin Inh. 100 mg (200 d.)	1,50	10,00	3,62	2,68	1,86	3,73	2,71	3,80	1,52	2,53	2,03	2,85	2,06	2,14	2,55
Total exclusions per country			3\11	6\11	9\15	5\15	7\7	5\12	3\12	6\11	5\13	5\15	5\12	4\12	3\15
Total impediments per country			4\11	1\11	6\15	6\15		5\12		5\11	1\13	7\15	2\12	8\12	12\15
Total exclusions	66\161														
Total impediments	57\161														

(*) Flixotide MDPI Diskus Inhaler in all countries except SP.

B. Prices at 29 June 1998

Prices for all other Member States at 27 April 1998, converted into ESP at 29 June 1998 exchange rates; prices in ESP per unit of product

Name of product	SP (4A)	SP (4B)	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,03	6,50	**8,04**	5,56	3,64	**7,56**	4,41	**8,63**	1,96	5,42	2,95	5,64	3,10	5,57	6,08
Ventolin Inh. 100 mg (200 d.)	2,10	2,65	**3,62**	**2,69**	1,86	**3,73**	**2,71**	**3,80**	1,43	2,55	2,04	**2,86**	2,07	2,14	2,57
Total exclusions per country				1\2	1\2		1\2			2\2	1\2	1\2	1\2	2\2	2\2
Total impediments per country			2\2	1\2		2\2	1\2	2\2				1\2			
Total exclusions	12\26														
Total impediments	9\26														

Table 4-2: The effect of Glaxo Wellcome's pricing system increased by a 5 % margin on parallel trade from Spain to other Member States (except Luxembourg)

Grey areas show exclusions of parallel trade (i.e. cases such that 4A < national price < 4B). Bold figures show products whose trade is made less profitable by GW's 4B price (i.e. cases such that 4A < 4B < national price). Slashes (/) indicate that the product is not available for comparison.

A. Prices at 9 March 1998

Prices for all other Member States at 27 April 1998, converted into ESP at 9 March 1998 exchange rates; prices in ESP per unit of product

Name of product	SP (4A)	SP (4B)	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,13	14,16	8,03	5,56	3,64	7,57	4,41	8,62	2,09	5,36	2,95	5,63	3,10	5,59	6,03
Becloforte Inh. 250 mcg × 180 d.	12,93	23,04	**26,44**	22,21	18,97	**26,59**	21,81	**30,71**	8,34	22,31	10,81	**23,43**	17,36	**23,53**	**25,65**
Beconase Sp. NA. 50 mcg × 200 d.	2,26	5,99	**6,30**	5,56	4,40	**7,35**	/	**7,68**	/	4,96	2,95	5,41	3,00	5,67	5,56
Flixotide 50 mcg Inh. × 120 d.	16,93	19,67	16,07	/	16,61	14,45	/	/	/	17,26	13,80	**19,57**	**19,76**	/	**21,15**
Flixotide 250 mcg Inh. × 120 d.	56,44	73,49	48,37	45,80	58,94	48,93	/	65,31	51,16	58,70	58,94	54,35	71,88	/	71,92
Flixotide 100 mcg Accuhaler × 60 (*)	33,86	39,33	34,50	/	33,51	28,90	/	/	31,22	/	/	22,91	/	**55,12**	**47,38**
Flixotide 500 mcg Accuhaler × 60 (*)	112,88	146,98	96,92	/	118,74	97,87	/	/	/	/	/	88,15	/	**152,77**	**148,92**
Imigran 50 mg (4 compr.)	787,50	866,25	828,99	739,71	**868,38**	**896,07**	/	749,32	420,39	/	591,67	**884,58**	741,60	**916,66**	**1 099,61**
Imigran 6 mg inject. (2 jeringas)	2 830,28	3 939,60	**4 054,51**	3 242,50	**4 179,53**	3 625,54	3 604,97	3 605,24	2 990,46	/	3 004,04	3 854,17	3 046,30	3 430,35	**4 347,25**
Lamictal 100 mg (56 compr.)	163,13	195,01	/	173,22	**213,17**	190,27	161,65	**208,86**	148,96	**203,14**	146,63	**235,85**	139,14	**222,21**	**232,33**
Lamictal 25 mg (56 compr.)	56,25	77,98	/	54,09	**78,06**	64,45	54,81	55,47	37,24	75,04	36,57	58,95	45,04	75,26	**79,19**
Lamictal 50 mg (56 compr.)	93,74	112,93	/	86,62	**125,23**	110,30	/	108,73	74,47	**117,78**	73,31	**117,92**	75,10	**132,64**	**134,68**
Lamictal 200 mg (30 compr.)	244,55	258,12	/	/	**394,25**	**330,28**	/	**385,26**	217,94	**365,65**	**283,86**	**471,69**	/	**389,39**	**394,92**
Serevent Inh. 25 mg (120 d.)	36,27	49,30	30,14	31,89	38,94	38,02	34,86	31,72	31,25	39,05	30,78	34,27	31,92	/	**52,95**
Ventolin Inh. 100 mg (200d.)	1,58	10,50	3,62	2,68	1,86	3,73	2,71	3,80	1,52	2,53	2,03	2,85	2,06	2,14	2,55
Total exclusions per country			4\11	6\11	7\15	7\15	4\7	5\12	1\12	8\11	5\13	6\15	6\12	5\12	4\15
Total impediments per country			3\11		6\15	4\15		4\12		3\11	1\13	5\15	1\12	7\12	11\15
Total exclusions	68\161														
Total impediments	45\161														

(*) Flixotide MDPI Diskus Inhaler in all countries except SP.

B. Prices at 29 June 1998

Prices for all other Member States at 27 April 1998, converted into ESP at 29 June 1998 exchange rates; prices in ESP per unit of product

Name of product	SP (4A)	SP (4B)	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,13	6,83	**8,04**	5,56	3,64	**7,56**	4,41	**8,63**	1,96	5,42	2,95	5,64	3,10	5,57	6,08
Ventolin Inh. 100 mg (200 d.)	2,21	2,78	**3,62**	2,69	1,86	**3,73**	2,71	**3,80**	1,43	2,55	2,04	**2,86**	2,07	2,14	2,57
Total exclusions per country				2\2	1\2		2\2			2\2	1\2	1\2	1\2	1\2	2\2
Total impediments per country			2\2			2\2		2\2				1\2			
Total exclusions	13\26														
Total impediments	7\26														

Table 4-3: The effect of Glaxo Wellcome's pricing system increased by a 15 % margin on parallel trade from Spain to other Member States (except Luxembourg)

Grey areas show exclusions of parallel trade (i.e. cases such that 4A < national price < 4B). Bold figures show products whose trade is made less profitable by GW's 4B price (i.e. cases such that 4A < 4B < national price). Slashes (/) indicate that the product is not available for comparison.

A. Prices at 9 March 1998

Prices for all other Member States at 27 April 1998, converted into ESP at 9 March 1998 exchange rates; prices in ESP per unit of product

Name of product	SP (4A)	SP (4B)	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,33	15,51	8,03	5,56	3,64	7,57	4,41	8,62	2,09	5,36	2,95	5,63	3,10	5,59	6,03
Becloforte Inh. 250 mcg × 180 d.	14,16	25,23	**26,44**	22,21	18,97	**26,59**	21,81	**30,71**	8,34	22,31	10,81	23,43	17,36	23,53	**25,65**
Beconase Sp. NA. 50 mcg × 200 d.	2,47	6,56	6,30	5,56	4,40	**7,35**	/	**7,68**	/	4,96	2,95	5,41	3,00	5,67	5,56
Flixotide 50 mcg Inh. × 120 d.	18,54	21,54	16,07	/	16,61	14,45	/	/	/	17,26	13,80	19,57	19,76	/	21,15
Flixotide 250 mcg Inh. × 120 d.	61,81	80,49	48,37	45,80	58,94	48,93	/	65,31	51,16	58,70	58,94	54,35	71,88	/	71,92
Flixotide 100 mcg Accuhaler × 60 (*)	37,09	43,08	34,50	/	33,51	28,90	/	/	31,22	/	/	22,91	/	**55,12**	**47,38**
Flixotide 500 mcg Accuhaler × 60 (*)	123,63	160,98	96,92	/	118,74	97,87	/	/	/	/	/	88,15	/	152,77	148,92
Imigran 50 mg (4 compr.)	862,50	948,75	828,99	739,71	868,38	896,07	/	749,32	420,39	/	591,67	884,58	741,60	916,66	**1 099,61**
Imigran 6 mg inject. (2 jeringas)	3 099,83	4 314,80	4 054,51	3 242,50	4 179,53	3 625,54	3 604,97	3 605,24	2 990,46	/	3 004,04	3 854,17	3 046,30	3 430,35	**4 347,25**
Lamictal 100 mg (56 compr.)	178,66	213,58	/	173,22	213,17	190,27	161,65	208,86	148,96	203,14	146,63	**235,85**	139,14	**222,21**	**232,33**
Lamictal 25 mg (56 compr.)	61,61	85,41	/	54,09	78,06	64,45	54,81	55,47	37,24	75,04	36,57	58,95	45,04	75,26	79,19
Lamictal 50 mg (56 compr.)	102,67	123,68	/	86,62	**125,23**	110,30	/	108,73	74,47	117,78	73,31	117,92	75,10	**132,64**	**134,68**
Lamictal 200 mg (30 compr.)	267,84	282,70	/	/	**394,25**	**330,28**	/	**385,26**	217,94	**365,65**	**283,86**	**471,69**	/	**389,39**	**394,92**
Serevent Inh. 25 mg (120 d.)	39,72	53,99	30,14	31,89	38,94	38,02	34,86	31,72	31,25	39,05	30,78	34,27	31,92	/	52,95
Ventolin Inh. 100 mg (200d.)	1,73	11,50	3,62	2,68	1,86	3,73	2,71	3,80	1,52	2,53	2,03	2,85	2,06	2,14	2,55
Total exclusions per country			4\11	5\11	8\15	7\15	4\7	6\12		7\11	3\13	8\15	6\12	8\12	8\15
Total impediments per country			1\11		2\15	3\15		3\12		1\11	1\13	2\15		4\12	7\15
Total exclusions	74\161														
Total impediments	24\161														

(*) Flixotide MDPI Diskus Inhaler in all countries except SP.

B. Prices at 29 June 1998

Prices for all other Member States at 27 April 1998, converted into ESP at 29 June 1998 exchange rates; prices in ESP per unit of product

Name of product	SP (4A)	SP (4B)	A	B	DK	FIN	FR	D	GR	IRL	I	NL	P	S	UK
Becotide Inh. 200 × 50 mcg	2,33	7,48	**8,04**	5,56	3,64	**7,56**	4,41	**8,63**	1,96	5,42	2,95	5,64	3,10	5,57	6,08
Ventolin Inh. 100 mg (200 d.)	2,42	3,05	**3,62**	2,69	1,86	**3,73**	2,71	**3,80**	1,43	2,55	2,04	2,86	2,07	2,14	2,57
Total exclusions per country				2\2	1\2		2\2			2\2	1\2	2\2	1\2	1\2	2\2
Total impediments per country			2\2			2\2		2\2							
Total exclusions	14\26														
Total impediments	6\26														

H. *GLAXO WELLCOME'S MAIN ARGUMENTS*

(76) In its supplementary notification of 28 July 1998, GW plc explains in detail the reasons for applying for negative clearance and, alternatively, for exemption ([52]). It expands on these reasons in its reply to the SO ([53]). Unless otherwise indicated, the following summary of GW plc's arguments has been drawn from these two documents. There is a degree of overlap between some arguments made in the context of Article 81(1) and others advanced in the context of Article 81(3).

1. ARTICLE 81(1) OF THE TREATY

(a) ***Clause 4 does not amount to an export ban or dual pricing — hence it does not have as its object the restriction of competition***

(77) GW admits that Clause 4 of its new sales conditions for Spain is liable to restrict parallel trade towards other Member States. However, it states that this clause does not amount to an export ban since it often leaves scope for parallel exports on a commercial basis. Nor can it be equated with a system of dual pricing, because GW SA is not free to set the domestic wholesale price. According to GW, one can only speak in terms of dual pricing where the supplier can determine both of the different prices at which the product is supplied.

