Legal and regulatory update

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Legal and regulatory update

RELEVANCE OF COMMUNITY ARBITRATION PROCEDURES TO THE VARIATION, SUSPENSION AND WITHDRAWAL OF NATIONAL MARKETING AUTHORISATIONS AND EVIDENTIAL REQUIREMENTS

Summary

In the joined cases of T-74/00,[1] T-76/00,[2] T-83/00,[3] T-84/00,[4] T-85/00,[5] T-132/00,[6] T-137/00[7] and T-141/00,[8] the Court of First Instance (Second Chamber, Extended Composition) examined, *inter alia*, the competence of the Commission to adopt three opinions of the Committee for Proprietary Medicinal Products (CPMP) following applications made under Article 15a Chapter III Second Council Directive 75/319/EEC[9] that the marketing authorisations for various nationally authorised medicinal products should be withdrawn. The products in question were the anorectic drugs amfepramone, clobenzorex, fenproporex, norpseudoephedrine and phentermine.

Although these anorectics had already been subject to a degree of harmonisation under Article 12 Chapter III, this was insufficient to bring them within the scope of Article 15a Chapter III. They remained national in nature and were not equivalent to authorisations harmonised by way of mutual recognition procedures. The adopted decisions in question[10] have consequently been annulled.

Finally, since the procedural requirements of Article 11 65/65/EC had not been met, the decisions adopted by the Commission would have been flawed in any event.

Background

The authorisations in question were all granted in accordance with Directive 65/65/EC[11] and were therefore national in origin. They were not products of the mutual recognition procedure provided for by Chapter III Directive 75/319/EEC. However, following concerns regarding the risk of primary pulmonary hypertension (PPH) in connection with such drugs, the German government referred the matter to the CPMP under Article 12 for advice.

Article 12 provides that member states may, in specific cases, refer a matter to the CPMP for advice following the procedure in Article 13 before reaching a decision on the grant, suspension, withdrawal or variation of an authorisation. In this case, the CPMP advised that while anorectic treatment had risks, there was no other pharmaceutical option for management of obesity. As such, the risk/benefit ratio was favourable and the authorisations for all five drugs should be maintained, subject to variation of the relevant summary of product characteristics (SmPCs) to reflect the dangers involved. In particular, the CPMP warned that treatment should not exceed three months since this appeared to increase the risk of PPH, which is usually fatal. This opinion was subsequently adopted by the Commission in a binding decision[12] pursuant to Article 14 requiring all member states concerned to amend the SmPCs accordingly.

Following Germany's application, Belgium became concerned about cardiac valve disorders resulting from the use of fenfluramine in monotherapy and in combination with phentermine or amfepramone. Since fenfluramine was already under investigation, the CPMP was asked to advise on the single use of amfepramone and phentermine. This reference was made under Article 15a Chapter III rather than Article 12.

Article 15a states that where a member state considers that the variation, suspension or withdrawal of a marketing authorisation granted under Chapter III is necessary for the protection of public health, that state shall refer the matter to

the CPMP for an opinion under Article 13, to be followed by adoption of a decision by the Commission under Article 14. The use of amfepramone and phentermine in the context of obesity and cardiac valve disease was therefore reassessed.

The initial view of the pharmacovigilance working party advising was that no causal link could be established between use of amfepramone or phentermine and cardiac disease. The earlier CPMP assessment as to the risk/benefit ratio for these drugs therefore remained unchanged. However, following the introduction of new guidelines[13] evaluating efficacy of anorectics by reference to long-term weight loss, the risk/benefit ratio for both drugs became unfavourable. Only anorectics capable of long-term use, or those that would produce a long-term reduction in weight after short-term use, would be therapeutically acceptable.

Using similar arguments for both amfepromone and phentermine, the CPMP recommended that since treatment was restricted to short-term use of the drugs and that no studies adequately demonstrated long-term benefit following such use, authorisations for both drugs should be withdrawn. Rejecting appeals to conduct trials to establish long-term efficacy, and observing that while neither drug had been clearly implicated in PPH or cardiac valve disorder, the Commission adopted final decisions withdrawing authorisations for amfepramone[14] and phentermine.[15]

In the third case, Austria applied under Article 15a for the CPMP's opinion regarding the use of clobenzorex, fenbutrazate, fenproporex, mazindol, mefenorex, norpseudoephedrine, phenmetrazine, phendimetrazine and propylhexedrine in obesity since they belonged to the same group of amphetamine-like anorectics as amfepromone and phentermine. Recommending withdrawal of the authorisations in question and rejecting appeals for further trials to establish long-term benefit, the CPMP noted that since there were few double-blind studies supporting weight loss and that there was no evidence of long-term benefit, short-term treatment lacked efficacy.

Furthermore, since it would be unacceptable to conduct trials involving long-term treatment due to the risk of dependency, such use was therefore irrelevant to the issue of efficacy. The Commission therefore adopted the CPMP's opinion to withdraw the authorisations for clobenzorex, fenproporex and norpseudoephedrine in its decision of March 2000.[16]

Reasons for decision on competence

The basic dispute centred on the fact that the authorisations in question were national in origin. Article 15a relates to authorisations 'granted in accordance with the provisions of' Chapter III. The authorisations for the products in question had clearly not been granted under any of them.

The competence of the Commission to adopt decisions withdrawing these anorectics depended on the effect, if any, of the previous variations following referral under Article 12. If Article 15