(78) Agreements which merely restrict parallel imports but are not equivalent to an export ban or to a system of dual pricing do not have the object of restricting competition within the meaning of Article 81(1) and cannot be regarded as per se illegal. An assessment of their restrictive effects must be made.

(b) ***Clause 4 produces no restrictive effects on competition***

(79) According to GW, it is incumbent upon the Commission to assess the restrictive effects of notified agreements in their economic and legal context when such agreements do not have the object of restricting competition. In GW's view, Clause 4 produces no such effects. It does no more than correct and compensate for a distortion of competition which results from State intervention, in this case Spain's maximum wholesale price, in the absence of harmonisation of national rules on the pricing of prescription medicines. Its effects resemble those produced by clauses in the agreements considered in the Commission decisions relating to Metro ([54]), Distillers-Victuallers ([55]) and Villeroy Boch ([56]). Finally, GW argues that Clause 4 enhances consumer welfare because it limits a from of trade (parallel trade) which is likely to cause harm to consumers in Spain, without causing any harm to UK consumers.

(c) ***Clause 4 merely compensates a distortion of competition created by Spain***

(80) All national authorities play a double role in the pharmaceutical sector. They regulate drug sales prices, directly, and effectively purchase the drugs since they reimburse the patients. When a national authority decides (as regulator) to impose low sales prices for drugs in order to achieve budgetary saving (as purchaser/reimbursing entity), it can undermine the pricing policy of another national authority which approves higher prices or even allows free pricing because it places a higher priority on the need to research and develop new innovative drugs and recognises that this requires higher sales revenues for the pharmaceutical companies. The actual distortion of competition is triggered by parallel trade from the low price (source) country to the higher price (target) countries. According to economic theory, this trade flow tends to force prices downwards tot the level of the source country. This in turn puts at risk R & D investments in the target country and frustrates that country's policy of promoting such investments. In the present case, Spain creates a distortion of competition because its system of maximum wholesale prices which aims at reducing the national healthcare budget puts at risk the policy of other Member States, including the United Kingdom, which consider adequate R & D investment to be a priority.

([52]) See section 16, pp. 19 to 26 [851 to 858] (negative clearance) and section 17, pp. 27 to 43 [859 to 875] (exemption).

([53]) See respectively pp. 22 to 35 [3529 to 3542] and pp. 35 to 45 [3542 to 3552].

([54]) Commission Decision 76/159/EEC in Case IV/847 — SABA (OJ L 28, 3.2.1976, p. 19), upheld by the Court of Justice in Case 26/76 *Metrov Commission*('Metro 1') [1977] ECR 1875.

([55]) Commission Decision 80/789/EEC in Case IV/26.528 — The Distillers Co. Ltd — Victuallers (OJ L 233, 4.9.1980, p. 43, recitals 15, 16 and 17).

([56]) Commission Decision 85/616/EEC (OJ L 376, 31.12.1985, p. 15, recitals 35 and 36).

(d) ***The analogy with the Distillers — Victuallers, Metro I and Villeroy Boch cases***

(81) The restrictive effect produced by Clause 4 of the new sales conditions is similar to that of the agreements which were given negative clearance in *Distillers — Victuallers*. In that case, Distillers had prohibited the victuallers (operators of a duty free trade) from supplying customers who would not use the goods for their own (duty free) end consumption but for resale in the (non-duty free) market. GW perceives an analogy between, on the one hand, the duty free segment and the Spanish market where special maximum prices prevail and, on the other hand, the non-duty free segment and the export markets where higher prices apply.

(82) Clause 4 also intends to remedy a distortion of competition which is similar to the distortion created by dual distribution, that is, when a wholesaler, who obtains a product at a lower price than retailers, sells directly to end-users in competition with these retailers. The Commission has twice granted negative clearance to companies who had prevented their wholesalers from doing so (*Metro I, Villeroy Boch*).

(e) ***Clause 4 enhances consumer welfare***

(83) Parallel trade is likely to cause harm to consumers in Spain. GW estimates that lost revenue due to parallel trade in its eight leading products from Spain to the United Kingdom amounted to GBP [...] million in 1998 (see recital 68). This causes harm to GW in two respects. On the one hand, these lost sales represent a net direct loss of GBP [...] million if account is taken of the extra sales revenues earned in the source country. On the other hand, a loss of GBP [...] million in domestic UK sales reduced the [...] % discount (see recital 45) which GW is allowed to deduct under the PPRS in the context of the NHS's profit-capping. This reduction amounted to GBP [...] million in 1998 ([57]). GW concludes that 'under these circumstances, it must seriously consider limiting the introduction of new products in Spain'.

(84) GW SA pricing policy causes no harm to UK consumers. Under the UK National Health Service, patients do not pay for the cost of prescribed pharmaceutical product, with the exception of a minimal flat-rate payment. This cost is rather borne by the State. The only real consumer is therefore the United Kingdom Government, which reimburses these patients. Parallel trade benefits the Government only to a limited extent, namely via the claw-back mechanism (see recital 49). GW stresses, however, that the Government has not set up this mechanism with the intent of benefiting from parallel trade but rather to prevent UK intermediaries and pharmacists from obtaining unjust enrichment by purchasing cheaper parallel imported products and still receiving reimbursement fees bases on domestic United Kingdom prices.

2. ARTICLE 81(3) OF THE TREATY

(85) Before discussing in detail the four cumulative conditions for an exemption set out in Article 81(3), GW formulates several arguments of a general nature in its notification of 28 July 1998 and develops these arguments in its reply to the SO. There are, by and large, three such arguments. All of those arguments contain submissions already made in the context of Article 81(1).

(86) First, GW argues that Article 81(3) must be interpreted in the light of various provisions of Article 3 of the Treaty. Second, it refers to the Court's judgements in *Merck* v *Primecrouwn* ([58])*Centrafarm* v *Winthrop* ([59]) which, in GW's view, demonstrate that private measures to impede parallel trade can be exempted. Third, it pleads for a balancing of the negative impacts of the restrictions against the benefits asserted by the parties (*bilan économique*) which in the present case rules in favour of the benefits achieved by the new sales conditions.

(87) These three general arguments will first be restated. The more specific arguments related to each condition set out in Article 81(3) will then be summarised.

([57]) The [...] % is calculated on the basis of domestic sales only. Sales stemming from parallel imports are excluded. For 1998, total UK sales amounted to GBP [...] million (see Annex 3 to GW notification of 28 July 1998). Had all these sales been domestic, [...] % would have meant a discount of GBP [...] million. However, parallel imports accounted for GBP [...] million (ibid.) thereby leaving only GBP [...] million domestic sales. GW was entitled to a discount of [...] % of that amount. This corresponded to GBP [...] million. The difference is GBP [...) million (GBP [...] million minus GBP [...] million). Since out of the total value of parallel imports (GBP [...] million), imports from Spain represented GBP [...] million (see Annex 10 to GW notification of 28 July 1998 [907] and recital above), GBP [...] million lost discount is directly attributable to these imports.

([58]) Joined Cases C-267 and C-268/95, [1996] ECR I-6285.

([59]) Case 16/74 [1974] ECR 1183.

(a) ***General arguments concerning Article 81(3)***

The combined application of Article 81(3) and Article 3

(88) Subsidiarity (Article 5, formerly Article 3b). In the absence of harmonisation of national regulations regarding pharmaceutical pricing, the Commission cannot use parallel imports to advance the goals of market integration. The price differences reflect different policy decisions of the Member States. The effect of parallel trade is to impose the fiscal, budgetary and industrial policies of one Member State on another.

(89) Economic and social cohesion (Article 3(1)(k), formerly Article 3(1)(j). According to GW, its pricing policy in Spain will ensure that there will be adequate supplies of innovative medicines on the Spanish market. It argues that the artificially low prices allowed by the Spanish Government have led to significant delays between the application for a product licence in Spain and the actual marketing of GW products there. In many cases, products only reach the market in Spain some six or seven years after they have been marketed in the United Kingdom.

(90) Competitiveness and R & D [Article 3(1)(m) and (n), formerly Article 3(1)(l) an (m)]. GW goes to considerable length to explain the immediate and long-term detrimental effects of parallel trade in the pharmaceutical sector. The immediate effect is to reduce revenues of companies in the target countries as prices are pushed down to levels in the source countries. GW provides figures from a NERA report concerning losses in 1996 for the industry as a whole. It also refers to its own losses in the United Kingdom for the period 1996 to 1998 (see recitals 64 to 67). The long-term effect is to reduce funds available for basis research and new product development due to the loss of revenues. GW reduced its total R & D investment by [...] % in 1997 'partly as a result of lower anticipated sales revenues in 1997 and 1998' ([60]), GW adds that this trend will contribute to the migration of the pharmaceutical industry and R & D efforts to countries such as the USA where higher profits can be earned.

The judgments in *Merck Primecrown* and *Centrafarm Winthrop*

(91) GW argues that the Court of Justice has recognised the legitimacy of private measures to reduce parallel trade and the need for the Commission to support such measures by exempting them pursuant to Article 81(3). In *Merck* v *Primecrown*, the Court acknowledged that 'the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States'. It then went on to observe that 'it is well settled that distortions causes by different price legislations in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement'. According to GW, the 'measures taken by the Community authorities' must include individual exemptions pursuant to Article 81(3). In this respect, GW relies on *Centrafarm* v *Winthrop*, where the Court described such measures as including 'the exercise of their powers in the competition field'.

The *bilan économique* argument

(92) In its notification of 28 July 1998, GW states that the United Kingdom Government has estimated the annual savings associated with all parallel imports for the NHS, via the claw-back mechanism, at about GBP [...] million. This benefit is small compared with the direct net loss of GBP [...] million due to imports from Spain (see recital 67) and the loss of GBP [...] million in GW's allowable R & D budget under the PPRS due to imports from all sources (see footnote 57). It conclude that the only real beneficiaries of parallel import are the parallel importers themselves.

(93) In its reply to the SO, GW expands on this argument. It points to the negative effects of parallel imports. They exacerbate the distortion of competition created by Member State intervention, lead to pricing that deviates from optimal welfare-enhancing pricing and cause delays in product introductions in lower-price countries. The classic benefits for consumers in high price countries, namely lower purchase prices, do not exist. The principal consumers in these countries are governments, because they fund the purchases. They do not necessarily regard lower prices generated by parallel imports as a benefit, particularly if they lead to less investment in R & D. All in all, parallel trade in pharmaceutical goods only involves arbitrage by commercial speculators.

([60]) Reply to the SO, p. 21 [3528].

(b) ***Specific arguments concerning each of the four conditions set out in Article 81(3)***

First condition (promotion of technical progress)

(94) GW reiterates its arguments about the importance of R & D as the most critical competitive parameter in the pharmaceutical sector and the negative impact of parallel trade on R & D financing.

(95) R & D as competitive parameter. GW states that its rate of R & D expenditure represents approximately 13 % to 14 % of turnover ([61]). In 1999, R & D investments amounted to GBP [...] billion ([62]). The overall rate of R & D expenditure is high for all companies operating in this market. Internal funds are the major source of funding for research projects. There are sound economic reasons, including issues of screening and commitment, for this ([63]).

(96) Negative impact of parallel trade on R & D financing. GW uses a host of figures concerning the size of R & D investments, the direct and indirect losses for R & D due to parallel trade and the importance of sales revenues for R & D to demonstrate the negative impact of parallel trade.

(97) It states that the average R & D investment to develop one single product is up to GBP 300 million and urges the Commission not to dismiss a small percentage decrease in R & D as *de minimis*, because the R & D not engaged in could be the very R & D that would led to the discovery of a major new product. Where success is unpredictable, opportunity costs may be infinite.

(98) GW then restates figures concerning the direct losses for R & D incurred by GW plc as a result of parallel trade in the eight leading product from Spain (offset against extra revenues from sales in Spain). These losses amounted to GBP [...) million between 1996 and 1998 and in 1998 alone GBP [...] (recital 68). Given that GW reinvests about [...] % of its pre-tax profits in R & D, this meant a reduction of the R & D budget of GBP [...] million in the period 1996 to 1998 (GBP [...] million in 1998). This represents a reduction in the contribution of GW plc sales to GW's world wide R & D budget of over [...] %. The GBP [...] million reduction would have been 'more than sufficient to cover the development costs for any one of a number of new products whose development or in-licensing GW has been forced to cancel or postpone as a result of the need to prioritise the use of scarce resources'. GW acknowledges that it may be difficult to identify the projects that might have been realised or continued had such a substantial sum been available. At the oral hearing, it nevertheless mentioned nine projects that could not be funded due to insufficient finances.

GW also repeats that parallel trade into the United Kingdom from all sources, as well as from Spain in particular, caused an indirect loss on R & D because it led to the reduction of the discount which the NHS deducts from its UK sales when determining the basis for capping its profits. In 1998 this loss of revenue amounted to GBP [...] million (parallel trade in all GW products from all sources, see recital 65) and GBP [...] million (parallel trade in the eight leading products from Spain, see recital 68). This led to a reduction of the allowable [...] % discount by GBP [...] million (all sources) and GBP [...] million (Spain) respectively (see footnote 57). This effectively reduced GW's 'permissible R & D budget'.

(99) GW finally stresses that pharmaceutical companies make their R & D investment decisions on the basis of the anticipated stream of returns. These depend on the value of the patent to be obtained. That value is directly related to the sales revenues, net of production costs. These in turn depend on the expected price that can be charged and quantity that can be sold. GW illustrates this point by referring to the increase in its R & D expenditures by some 230 times during the period 1980 to 1993. During that period, GW had succeeded in bringing a number of successful innovative products to the market. Zantac was by far the most important product. Up to 1994, it accounted for about [...] % of word wide revenues.

First condition (improvement of distribution)

(100) According to GW, parallel trade is detrimental for the distribution of pharmaceutical products in at least three respects.

To start with, parallel trade interferes with producers' ability to plan distribution rationally because it leads to shortages in source countries and oversupply in target countries. Cofares, the largest domestic Spanish wholesaler, and the association of Spanish laboratories are said to have complained about such shortages in Spain.

([61]) London Economics study pp. 32 and 44, footnote 31 [1036, 1048] pointing out that the R & D ratio is relatively constant over the years. For 1997, GBP 1,148 billion out of 7,980 billion (14,5 %) was spent and for 1998 GBP 1,163 billion spend out of 7,983 billion (14,5 %) (*source*: Annual Reports).

([62]) Slide presentation by Glaxo in the oral hearing of 8 and 9 December 1999 [4175].

([63]) See p 37, footnote 39, of supplementary notification by GW of 28 July 1998 [869].

Parallel trade also disrupts producers' distribution systems by removing the incentive and the means for wholesalers to provide a level of service for which they are remunerated.

Finally, the combination of low domestic prices and the parallel trade to which they give rise provide a strong disincentive to the rapid introduction of innovative medicines in the low-price countries which results in marketing delays for new products.

(101) Where these detrimental effects are the results of differences in prices due to exchange-rate fluctuations or the lower costs of distributors, they may be excused or at least tolerated as a reflection of the workings of a free market. In contrast, where these effects result from Member State intervention, they cannot be justified. The new sales conditions thus provide objective improvements in distribution by remedying the negative effects of parallel trade.

Second condition (consumer benefits)

(102) GW argues that consumers profit from its enhances R & D activities as well as from its improved distribution. Beyond the benefit for consumers, there are benefits for the national governments involved. The GW system allows the United Kingdom to achieve its goal of stimulating R & D while permitting the Spanish Government to share these benefits while setting maximum wholesale prices domestically.

Third condition (indispensability)

(103) GW considers Clause 4 to be indispensable since there is no other way to reduce the distortion of competition created by Spain. It had contemplated an action against the Spanish authorities on the basis of Article 28 of the Treaty, on the ground that the maximum wholesale prices limit imports. However, it was 'advised that in the absence of evidence that the Spanish pricing system allows higher prices for products produced in Spain, that system would probably not be viewed as a restriction on imports in the light of the lack of harmonisation on pharmaceutical pricing'.

Fourth condition (no substantial restriction of competition)

(104) GW refers to its submissions in the context of Article 81(1) concerning the 'competition' created by parallel imports of pharmaceutical products into the United Kingdom. Such competition does not benefit consumers to any significant degree but only serves, at the expense of the United Kingdom Government, the profits of parallel traders whose sales of parallel imports exceed the levels assumed by the PPRS. GW also notes that it does not operate exclusive distribution in the countries affects by parallel imports from Spain. Intra-band competition would therefore continue in respect of GW's products if the new sales conditions were in force.

I. *ARGUMENTS PRESENTED BY THE COMPLAINANTS*

(105) All complainants regard Clause 4 of GW SA's new sales conditions as an agreement that puts in place a system of dual pricing impeding parallel trade. Such systems are per se illegal. They cannot be exempted.

(106) Aseprofar claims that parallel trade often constitutes the only source of competition to patented medicines ([64]). EAEPC stresses that the notified system will influence the availability of parallel traded medicines in all Member States, not just the United Kingdom and that parallel trade does often yield benefits for consumers in high price countries ([65]).

(107) Aseprofar rejects the argument that governments must be given the opportunity to foster R & D by accepting high prices. This mechanism is inefficient because there is no guarantee that high profits necessarily lead to the desirable level of R & D. Furthermore, nobody knows what the desirable level of R & D is. In any event, governments can revert to alternative, more direct means to stimulate R & D, for example, by subsidising these activities.

(108) Aseprofar also casts doubt on the existence of conflicting policy goals in Spain and the United Kingdom. Had the NHS wished to stop or discourage parallel trade, it could have done so by reimbursing pharmacists on the basis of their actual purchase costs instead of paying them a fixed fee which is unrelated to these costs.

([64]) Professor Corchon study I, pp. 1 to 11 [Case 36.997, 3144 to 3154].

([65]) Submission by the EAEPC of 22 December 1999, p. 7 [Case 37.380, 111].

II. LEGAL ASSESSMENT

A. *ARTICLE 81(1) OF THE TREATY*

1. AGREEMENT BETWEEN UNDERTAKINGS

(109) The Commission considers that Clause 4 of the new sales conditions constitutes an agreement between GW SA (and its subsidiaries) and all Spanish wholesalers who have subscribed to these conditions after having received a copy thereof (see recital 12). GW plc does not dispute that the new conditions of sale constitute an agreement between undertakings within the meaning of Article 81(1).

2. RELEVANT MARKET

(110) The Commission usually defines the relevant products market by reference to the 'Anatomical therapeutic classification' (ATC) recognized by the WHO. It has, however, also occasionally accepted the ATC classification drawn up by EphMRA on which GW relies in the present case ([66]). In pharmaceutical cases the Commission uses the third ATC level, which reflects therapeutical/pharmacological subgroups of drugs, as a starting point of its analysis.

(111) However, in specific cases, the market definition may be narrower or wider than ATC third level. Ultimately, the substitutability of products depends on the indication for which they are approved and used ([67]). In the case of prescription drugs, it therefore depends on the diagnosis of prescribing doctors.

(112) In its supplementary notification of 28 July 1998, GW provided for each product market share data based on either the second or third level of the ATC classification. GW observes, however, that the Spanish pricing system and the problems caused by parallel imports give rise to issues that go beyond the individual products covered by the agreement. These issues might point to a wider product market comprising all prescription medicines ([68]).

(113) Taking account of these observations and of the fact that the new sales conditions apply to all GW products sold in Spain (82 in total) and affect parallel trade throughout the Community, it is not necessary to determine precisely GW's market shares for each product for the purpose of this decision.

(114) For the same reason, it is not necessary to dwell upon the scope of the relevant geographic market. In all Commission decisions adopted hitherto, this scope has been defined as national. In the present case, the Commission does not divert from this because of a number of factors. These include different price and reimbursement regulations, different brand and packing strategies and different distribution systems as well as different prescribing habits of physicians (reflected by the different market shares for the same product in different Member States). At this stage, Community harmonisation is limited to technical requirements for medicines and the entry into force of a procedure enabling pharmaceutical companies to apply to the European Agency for the Evaluation of Medicinal Products for the purpose of obtaining a single market authorisation for the entire Community ([69]). Even with these developments, pharmaceutical companies still continue to use the national market authorisation procedures.

3. RESTRICTION OF COMPETITION

(115) Below, the Commission addresses all arguments submitted by GW in the context of Article 81(1), except those in which it submits that its pricing policy in Spain enhances consumer welfare in so far as it limits a form of trade (parallel trade) which causes harm to consumers in Spain while causing no harm to UK consumers. GW reiterates these arguments in detail in the context of Article 81(3) and they will therefore be addressed in that context.

(a) ***Clause 4 is tantamount to an export ban or a dual-pricing system***

Objective to impede parallel trade

(116) Although GW contends that the new sales conditions do not block and are not intended to block exports by Spanish wholesalers where these have an advantage due

([66]) Commission Decision 97/469/EC in Case IV/M.737 — Ciba-Geigy/Sandoz (OJ L 201, 29.7.1997, p. 1, recital 22.

([67]) See also Commission notice on the definition of relevant market for the purposes of Community competition law (OJ C 372, 9.12.1997, p. 5, recital 36 on intended use.

([68]) Supplementary notification, p. 10 [842].

([69]) See Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1). Regulation as amended by Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

to superior efficiency or differences in exchange rates (see recital 21), it admits in the London Economics study that the agreement is 'intended to reduce the incentive for Spanish traders to engage in parallel trade of prescription medicines purchased at the low prices set by the Spanish Government ([70])'. It follows that GW's objective is clearly to impede parallel trade by obliging Spanish wholesalers to purchase the drugs at prices which are higher than the maximum industrial price for domestic sales.

Effective exclusion or restriction of parallel trade

(117) As shown above with regard to GW's eight leading products which GW considers to be most subject to parallel trade, the Clause 4B prices either exclude or restrict parallel trade in a large majority of cases (see recitals 72 to 75 above). The Clause 4B prices exclude such trade by making it economically uninteresting for wholesalers in more than 40 % of the cases: 66 out of 161 cases if no account is taken of the wholesalers' own costs. This percentage increases slightly if a 5 % wholesale cost margin is added to domestic and export prices (68 cases) and even more in a 15 % cost margin scenario (74 cases). In around 35 % of the cases, the Clause 4B prices impede parallel trade by making it economically less interesting for the wholesalers (57 cases). Admittedly, that percentage decreases when one adds a 5 % wholesale cost (45 cases) or a 15 % cost (24 cases). I follows that Clause 4 produces an effect tantamount to that of an export ban in a considerable number of cases while impeding parallel trade in other cases in very much the same way as a system of dual pricing.

Analogy with export bans

(118) The Commission has already imposed a fine on a pharmaceutical company for a policy aimed at banning parallel trade. In Sandoz ([71]), it prohibited a practice whereby the company had displayed the words 'export prohibited' over a number of years on its sales invoices. The Court of Justice upheld the Commission's decision ([72]). A pricing policy which makes it economically uninteresting for wholesalers to indulge in parallel trade must be considered to be at least as effective as an outright contractual export ban in excluding such trade because it involves in principle no cost of monitoring compliance. A parallel can be drawn with the Commission's decision in Distillers ([73]) according to which 'the non-applicability of price allowances on spirits for export and the application to the same customers of different prices for spirits for export and for spirits for United Kingdom consumption are clearly an attempt to impede parallel imports from the United Kingdom into EEC countries other than the United Kingdom, with the same object as a formal export prohibition and can be regarded as a more efficient way to discourage exports'.

Analogy with dual pricing

(119) To the extent that the Clause 4B prices render parallel trade more costly and thus economically less interesting, GW's policy can be equated with systems of dual pricing of the kind prohibited in Moët Chandon ([74]) or Distillers and Gosme/Martell ([75]). In the first case, the Commission qualified a clause which reserved list prices for champagne to products for consumption in the United Kingdom as a restriction by object. Since it was not allowed to export products at these list prices, the system was classified as tantamount to a ban on export of champagne 'on the said terms'. This resembles the present situation, where the wholesalers are not allowed to export at the Clause 4A price. Exports are only possible at the higher Clause 4B price and therefore not on the terms which prevail in Spain. Likewise in Distillers, UK customers were charged different prices depending on whether they resold inside or outside the United Kingdom. The Commission declared that the price terms amounted to an indirect export prohibition because they rendered sales to other Member States at the very least more difficult. In Gosme/Martell, the Commission held that Martell's discount system which made exports more expensive and less profitable, was contrary to Article 81(1) since its object and effect was to protect a higher price level in France resulting from government intervention in the form of price freezes and price controls. The impediment to parallel importation resulting from a dual-pricing system has also been prohibited in the Commission Decision Pittsburgh Corning ([76]).

([70]) Executive summary of the LSE study, introduction p. 1 and also at v [1007, 1003].

([71]) Commission Decision 87/409/EEC in Case IV/31.741 — Sandoz (OJ L 222, 10.8.1987, p. 28).

([72]) Case 277/87 *Sandoz* v *Commission* [1990] ECR I-45.

([73]) Commission Decision 78/163/EEC in Case IV/28.282 — The Distillers Company Limited — Conditions of sales and price terms, OJ L 50, 22.2.1978, p. 16, point 2.

([74]) Commission Decision 82/203/EEC in Case IV/30.188 — Moët et Chandon (London) Ltd, (OJ L 94, 8.4.1982, p. 7, paragraph 11.

([75]) Commission Decision 91/335/EEC in Case IV/32.186 — Gosme-/Martell —DMP (OJ L 185, 11.7.1991, p. 23, in particular paragraphs 19 and 32.

([76]) Commission Decision 72/403/EEC in Cases IV/26.894, 26.876 and 26.892 — Pittsburgh Corning Europe — Formica Belgium — Hertel (OJ L 272, 5.12.1972, p. 35).

(120) GW contests that Clause 4 can be compared with dual pricing. It argues that the national authorities determine the level of one set of the prices involved (the domestic Clause 4A price) and impose that level upon it. This argument overlooks the fact that the pharmaceutical companies have negotiating power when discussing prices for domestic sales.

(121) First of all, these discussions open on the basis of price proposals made by the companies themselves. The Spanish authorities allow the companies to base their proposals on all their costs, including those related to R & D. article 3(3) of Royal Decree 271/1990 expressly refers to the cost involved in R & D as included in the complete cost which must be taken into account (see recital 38). The proposals are then negotiated. Furthermore, the companies can apply for price increases by proving 'mandatory modifications to social-sanitary, technical, economical or budgetary status' (see recital 40). The possibilities of obtaining price increases are not theoretical and, where they materialise, not even exceptional. Indeed, for four of the eight products which are claimed to be the prime candidates for parallel trade, GW managed to obtain substantial price increases. The price increases for Serevent, Imigran and Lamictal in May 1997 and for Ventolin in July 1998 provide telling examples (see recitals 41 and 42).

(122) GW itself admits that it managed to align the domestic prices for Severent, Lamictal and Imigran in Spain on the European average price level but argues that all the benefits of these price increases were neutralised by the simultaneous reduction of the price for Zantac ([77]). However, what matters is that GW SA itself proposed this reduction in exchange for price increases for the abovementioned three products ([78]) and that it did so at a time when Zantac was, in any event, going off-patent in the United Kingdom and other Member States and already faced price competition form generic products ([79]). This illustrates that the Spanish authorities leave room for real price bargaining and do not set the prices unilaterally.

([77]) Reply to the SO, Annex 9, Letter GW-Ministry of Health of 1 April 1997 [3799/37800].

([78]) Reply to the SO, Annex 9, Letter GW-Ministry of Health of 1 April 1997 [3799/37800].

([79]) Annual Report GW 1997, p. 12 and 17 where GW also states that Zantac has come under increasing pressure from generic competition. See also response of 14 February 2000, p. 13 [4519].

(123) Furthermore, once a company has negotiated the industrial prices with the national authorities, it can still decide to effectively charge a lower price. In May 1997, GW SA sold the three product variations of Severent at a price lower than the authorised price ([80]). There are also other cases in which GW SA has set the commercial prices below the maximum allowed ([81]).

Restrictions by object

(124) The Court of Justice (and Court of First Instance) have always qualified agreements containing export bans, dual-pricing systems or other limitations of parallel trade as restricting competition 'by object'. That is to say, prohibited by Article 81(1) without there being any need for an assessment of their actual effects. In principle they are not eligible for exemption pursuant to Article 81(3). Reference can be made to the judgments in *NV IAZ International Belgium* v *Commission* ([82]), *Sandoz* v *Commission* and more recently to *Volkswagen* v *Commission* ([83]). In the latter case, the Court of First Instance upheld the Commission's decision which had classified various measures making parallel imports more difficult (without excluding them altogether) as restrictions 'by object'. These included measures reducing the bonus granted to retailers in the cases of exports thereby reducing the incentives to engage in parallel trade,

(125) GW's new sales conditions entail restrictions of competition 'by object' within the meaning of Article 81(1). It is settled case-law that for the purpose of the application of Article 81(1) there is no need to take account of the actual effects of an agreement when it has as its object the prevention, restriction or distortion of competition within the common market. Consequently, the Commission is not required to show actual anti-competitive effects where the anti-competitive object of the conduct in question is proved ([84]). However, for the sake of

([80]) For Serevent Acc. GW charged ESP 72,5/unit instead of the authorised 75,53. For Inh. 25 × 120, ESP 34,54/unit has been charged, compared to an authorised price of ESP 36,05. For Inh. 25 × 60, only ESP 37,5/unit of the authorised 38,86 charged. See reply to the SO, Annex 9, present PTW [3795].

([81]) See response of 14 December 1998, Annex 5 [1693 to 1703] where GW's indications show differences between the commercial and authorised price for the following products: Becloforte 250 mg Inh. (commercial price: 2 215,60; authorisation price: 2 296,00); Beconase (commercial price: 430,10; autorisation price 442,00), Becotide (commercial price: 406,30; autorisation price: 417,60).

([82]) Joined Cases 96-102, 104, 105, 108, 110/82 [1983] ECR 3369, paragraphs 24, 25 and 27.

([83]) Case T-62/98 [2000] ECR II-2707, paragraphs 89 and 178.

([84]) See e.g Case T-62/98, *Volkswagenv Commission*, paragraph 178.

completeness, the Commission has undertaken this analysis and assessed the new sales conditions in their legal and economic context.

(b) ***Clause 4 produces restrictive effects on competition***

(126) Tables 4-1 to 4-4 set out in detail the impact of GW's new sales conditions on parallel trade between Spain and all other Member States (except Luxembourg). They do so for GW's eight leading products which GW considers to be most subject to parallel trade (see recital 15). It emerges from these tables that the Clause 4B prices exclude such trade by making it economically uninteresting for wholesalers in more than 40 % of the cases: 66 out of 161 cases if no account is taken of the wholesaler's own costs. This percentage increases slightly if a 5 % wholesale cost margin is added to domestic and export prices (68 cases) and even more in a 15 % cost margin scenario (74 cases). This shows that the agreements produce a restrictive effect on competition by excluding or limiting the possibilities of parallel trade (see recital 75).

Clause 4 does not merely compensate a distortion of competition created by Spain

(127) The Commission rejects GW's argument that Clause 4 does no more than compensate a distortion of competition created by Spain, for essentially four reasons. These will first be summarised and then developed in more detail. First, in applying Article 28 of the Treaty on free movement of goods, the Court of Justice has consistently condemned State measures which restrict parallel imports of medicines from countries where prices are lower and which provided less (or no) incentives for pharmaceutical companies to undertake R & D. It will be demonstrated that the competition rules equally aim at preventing the partitioning of the common market along national lines. Second, in other sectors (for example cars) where — in contrast to the pharmaceutical sector — companies have no say in the regulatory process, these companies have not been able to rely on the difference between national regulations to justify restrictions on parallel trade. Third, the difference between national price regulations (and the underlying policy objectives) should not be overstated in the present case. Fourth, it is too simplistic to refer to conflicting national price regulations as unilateral State measures which pharmaceutical companies have been imposed on since these companies have negotiating power vis-à-vis the national authorities.

(128) Case-law on Article 28 in the pharmaceutical sector. In *Merck* v *Primecrown* ([85]), the Court explicitly stated, 'although the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States, that circumstance cannot justify a derogation from the principle of free movement of goods'. In that case the Court prevented a pharmaceutical producer from invoking its UK patent to stop parallel imports from Spain where the products did not enjoy patent protection and were subject to government price control. In *Centrafarm* v *Winthrop* ([86]) the Court had already stated: 'It is a matter of no significance that there exist, as between the exporting and importing Member State, price differences resulting from governmental measures adopted in the exporting state with a view to controlling the price of the product'.

(129) Given that the Court held in *Centrafarm* v *Winthrop* and *Merck* v *Primecrown* that undertakings may not rely on national patent legislation to restrict the free movement of goods placed on the common market with their consent, there is no reason why Community law should permit undertakings to restrict the free movement of such goods by means of private law contracts where the conditions of Article 81(1) are met.

(130) To begin with, it is well established that Article 28 and Article 81, while dealing with different types of restrictions on parallel trade, both seek to achieve the same goal, i.e. market integration. As the Court observed in *Merck* v *Stephar* ([87]), the patent-holder who availed himself of a national patent right to block parallel trade 'would bring about a partitioning of the national markets which would be contrary to the aims of the Treaty'. In *Consten* and *Grundig* ([88]) the Court stated that Article 81(1) is designed to pursue the Treaty's fundamental objective of abolishing the barriers between Member States and therefore opposes agreements between undertakings which restore national divisions.

([85]) Joined Cases C-267/95 and C-268/95,*Merck & Co*.Inc. V *Primecrown Limited*, paragraph 47; see also Case C-436/93 *Bristol Myers Squibb*v *Paranova A/S*, [1996] ECR I-3457, paragraph 46.

([86]) Case 16/74, *Centrafarm BV and De Peijper*v *Winthrop BV* [1974] ECR 1183, paragraph 15, 16 and 17.

([87]) Case 187/80, [1981] ECR 2063, paragraph 13.

([88]) Case 56 and 58/64 of, *Consten and Grundig-Verkaufs-GmbH*[1966] ECR 299, at p. 340.

(131) Furthermore, there is a thin line between Member State measures and private company measures in these intellectual property cases. Indeed, the effect of applying Article 28 in such cases, has been to prohibit private actions by companies relying on monopoly rights which a Member State has granted them. If Article 28 prohibits these unilateral private actions, then Article 81(1) logically applies to concerted actions involving these same companies trying to achieve the same result. Thus, in *Sirena r.l.v Eda* ([89]) the Court ruled on the exercise of a trademark right against imports from another Member State under Article 28. The only obstacle it saw to the application of Article 81 was that the exercise of a trademark right does not in itself posses the elements of an agreement or a concerted practice within the meaning of Article 81(1). Nevertheless, the Court acknowledged that the exercise of that right might fall within the scope of Article 81(1). It observed that 'such situations (i.e. where Article 81(1) applies) might in particular arise from restrictive agreements between proprietors of trademarks or their successors in title enabling them to prevent imports form other Member States.'

(132) Analogy with other sectors where pricing is influenced by national regulations. In other sectors, the Commission has refused to consider the difference between national regulations as an exculpatory factor for companies which restrict competition ([90]). That approach has been upheld by the Court of Justice. In the car sector, the Commission acknowledges that Member States' tax regimes differ considerably (leading to high price differences, sometimes around 80 %) ([91]), that this difference stands in the way of genuine market integration and that it interferes with free pricing. Nonetheless, the Commission has never accepted this as a justification to block parallel trade ([92]). For example, in *Volkswagen* ([93]), it held that the block exemption in Commission Regulation (EC) No 1475/95 of 28 June 1995 on the application of Article 85(3) of the Treaty to certain categories of motor vehicle distribution and servicing agreements ([94]) was inapplicable as a result of the concerted actions between a manufacturer and importers aimed at restricting parallel trade. However, car manufacturers have no say at all in the fiscal regulatory process (which can cause substantial differences in car prices between the Member States and, as a consequence, trigger parallel trade), whereas pharmaceutical companies are always involved in the regulatory process governing their sales prices. The argument that cars or other freely traded goods cannot be compared with medicines because parallel trade does not benefit the final consumers of medicines is a separate argument and will be addressed in the context of Article 81(3).

(133) Conflict between the United Kingdom and Spain's policy objectives should not be overstated. The Professor Rey study I argues that parallel trade from Spain endangers UK prices and therefore compromises the UK policy choice to foster R & D. However, the study's basic assumption of downward pricing (see recital 80) has no foundation. Parallel trade constitutes only a very negligible percentage of pharmaceutical sales (see recital 29) and can therefore only produce a marginal effect on the prices in the target country. The best illustration of this fact can be seen in Tables 2 and 3, which show that despite the long history of parallel trade, prices in the United Kingdom are still substantially higher than in other Member States. There is no proof that UK prices have gone or are likely to go down because of Spanish imports. Furthermore, the difference of policy choices between the two Member States should not be overstated. On the one hand, the Spanish regulatory authorities expressly allow pharmaceutical companies to propose prices which fully reflect their R & D costs. This is clearly stated in the relevant

([89]) Case 40/70, *Sirena Srl* v*Eda Srl and others*[1971] ECR 69, paragraph 5. See also Case 96/75 *EMI Records Limited*v *CBS Schallplatten Gmbh*[1976] ECR 913, paragraph 5.

([90]) See Joined Cases 209-215, 218/78 *Heintz van Landewyk Sarl*v *Commission*[1980] ECR 3125, at paragraph 153 where the Court acknowledges that the Belgian taxation system might have a definite influence on competition, but nevertheless refused to accept restrictions of competitions based on that reason.

([91]) See Commission report on car prices within the European Union on 1 May 2000, COP/F2/0500 which shows for example a price difference between a Honda sold in Denmark and in France of 87 % (pp. 52 and 53) after tax.

([92]) In its notice concerning Regulation (EEC) No 123/85 on the application of Article 85(3) to certain categories of motor vehicle distribution and servicing agreements (OJ C 17, 18.1.1985, p. 4), the Commission specifies that it can withdraw the benefit of the block exemption for selective distribution networks if the price differences exceed 12 % and if there are indications that these differences are chiefly due to obligations subscribed to by the approved dealers. It has, however, never supported any attempt to block parallel trade. The notice remained applicable after the adoption of Regulation (EC) No 1475/95, see press release IP(95) 648; also in its Decision 2001/146/EC in Case IV/36.653 — Opel (OJ L 59, 28.2.2001, p. 1), the Commission prohibits measures to block parallel trade despite the price differentials resulting from different tax burdens.

([93]) Commission Decision 98/273/EC in Case IV/35.733 — Volkswagen (OJ L 124, 25.4.1998, s. 60, paragraph 187). The Decision was upheld by the Court of First Instance in Case T-62/98, *Volkswagen AG*V *Commission*[2000] ECR II-2707.

([94]) OJ L 145, 29.6.1995, p. 25.

statute ([95]). On the other hand, the United Kingdom, while encouraging R & D, recognises the need for affordable prices. In paragraph 2.1 of the 1999 PPRS scheme, the Department of Health recognises that continuous innovation is the key to competitive success in a research-based industry and wishes to encourage the research, development and supply of innovative treatments for the benefit of NHS patients ([96]). However, in paragraph 2.3 of the 1999 PPRS scheme, the Association of British Pharmaceutical industry (ABPI) 'recognises that it is in the public interest that prices of pharmaceutical products supplied under the NHS are fair and reasonable'. In the introduction to the 1999 scheme, the Department of Health and the ABPI state that they 'have a common interest in ensuring that safe and effective medicines are available on reasonable terms to the National Health Service and in a strong, efficient and profitable pharmaceutical industry in the United Kingdom'.

(134) While wishing to promote R & D, the NHS appears to be equally concerned that prices are kept at a reasonable level. This is demonstrated by the general price cut of 4,5 % applied in October 1999 (see recital 47). Furthermore the NHS *de facto* encourages parallel trade in two respects. First of all, it reimburses pharmacists a fixed fee without taking into account their actual purchase prices. As a result, the pharmacist who purchases cheaper parallel imported products proportionally receives a higher rate of reimbursement than a colleague who buys domestic higher prices products. If the NHS had an avowed policy in favour of high prices and against parallel imports, it could have introduced a 'cost-plus' system whereby pharmacists' margins are fixed as a proportion of the actual price paid to the wholosaler. In the Frontier Economics study II, GW itself admits that by introducing such a system, the United Kingdom Government could avoid incentives the pharmacist to buy at the lowest price ([97]). It has not done so. Secondly, the only measure the NHS has taken in order to — as Glaxo perceives it — avoid unjust enrichment by pharmacists is to claw back 4 % to 5 % of the reimbursements from all pharmacists on the assumption that this corresponds to the level of parallel trade effected by intermediaries and pharmacists. Here again, pharmacists who import more are, proportionally speaking better off. So the claw-back mechanism provides pharmacists in fact with an incentive to increase parallel imports. The United Kingdom has not established any measure to reduce parallel trade and might actually seek to achieve the best of two worlds: fostering R & D while at the same time creating possibilities to achieve savings. Also, the fact that the NHS has recently created the National Institute for Clinical Excellence (see recital 49) shows that the United Kingdom is interested in the use of cost-effective medicines.

(135) Negotiating power of pharmaceutical companies vis-à-vis the national authorities. As already explained above, given the fact that companies actually negotiate the prices with the Spanish Government and manage to achieve price increases by invoking one or more of the justifications set forth in the relevant Royal Decree, it is too simplistic to regard pharmaceutical companies as price takers because the national competent authorities set maximum prices (see paragraphs 121, 122 and 123).

The present case differs from Distillers/Victuallers, Metro I and Villeroy Boch

(136) GW relies on *Distillers/Victuallers* to conclude that its sales conditions, like the agreements between Distillers and the victuallers, do not entail any distortion of competition. The first point to make is that the Commission actually found a restriction of competition in *Distillers/Victuallers*. It simply went on to consider that the restriction was rather theoretical and therefore not appreciable within the meaning of Article 81(1). The second point to make is that the regulatory framework in that case cannot be compared with the one faced by GW.

(137) As regards the first point (non appreciable restriction), the Commission highlighted the fact that the victuallers' customers (for example, international ships and airlines) were not oriented towards the non-duty free market segment anyway. Hence the restriction of their freedom to choose their customers and terms of sale did 'not result in any real restriction' and the obligations imposed on the victuallers 'does not have the effect of appreciably restricting competition in the common market'. In contrast, Clause 4 of GW's new conditions of sale imposes a restriction of the wholesalers' freedom of action which matters a lot to many of them, as the complaints and the demonstrated decline in sales to

([95]) See Article 3(3) of Royal Decree 271/90 (see recital 38).
([96]) Reply to the SO, Annex 4 on the PPRS, p. 2 [3676].
([97]) Frontier Economics study II, p. 10 [4557].

them demonstrate. The restriction is thus no purely theoretical but, indeed, appreciable.

(138) As to the second point (different regulatory framework), it must be noted that it was Community legislation which has put in place a clear segmentation of the duty-free and the non-duty free market segments. Only a certain customer group (travelers), which had been clearly identified by Community law, could buy duty free. The victuallers' agreement merely aimed at consolidating this legal situation by limiting the victuallers' freedom to sell duty-free goods outside the special distribution channel. Besides, the segmentation at stake did not interfere with the integration of national markets.

(139) The present case is different. To start with, the segmentation between Spain and the export markets has not been brought about by either Community or national legislations. Even the amendment to the Ley de Medicamento which limits the Spanish maximum price to products dispensed in Spain, leaves it at the discretion of the pharmaceutical companies to apply a higher or the same price to exports. There is specific regime which legally reserves the Clause 4A price to the Spanish market. It is GW's agreements with the wholesalers which do so. Moreover, the segmentation created by GW's sales conditions directly lead to a compartmentalisation of the common market.

(140) As regards *Metro I* ([98]) and Villeroy Boch ([99]), these are not relevant because they deal with contract clauses which address a different type of price differential, namely one from which vertically integrated wholesalers benefit vis-à-vis retailers who have to purchase their goods from wholesalers. In the present case, the price differential is created by an agreement between the manufacturer and this wholesalers in one country and it has an impact on competition between exporting wholesalers and intermediaries operating at the same level of the distribution chain in other Member States. Moreover, it is a price differential which interferes with market integration, unlike the one in *Metro I* and Villeroy Boch. It should also be noted that in *Metro I* the Court has not allowed the maintenance of the price differential as such, but only under the condition that the system does not reinforce the structural rigidity on the market.

Clause 4 restricts opportunities for parallel trade created by currency fluctuations

(141) GW itself acknowledges that the detrimental effects of parallel trade for ist distribution of pharmaceutical products may be 'excused or at least tolerated as a reflection of the workings of a free market' where the differences result from 'exchange rate fluctuations or the lower cost of distribution' ([100]). GW contends however, that the price differences which its new sales conditions seek to tackle result entirely from Member State intervention and that this intervention distorts competition. The appreciation of the British pound during the period for which GW has supplied data concerning parallel trade of its products (1996 to 1998) tells a different story.

(142) As pointed out above (recital 54), the GBP/ESP exchange rate rose from 188,65 in January 1996 to 240,09 in December 1998. This represented an appreciation of the GBP against the ESP of 27 %. The gap was even considerably wider between January 1996 and April 1998 (that is to say, the month after GW SA notified its new sales conditions). In April 1998, the exchange rate had risen to 262,09 and had constantly risen from October 1996 (when it was at 200,27). It must be concluded that the appreciation of the GBP has been a major factor in causing the price differences that triggered parallel trade between Spain and the United Kingdom. GW cannot maintain that these price differences results entirely from differences between the Spanish and British regulatory systems.

(143) The importance of currency fluctuations, and more in particular, of the appreciation of the British pound, for the increase in parallel imports into the United Kingdom is further illustrated by a comparison of the Spanish-sourced imports and imports from other source countries into the United Kingdom during the period 1996 to 1998. Although the absolute volume of Spanish-sourced imports increases, their share of all imports into the United Kingdom remained stable. It must therefore be concluded that the appreciation of the British pound attracted imports from all sources without the alleged discrepancies between the Spanish and UK regulatory systems playing any material role in this process.

([98]) Case 26/76, *Metro SB Großmärktev. Commission*.
([99]) Commission Decision 85/616/EEC.
([100]) Supplementary notification of 28 July 1998, p. 41 [873].

4. APPRECIABLE RESTRICTION OF COMPETITION

(144) GW's new sales conditions restrict competition to an appreciable effect for a number of reasons. Firstly, they affect 80 % of Spanish pharmaceutical wholesalers and these wholesalers are responsible for over [...] % of sales in GW's products in Spain (see recital 12). Moreover, for many of the products covered GW has high market shares in Spain as well as in the target countries. It emerges from Annex 2 to this Decision that GW holds substantial (second or third ATC level) market shares for most of the products particularly affected by the Spanish pricing system because they are the prime candidates for parallel trade (see recital 18). This is especially true for Becotide, Becloforte, Flixotide, Serevent and Ventolin, which all belong to the class of bronchodilators/A-Asthma as well as for Imigran. In all these cases, the Community market share is above the [...] % mark. Market shares in the United Kingdom (considered by GW to be the main target country) even exceed [...] % for Becotide, Becloforte, Flixotide, Serevent and Ventolin and [...] % for Imigran. Community-wide and UK market shares are also high for products like Zofran, Zyloric and the anti-herpes products Zovirax and Valtrex. Finally, the GW group is one of the largest pharmaceutical producers in Europe and indeed in the world. This is reflected in the group's high turnover figures (see recitals 9 and 10).

5. APPRECIABLE EFFECT ON TRADE BETWEEN MEMBER STATES

(145) An agreement is capable of affecting trade between Member States to an appreciable extent when it is foreseeable with a sufficient degree of probability, on the basis of a set of objective elements of law or fact, that it will influence, directly or indirectly, actually or potentially, on the pattern of trade between Member States and will hinder the attainment of the objectives of a single market ([101]).

(146) Since the object and effect of the new sales conditions are to restrict or prevent parallel exports, trade between Member States is affected in two ways: the sealing off of the market of origin for such exports (Spain) on the one hand and the protection of the destination markets (all other Member States) on the other. These markets cover the whole Community. Furthermore, the new sales conditions concern almost the entire Spanish market. An agreement of this type which extends over the whole territory of a Member State, has by its very nature the effect of reinforcing the compartmentalisation of markets on a national basis, thereby holding up the economic interpenetration which the Treaty in intended to bring about ([102]). GW itself admits such an effect, in particular by arguing that its system has reduced the lost revenue of GW plc in the United Kingdom by GBP 13 million-during the months of its application in Spain ([103]).

B. *ARTICLE 81 (3) OF THE TREATY*

1. GENERAL OBSERVATIONS

(a) ***The combined application of Article 81(3) and Article 3***

(147) The Commission has already responded to GW's argument relating to subsidiarity (Article 5 of the Treaty, see recital 88) when addressing the claim that the new sales conditions do no more than compensate a distortion of competition created by Spain. With reference to social and economic cohesion (Article 3(1)(k) of the Treaty, see paragraph 89), GW points to significant delays in product launches in Spain due to the artificially low prices prevailing there. Although this argument does not suggest that parallel trade (caused by these allegedly low prices) will exacerbate the delay problem, this argument will be addressed later in the context of the second condition set out in Article 81(3) (consumer benefits). Finally, GW's argument concerning the competitiveness of the Community's pharmaceutical industry and promotion of research and technological development (see recital 90) overlaps entirely with the arguments it advances in the context of the first condition of Article 81(3) (technical progress). That argument will therefore be addressed in that context.

(b) ***The judgments in Merck* v *Primecrown and Centrafarm* v *Winthrop***

(148) In both cases, the Court states very clearly that Member States cannot in principle — subject to the derogations set out in Article 30 (formerly Article 36) or in the *Cassis de Dijon* case-law — unilaterally adopt measures restricting the import of goods from other Member States when the goods have been lawfully marketed in those Member States. Any distortions of competition

([101]) *Volkswagen*AG v *Commission*, op. cit.; Case T-77/92, *Parker Pen*V *Commission*, [1994] ECR-II, p. 549, paragraph 39.

([102]) *Volkswagen AG*v Commission, op. cit.; Case 42/84, *Remia BV and others*V *Commissions*[1985] ECR 2545, paragraph 22.

([103]) Response by GW of 14 February 2000, p. 1 [4507].

resulting from differences between national regulations in the source and target countries can be tackled by Community-wide harmonisation measures enacted by the Community institutions. According to GW it follows from *Centrafarm* v *Winthrop* that Community institutions could, alternatively, tackle the problem by adoptin measures in the competition field.

(149) The first point to make is that in *Merck* v *Primecrown* the Court no longer uses the *Centrafarm* v *Winthrop* language on the exercise of powers in the competition field. Secondly, and more importantly, this language suggests at most that the Commission must consider the applicability of Article 81(3) when a private party raises obstacles to the parallel trade of pharmaceutical products and argues that there are objective justifications for doing so (in very much the same way as the Commission must examine the applicability of Article 30 or the *Cassis de Dijon* justification grounds when it assesses the legality of public measures impeding the parallel trade of these products). It is for the notifying party to provide the necessary evidence that the restrictions of competition resulting from the notified agreements fulfil all four conditions of Article 81(3) of the Treaty ([104]). As emerges from recitals 153 to 191, the Commission has carefully examined whether or not GW's new sales conditions for Spain meet the conditions set out in Article 81(3).

(c) ***The 'bilan économique' argument***

(150) GW argues that the Commission should weigh the beneficial effects of the new sales conditions (promotion of technical progress and improvement of distribution) against their restrictive effects upon competition. The Commission does not deny that the assessment of an agreement under Article 81(3) involves a balancing exercise between the benefits achieved by the parties to an agreement and the restrictions of competition they have caused. The text of Article 81(3) itself reflects the need for such a balancing exercise by incorporating two 'positive conditions' and two 'negative conditions'. The first two concern the benefits, the latter two deal with the restrictions (which must be indispensable and should not lead to an elimination of competition for a substantial part of the products in question).

(151) However, it is established case-law that the conditions set out in Article 81(3) are cumulative. Each of them must be met for the agreement to be considered for exemption ([105]). Therefore, before carrying out this balancing exercise, the Commission must be convinced that the notified agreement genuinely contributes to the achievement of the benefits claimed (promotion of technical progress or improvement of production or distribution) while allowing consumers a fair share of these benefits. In this case, GW has not proven that Clause 4 of the new sales conditions makes such a contribution. As will be shown below, there is no convincing evidence that parallel trade has actually affected GW's R & D budget. In any event, there is no proof that parallel trade has had anything other than a minimal effect upon that budget. Nor has GW been able to demonstrate that parallel trade has caused undue harm to GW distributors located outside Spain or to consumers in Spain.

(152) Under these circumstances, there is no need for a balancing test. In any event, if the Commission had to undertake such a balancing exercise, any positive effects generated by the new sales conditions would be outweighed by the negative effects they have produced on the integration of national markets within the Community. GW recognises that its new sales conditions partition markets. In the Frontier Economics Study I GW makes a clear distinction between so-called 'low-price' and 'high-price' countries ([106]).

2. SPECIFIC OBSERVATIONS REGARDING EACH OF THE FOUR CONDITIONS SET OUT IN ARTICLE 81(3)

(153) It is important to note that it is for the notifying party to justify the restrictions of competition resulting from the notified agreement by demonstrating that these restrictions fulfil all four conditions of Article 81(3) of the Treaty. It is not for the Commission to prove that its intervention against these restrictions of competition produces a benefit for consumer welfare. Furthermore, the restriction at issue in this case constitutes a particularly serious attempt to partition the common market. Although there is in principle no restriction which cannot be exempted under Article 81(3) ([107]), GW has failed to provide sufficient evidence that the restriction of competition resulting from the new sales conditions should benefit from an exemption.

([104]) Case T-66/89, *Publishers Association* v *Commission*, [1992] ECR II-1995, paragraph 69.

([105]) Case T-17/93, *Matra hachette SA* v *Commission*, [1994] ECR II-595, paragraph 104.

([106]) Frontier Economics study I, p. 15 [3711].

([107]) Case T-17/93 *Matra SA Hachette* v *Commission*, paragraph 85.

(a) ***First condition (technical progress)***

(154) GW argues that parallel trade has caused losses for R & D since the revenue lost due to parallel trade is revenue that would have been spent on the development of innovative products in the absence of such trade. According to GW, Clause 4 of its new sales conditions aims at remedying this situation by restricting parallel trade. By combatting parallel trade, the new sales conditions create extra financial resources for R & D and thus promote technical progress. In the Commission's view, GW has not proven that there is a causal link between parallel trade and R & D investments. In any event, it has overstated the magnitude of any impact that parallel trade might have on such investments.

Impact of parallel trade on R & D: no causal link

(155) The Commission does not dispute that R & D is an important parameter of competition in the pharmaceutical sector and needs appropriate financing. However, there is no evidence that parallel trade has caused reductions in GW's R & D budget or that it has prevented that budget from growing. In this respect, the Commission offers the following observations.

(156) Parallel trade and profits: it is a matter of discretion for pharmaceutical companies to decide how much they wish to invest in R & D. Any savings they might hypothetically make by preventing parallel trade would therefore not automatically lead to higher R & D investments. It is conceivable that these savings might merely be added to the companies' profits. Obviously, the generation of extra profits alone cannot justify an exemption. In this regard, GW's argument would mean that the first condition for exemption would be fulfilled for every agreement that could be said to contribute to an increase in the revenues of a firm engaged in R & D. The condition would in any case be meaningless, since it is in the nature of any agreement restricting competition to be likely to increase a firm's earnings.

(157) Parallel trade and costs: GW itself admits 'that parallel trade is not the key driver for decisions on R & D' ([108]). A whole series of factors influence decisions on R & D expenditure, including — as GW admits — the general level of current profits, the expected profitability of the products in the R & D pipelines as well as interest rates, exchange-rate volatility, uncertainty about future demand, etc. ([109]). Parallel trade may have some impact on revenue and profits. However, there is no reason why a pharmaceutical company should react to losses of revenue resulting from parallel trade by cutting the R & D budget rather than any other budgetary item. In this context, it should be borne in mind that the R & D costs take up around 15 % of the turnover and that the remaining 85 % goes into sales costs, administrative costs and profits. This can be illustrated with figures for 1999. On the basis of a turnover of GBP 8,49 billion, GW financial records shows GBP 1,98 billion costs of sale (23 %), GBP 2,9 billion selling and administrative costs (34 %), GBP 1,3 billion R & D (15,3 %) and a profit of GBP 2,6 billion (30,6 %) ([110]). If R & D is the main factor of competition between pharmaceutical companies and if savings must be made, GW would be expected to cut expenditure on budgetary items which represent high costs but are less important for its competitive position or to actually use part of its substantial profits for R & D purposes.

(158) Pattern of parallel trade and R & D expenditure in general: parallel trade in pharmaceutical products has been a reality for more than 20 years. Yet, R & D expenditure grew tremendously during the 1980s and 1990s ([111]). GW itself admits that between 1980 and 1993, its R & D budget increased by some 230 times ([112]).

(159) Relationship between parallel trade in GW products and GW's R & D between 1996 and 1998: GW's contends that parallel trade has had a significant impact on its revenues only in the last few years ([113]). The alleged magnitude of this parallel trade problem for GW will be addressed in recitals 162 to 169. At this stage, however, it is sufficient to note that GW's R & D expenditure increased from 13,9 % of turnover in 1996 to 14,4 % of turnover ([114]) in 1997 even though it reduced that expenditure in absolute terms by [...] % ([115]). As to the causes for the revenue decline, GW confirmed that its 1997 revenue suffered from the expiry of the patents for Zantac and Zovirax. Its R & D expenditure continued to increase in relative terms in the years thereafter: 14,5 % of turnover in 1998 and 15 % in 1999. Again no causal link can be identified between parallel trade and R & D, even during the years which GW has qualified as particularly problematic.

([108]) Frontier Economics study II, p. 7 [4554].

([109]) Ibid.

([110]) GW's annual report 1999, p. 92.

([111]) Professor Corchon Study I, p. 6 [Case 36.997, 3149].

([112]) Supplementary notification by GW of 28 july 1998, p. 37, footnote 40 [869].

([113]) Frontier Economics study II, p. 7 [4554].

([114]) See annual reports of those years (in particular p. 27 of the 1997 report)).

([115]) See reply to the SO, p. 21 [3528].

(160) R & D projects postponed or abandoned as a result of parallel trade: GW refers to nine products which were significantly delayed or abandoned in 1999 and 2000. However, all of these products were in their pre-clinical phase at the time the decision to abandon them was made and all but one constituted high-risk projects ([116]). The pre-clinical phase is normally at least 10 to 15 years prior to market introduction. GW further asserts that due to a lack of financial resources a shift to less risky projects occurred, thereby cancelling high-risk products which might have yielded the biggest benefit for future patients ([117]). It should be noted that there is no proof that high-risk projects are automatically those which yield the greatest benefits to patients. As GW states itself ([118]), the nature of a 'high risk' project just lies in the fact that all the projects constitute 'unproven mechanisms for treating diseases'. This says nothing about the quality of the project if it ever comes to existence. All in all, the information provided by GW only allows a very conservative conclusion, namely that one or more projects might have had greater chances of being continued, had GW gained higher sales revenues and profits. To add to this, as GW does, that the loss of revenues stemming specifically from parallel trade has had an incremental effect on these chances is entirely speculative.

(161) Parallel trade within the Community and migration of R & D to the USA: there is not nexus between the loss of revenue resulting from parallel trade within the Community and the migration of R & D to third countries, in particular the USA. Pharmaceutical companies pursue their R & D activities on a global scale ([119]). The reasons why certain locations are chosen for research and development are multiple and complex. For example, the communication on the single market in pharmaceuticals states that productivity in the United States of America may be higher than in Europe and also points to more favourable legislative conditions (for example, patent protection for biotechnology) ([120]). This has nothing to do with reductions in earnings caused by parallel trade. In any event, the communication also states that the migration trend of previous years may be about to change.

([116]) Response of 14 February 2000, p. 5 [4511].
([117]) Response of 14 February 2000, pp. 3 to 8 and Annexes [4509 to 14, 4520 et seq.].
([118]) Response of 14 February 2000, p. 5 [4511].
([119]) Commission Decision in Case IV/1378 — Hoechst/Rhône Poulenc (OJ C 254, 7.9.2000, p. 5, paragraph 45).
([120]) COM(98) 588 final, chapter 1.

Impact of parallel trade on R & D: magnitude

(162) Prices in Spain are often not considerably lower than the Community average: the Commission acknowledges that different prices levels exist within the Community. For the purpose of this decision, the Commission does not object to the grouping together of Germany, the United Kingdom, Denmark, Sweden, Finland, Ireland and Austria as high price countries and Belgium, Portugal, Italy, France, Greece and Spain as countries with relatively lower prices ([121]). However, the Commission does not accept that only one Member State, for example Spain, can be singled out as the source of the whole parallel trade 'problem'.

(163) As can be seen from Table 3, Spanisch prices for some heavily parallel-traded products are not dramatically lower than the Community average price. GW attempts to inflate the price gap between Spain and other Member States, especially the United Kingdom, by weighting the price levels in the various Member States according to their market size ([122]). However, parallel traders make decisions on where to sell primarily on the basis of price differences, not on the basis of the size of the target market. For that reason, simple arithmetic average prices are more representative than weighted ones.

(164) Parallel trace between 1996 and 1998 was cyclical at is was essentially caused by currency fluctuations: while GW singles out Spain as the main source country for parallel trade, therefore warranting a special pricing policy, the Commission emphasises instead that the main target country for parallel imports, the United Kingdom, saw a considerable appreciation of its national currency. The magnitude of any parallel trade problem for GW plc appears to have more to do with currency fluctuations than with the price levels in Spain (see recitals 141, 142 and 143).

(165) In this respect, it should be recalled that the British pound appreciated by 30 % against the Spanish peseta between October 1996 (when the pound started to rise) and April 1998 (just after GW's notification) and 27 % between January 1996 and December 1998. When the volume of parallel trade into the United Kingdom from all sources is compared with the volume of parallel trade from Spain during this period, the share of the Spain-sourced imports, while increasing in absolute terms, is found to have remained stable at around 40 %.

([121]) Frontier Economics study I, Annex 6 to the reply to the SO, p. 64 and 65 [3760/1].
([122]) Reply to the SO, p. 16 and Frontier Economics study I, Annex 6 to the reply to the SO, p. 17 et seq [3523, 3713 et seq].

(166) Community law does not allow undertakings to invoke the effect of currency fluctuations to justify any limitations on parallel trade. This principle is longestablished, as explained in the Commission's Decision in Volkswagen ([123]). According to the Commission's communication on the impact of currency fluctuation on the single market, such behaviour would constitute a clear infringement of Community law ([124]).

(167) GW plc's loss of revenue has been insignificant relative to GW's R & D expenditure: GW plc estimates that Spain-sourced parallel trade of the eight leading products into the United Kingdom caused a net loss of GBP [...] million between 1996 and 1998 (taking into account extra revenues from sales in Spain, see recital 67) According to it, this represents a reduction in the R & D budget of GBP [...] million ([...] % of its pre-tax profits, see recital 98). Whilst the Commission disputes any direct causal link between such lost revenue and any reduction in R & D expenditure, it in any event considers that the reductions claimed by GW are minimal. When spread over the three years concerned and compared with GW's total R & D expenditure, these losses represent no more than [...] % ([125]).

(168) Furthermore, the figures concerning the lost revenue from UK sales (based on data in annexes to GW's notification) may be exaggerated. In its response of 14 December f1998, GW reduced the 'gross' UK losses resulting from Spain-sourced imports for its eight leading products from GBP [...] million to GBP [...] million by applying a 'Forex-adjustment'. Only later, after the oral hearing, in its 14 February 2000 response to a formal request for information, did GW state that the GBP [...] million reflected the real, not the estimated, losses. The real losses were allegedly lower because the new sales conditions had come into force in Spain in April 1998.

(169) As already indicated (recitals 155 to 161), there is no evidence of any direct causal link between the lost UK sales resulting from parallel trade from Spain and any reduction in R & D. The [...] % referred to in recital 167 is given to illustrate the magnitude of the problem.

([123]) Op. cit. recital 222.
([124]) COM(95) 503 final.
([125]) Total R & D expenditure amounted to GBP 1,13 billion in 1996, GBP 1,16 billion in 1997 and GBP 1,148 billion in 1998.

(b) ***First condition (improving distribution)***

(170) GW puts forward several arguments to demonstrate that parallel trade is detrimental to the distribution of its pharmaceutical products. Firstly parallel trade causes a disruption of its distribution system. Secondly, it prevents the manufacturer from planning its distribution rationally since parallel trade leads to a situation of undersupply in the source country and of oversupply in the target country. Thirdly, parallel trade enhances the risk of late introduction of innovative products in low price countries. The new sales conditions should remedy this situation and ensure that GW will not cease commercialising particular products in Spain ([126]).

(171) Parallel trade does not disrupt GW's distribution system: although GW argues that parallel trade removes the incentive and the means for wholesalers located outside Spain to provide the level of services for which they are remunerated by GW, it does not provide any examples of such services. Nor does it elaborate on the extent — if any — to which it, as producer, is required to pay for these services; As outlined above, the GW's products are distributed by independent wholesalers. Wholesalers set their own resale price taking into account the level of service they wish to provide.

(172) Parallel trade does not disrupt GW's ability to plan distribution rationally: GW argues that parallel trade leads to oversupply in the target countries of parallel trade, for example, the United Kingdom, and product shortages in the source country, for example, Spain. However, it does not elaborate on this argument and, in particular, has provided no evidence to show a causal link between parallel trade and any alleged shortage of supply in Spain. Any such shortage may, for example, result from the pharmaceutical company's deliberate policy. A company's threat to discontinue supplies if parallel trade continues, however, cannot serve as a justification for restricting competition. Moreover, over- or undersupply will be corrected by preserving the possibility of parallel imports and not by raising obstacles against them. GW's argument amount to saying that the allocative efficiency is optimal when supply decisions are taken by a single firm and markets are divided and not when competitive forces are at play. The Commission does not share this view.

(173) In any event, GW has failed to give examples of product shortages in Spain or examples where it had not introduced a product to the Spanish market, presumably

([126]) Notification, p. 75 [76].

because despite a lower price the sales in Spain still make a positive contribution to GW's profits. GW simply submits several press clippings taken from Spanish newspapers which refer generally to the potential danger that there might be shortages due to parallel trade. One of the press reports of 15 October 1999 states, however, that the Ministry of Health was not aware of any such problem ([127]). GW also refers to communications by the Spanish Medicine Agency to the Spanish autonomous communities and the Association of Pharmaceutical Cooperatives ([128]). This reference is equally vague. In any event, the national law provides a means for preventing such shortages by imposing an obligation upon wholesalers to keep a sufficient volume of products in stock ([129]).

(174) Parallel trade does not cause delays for product launches in Spain: GW refers to the London Economics study which reports average introduction delays for countries such as the United Kingdom, Germany and the Netherlands of one to two months, whereas in Spain and France these delays range from five to six months (Spain) to nine to twelve months (France) ([130]). It also submits IMS data suggesting that product delays in Spain extend to six quarters compared to three quarters in the United Kingdom ([131]). The question is, however, whether parallel trade has anything to do with this and, as a consequence, whether measures limiting such trade will contribute to reducing these market delays.

(175) The Commission sees no causal link. Product launches depend on a number of factors, not least on the outcome of price discussions between the pharmaceutical company and the national authorities. In fact, GW itself cites this as the main reason for the late introduction of some of its products in Spain ([132]). Incidentally, this illustrates that it is the company itself that has full discretion to decide whether it is profitable enough to introduce a particular product on the market. More generally, GW admits that there may be many reasons why product launches are delayed: reimbursement delays, marketing decisions, price negotiations or simply lack of demand ([133]). None of these reasons is related to parallel trade.

(176) Furthermore, there is no compelling evidence that launches of GW products in Spain have been particularly delayed. From the very beginning of GW's activities in 1972 until 1998, there were five delays in Spain, three delays in Sweden, 11 delays in the Netherland, 10 delays in Denmark, eight delays in Germany and five delays in France. The highest number of delays have actually occurred in so-called high-price countries. It is striking that in the United Kingdom there have also been eight market introduction delays ([134]). Parallel trade clearly cannot have caused these delays.

While GW does not give any reason for the delays in the United Kingdom, most of the other delays are explained as 'reimbursement delays' or 'marketing delays'. The latter refer to a decision of GW's local operating company not to launch a product with a new reference price because this might have a negative impact on the reference price discussion with another product. 'Reimbursement delays' are caused by the necessity of GW to have a market authorisation before being able to submit the file for reimbursement. Negotiations between GW and the authorities become protracted These reasons are not linked to the parallel trade phenomenon. In any event, the fact that a company decides or threatens to launch products later in a lowprices country, cannot serve as a justification to restrict competition.

(c) ***Second condition (benefit to consumers)***

(177) As already (recital 153), it is for the notifying party to substantiate that the restriction of competition which it proposed to put in place will contribute to improving production or distribution or to promoting technical or economical progress as set out in Article 81(3) and that consumers will receive a fair share of these benefits. It is not for the Commission — as GW seems to require — to prove that its intervention against the proposed restriction of competition will enhance consumer welfare. It is GW's notified system which has to fulfil the criteria of Article 81(3), not the Commission's decision.

([127]) Reply to the SO, Annex 5 'Drug exports could prevent many diabetics from obtaining insulin' La Razon 15.10.1999 [3686/7].
([128]) Rebuttal of GW on EAEPC' comments of 23 February 2000, p. 5 [4582].
([129]) Ley 15/1990, Article 79 as well as Oficio of the Ministry of Health and Consumers dated 6 April 1998.
([130]) London Economics study, p. 42 [1046].
([131]) Reply to the SO, Annex 11 [3809].
([132]) Supplementary notification by GW of 28 July 1998, Annex 9 [905].
([133]) Response of 14 December 1998, Annex 10 [1762 to 1772].
([134]) One for four years (Ventolin Respirator), another for two years (Imigran Injection), two for one year (Imigran tab and Ventolin Nebules) and the remaining for at least half a year. Response by GW of 14 December 1998, ibid.

(178) GW argues that the consumer benefits from the new sales conditions in terms of enhanced research and development and improved distribution. Spanish consumers will benefit directly to the extent that the agreements ensure that GW products are available in Spain. The new conditions will also ensure that GW is able to maintain its investment in R & D which has produced substantial benefits in the past and has considerable potential for doing so in the future. The notified sales conditions will ensure that the United Kingdom's industrial and social policy decision to encourage research and development is not frustrated by Spanish policy implications ([135]).

(179) This argumentation is nothing but a reiteration of the arguments put forward by GW to demonstrate that its new sales conditions fulfil the first condition of Article 81(3). As has been explained (recitals 155 to 161), GW has failed to demonstrate any causal link between the restriction of competition and the objectives set out in the first condition. Moreover, it has already been established that the difference in policy goals of the United Kingdom and Spain has been overstated (see recital 133). In any event, it is not for a private company to safeguard governmental policy choices by restricting competition. Since GW has not demonstrated that the restriction of parallel tade actually achieves any of the benefits required under the first condition, the second condition of Article 81(3) can also not be fulfilled and therefore needs no further examination.

(180) GW insists that for pharmaceutical products parallel trade cannot achieve any benefits for the consumer. From a consumer welfare perspective, according to GW, the consumer is in a better position with GW's system than with parallel trade. GW asserts more specifically that parallel trade in pharmaceutical products is different from that in other commodities (such as cars or hi-fi equipment) because the patient does not derive any benefit from parallel trade in the form of lower prices. This is so, according to GW, because patients are reimbursed by the national health organisations. These organisations are the real consumers, because in economic terms, they purchase the drugs. As far as the United Kingdom is concerned, GW's new sales conditions for Spain allegedly even benefits the NHS as they enable it to maintain a policy which promotes R & D. Any savings made by the NHS via the claw-back mechanism (GBP 19 million from all parallel imports) are said to be outweighed by GW plc's lost sales (GBP 18 million in 1998).

(181) In this respect, it should be recalled once more that it is for the notifying party to justify its restriction of competition by showing that its agreement fulfils the conditions of Article 81(3). It is not for the Commission to prove that its intervention against this restriction increases consumer welfare. It is therefore only for the sake of completeness that the Commission addresses a number of arguments by which GW contests that its intervention as a competition authority will serve general consumer welfare interests.

(182) Since the new sales conditions cover exports to all other Member States, not just to the United Kingdom, the beneficial effects of parallel trade will be illustrated on this broader basis.

(183) First, parallel-traded products offer a second source of supply. This is especially important from a consumer's point of view when branded and patented products are involved. Patented medicines enjoy protection for at least 20 years. In cases where only a few alternatives are available, parallel trade will offer the only source of competition.

(184) Second, GW's unqualified assertion that the nature of reimbursement systems precludes any benefit for patients from parallel trade is incorrect. Patients benefit directly from parallel trade either when they have to pay the full amount of the purchase price themselves or when reimbursement is only partial and is expressed as a percentage of the actual purchase price (in contrast with a flat fee). For example, German patients have to pay the full price for contraceptives. EAEPC has referred to two contraceptives, Marvelon and Minulet, for which parallel trade leads to direct savings for patients ([136]). Although GW contests the exact amount of the price differences between the parallel-traded and the domestically sold contraceptives, it admits that the parallel-traded ones are between 10 % and 32,9 % cheaper ([137]). Furthermore, partial reimbursement and co-payment exists in many Member States. When patients receive reimbursement calculated as a percentage of the actual purchase price (for example, Belgium an France) parallel trade may benefit them directly.

(185) Finally, it can be observed that some high price countries (for example, the Netherlands) *de facto* provide incentives to parallel trade without any cost-saving effects for the health care budget. Where reimbursement is in the form

([135]) Supplementary notification, p. 42 (874).

([136]) Case 37.380, submission 'Parallel trade of pharmaceuticals', p. 6 (193).

([137]) Letter of 23 February 2000, p. 4 (4581).

of a flat fee, pharmacists and other intermediaries benefit from purchasing cheaper parallel-traded products because such purchases yield higher profits. The notion of the consumer is not restricted to the final consumer, that is, the patient. Therefore, the interests of wholesalers, pharmacies, national health budgets, insurance schemes can also be taken into account. Furthermore, the possibility of these pharmacies passing on part of their savings to their clients, for example via annual bonuses where authorised by national legislation, should also not be ruled out.

(186) Ultimately, all patients pay for the national health system. Public health systems are financed via contributions or by general taxes. Any savings made by these schemes via the purchase of cheaper parallel-traded drugs indirectly benefit the schemes' members. As emerges from Table 1, many Member States have enacted measures providing incentives to parallel trade and thus leading to such savings. The UK reimbursement system with fixed reimbursement fees and its claw-back system (see recital 49) *de facto* provides an incentive for intermediaries and pharmacies to purchase cheaper parallel-traded drugs. It has also been shown that other Member States give more specific incentives to parallel trade, in order to achieve cost savings for the health care budget. Denmark, Germany and Sweden (see recital 52) serve as an example.

(d) ***Third condition (indispensability)***

(187) As the conditions of Article 81(3) are cumulative, it is not necessary for the Commission to assess each individual condition of Article 81(3) ([138]). Nonetheless, it notes that the new sales conditions do not fulfil the third condition. Since there is not evidence that they achieve the objectives of promotion of technical progress and improvement of distribution, it follows that there is no contribution whose indispensability to the attainment of these objective could be analysed.

(e) ***Fourth condition (no elimination of competition in respect of a substantial part of the products in question)***

(188) As noted in recital 104, GW does not put forward any arguments concerning this condition which it has not already submitted elsewhere. Those arguments have already been rejected. In any event, for several of the leading product affected by the new sales conditions (for example, Zofran, Flixonase, Zovirax and Imigran) GW holds substantial market shares in one or more Member States.

([138]) *Matra SA Hachette* v *Commission*, op. cit.

III. **CONCLUSION**

(189) For the above reasons, it is concluded that the new sales conditions have as their object and effect to restrict competition and affect trade between Member States to an appreciable extent within the meaning of Article 81(1). They do not meet the conditions for an exemption pursuant to Article 81(3).

(190) GW should be required pursuant to Article 3 of Regulation No 17, to bring the infringement to an end.

(191) Although GW SA filed the original notification, GW plc filed a supplementary notification on 28 july 1998. In the latter notification, GW plc explains that it has effective ownership and control of GW SA (see recital 11). In a letter of 29 October 1998, GW plc requested that all correspondence in respect of both notifications should be addressed to it and copied to its subsidiary GW SA. Consequently, all subsequent correspondence, including the statement of objections adopted on 13 July 1999, was addressed to GW plc. Following the merger with Smithkline Beecham, the company name of GW plc has changed. The decision is therefore addressed to GlaxoSmithKline plc in the United Kingdom.

HAS ADOPTED THIS DECISION

Article 1

Glaxo Wellcome has infringed Article 81(1) of the Treaty by entering into an agreement with Spanish wholesalers operating a distinction between prices charged to wholesalers in the case of domestic resale of reimbursable drugs to pharmacies or hospitals and higher prices charged in the case of exports to any other Member State.

Article 2

The request by Glaxo Wellcome for an exemption of the agreement referred to in Article 1, pursuant to Article 81(3) of the Treaty, is rejected.

Article 3

Glaxo Wellcome shall immediately bring to an end the infringement referred to in Article 1 in so far as it has not already done so. It shall refrain from repeating any measure

constituting this infringement and shall refrain from adopting any measure having similar object or effect.

Article 4

Glaxo Wellcome shall inform the Commission, within two months of notification of this Decision, of the steps which it has taken to bring the infringement to an end.

Article 5

This Decision is addressed to:

GlaxoSmithkline PLC, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom.

Done in Brussels, 8 May 2001.

For the Commission

Mario MONTI

Member of the Commission

ANNEX 1

Products covered by Glaxo Wellcome SA's new conditions of sale (Spanish denomination):

Alquen 150 mg 20 comp. Efervescente
Bacisporín Pomada 10 gramos
Becloforte Inhalador 250 mcg × 180 dosis
Beconase Spray Nasal Acuoso 50 mcg × 200
Becotide Inhalador 200 × 50 mcg
Busulfán Wellcome 0,5 mg 100 comp.
Busulfán Wellcome 2 mg 100 comp.
Curoxima 250 mcg 1 vial + amp. 2 ml
Curoxima 750 mg Vial + amp. 6 ml
Daraprim 30 comp.
Dexnón 100 mcg 100 mg Comp.
Flixonase 50 mg spray nasal/120 dosis
Flixotide 100 mcg Accuhaler × 60 dosis
Flixotide 250 mcg Inhalador/120 dosis
Flixotide 50 mg Inhalador/120 dosis
Flixotide 500 mg Accuhaler × 60 dosis
Fortam 1 gr Im/iv + amp. 10 ml
Fortam 500 mg 1 vial + amp. 5 ml
Greosín 125 mg 25 comp.
Greosín 125 mg 100 comp.
Igril 10 comp.
Imigrán 50 mcg/4 comp
Imigrán 6 mg Iny/2 jeringas sub-cut
Kemadrén 25 comp.
Lacipil 4 mg/28 comp.
Lamictal 100 mg/56 comp.
Lamictal 200 mg/30 comp.
Lamictal 25 mg/56 comp.
Lamictal 50 mg/56 comp.
Lanacordín ampollas 5 amp.
Lanacordín comprimidos 25 comp.
Lanacordín comprimidos 50 comp.
Lanacordín pediátrico 60 ml Sol.
Leukerán 2 mg 100 comp.
Leukerán 5 mg 100 comp.
Melfalán 2 mg 25 comp.
Melfalán 5 mg 25 comp.
Mercatopurina Wellcome 25 comp.
Metoxamina Wellcome 5 mg Amp. Iny
Otosporín 5 ml
Pilorid 400 mg/28 comp.
Pro-Actidil 10 comp.
Serevent Inhalador 25 mcg × 60 dosis
Serevent Inhalador 25 mcg × 120 dosis
Serevent Accuhaler 50 mcg × 60 dosis
Tioguanina Wellcome 25 comp.
Trandate 100 mg 30 comp.
Trandate 200 mg 30 comp.
Valtrex 500 mg/10 comp.
Valtrex 500 mg/42 comp.
Ventolín 30 sol resp. 10 ml × 5 mg
Ventolín 2 mg 30 comprimidos
Ventolín 4 mg 30 comprimidos
Ventolín Inhalador 200 × 100 mcg
Ventolín Inyectable 0,5 mg 1 ml 6 amp
Ventolín Jarabe 2 mg/5 ml 100 ml
Wellferón 10 MU/1 vial de 1 ml
Wellferón 3 MU/1 vial de 1 ml
Wellferón 5 MU/1 vial de 1 ml
Zantac 150 mcg/20 comp.
Zantac 300 mcg/10 comp.
Zinnat 125 mg/12 comp.
Zinnat 125 mg 12 sobres
Zinnat 125 mg 6 ml susp.
Zinnat 250 mg/12 comp.
Zinnat 250 mg 12 sobres
Zinnat 500 mg/12 comp.
Zinnat 500 mg Sobres
Zofrán 4 mg/15 comp.
Zofrán 4 mg/6 comp.
Zofrán 8 mg/15 comp.
Zofrán 8 mg/6 comp.
Zovirax 200 mg Comp. Disper./25 comp.
Zovirax 800 mg Comp. Disper./35 comp.
Zovirax crema 2 gr
Zovirax crema 15 gr
Zovirax Pom. Oftalm./4,5 gr
Zovirax Suspensión Forte 100 ml
Zovirax Suspensión Forte 200 ml
Zyloric 100 mg 25 comp.
Zyloric 100 mg 100 comp.
Zyloric 300 mg 30 comp.

ANNEX 2 (*)

	SP	FR	UK	DE	NL	DK	EU
A2B Antipeptic ulcerants							
Zantac Alquen Pylorid							
A4A Antiemetics-Antinauseants							
Zofran							
R3 Bronchodilators/A-Asthma							
Becotide + Becloforte Serevent Ventolín Flixotide							
R1A Topical nasal decongestants							
Beconase Flixonase							
R6 Antihistamines systemic							
Actidil (Proc-Actidil)							
J1 Antiinfectives							
Zinnat Zinacef (Curoxima) Fortum (Fortam)							
D7 Topical corticosteroids							
Bacisporin							
D1 Dermatological antifungals							
Grisovin (Greosín)							
L1 Cytostasics							
Alkeran (Melfalán) Leukeran Thioguanine Mercatopurina Busulfán							
L3B Interferons							
Wellferon							
P1D Antimalarians							
Daraprim							
H3A Thyroid preparations							
Eltroxin (Dexnon)							

	SP	FR	UK	DE	NL	DK	EU
C7 Beta blocking agents							
Trandate							
C8 Calcium antagonists							
Lacipil							
C1 Cardiac therapy							
Lanoxin (Lanacordín) Metoxamina							
M4 Anti-gout preparations							
Zyloric							
N3 Anti-epileptics							
Lamictal							
N4 Anti-Parkinson							
Kemadrin (Kemadrén)							
S2 Otologicals							
Otosporín							
Hsv (**)							
Zovirax Valtrex							
ICD 346 (***)							
Imigran Migril (Igril)							

(Community except DK, PO, LU, IR, FL)

(*) Business secrets, not disclosed.
(**) Anti-herpes products from classes J5B, D6D, J7A, S1D.
(***) Indicated as such by GW.

ANNEX 3

GBP/ESP Exchange rates

March 94 to November 98

Date	Value GBP/ESP	Date	Value GBP/ESP
Mar–94	207,56	Aug–96	196,28
Apr–94	203,73	Sep–96	194,88
May–94	205,30	Oct–96	200,27
Jun–94	204,48	Nov–96	207,82
Jul–94	201,78	Dec–96	216,68
Aug–94	198,68	Jan–97	221,56
Sep–94	201,22	Feb–97	224,46
Oct–94	202,52	Mar–97	233,07
Nov–94	203,73	Apr–97	231,56
Dec–94	204,37	May–97	236,83
Jan–95	205,46	Jun–97	236,24
Feb–95	209,08	Jul–97	244,20
Mar–95	203,71	Aug–97	252,78
Apr–95	205,66	Sep–97	245,70
May–95	198,17	Oct–97	240,47
Jun–95	193,71	Nov–97	241,44
Jul–95	192,97	Dec–97	249,59
Aug–95	189,86	Jan–98	251,17
Sep–95	194,99	Feb–98	252,20
Oct–95	194,07	Mar–98	257,74
Nov–95	192,48	Apr–98	262,09
Dec–95	187,30	May–98	254,99
Jan–96	188,65	Jun–98	246,36
Feb–96	189,31	Jul–98	256,19
Mar–96	188,78	Aug–98	246,46
Apr–96	189,57	Sep–98	250,64
May–96	190,66	Oct–98	243,07
Jun–96	198,26	Nov–98	234,95
Jul–96	197,44	Dec–98	240,09

Source: Europa Plus-Infor Euro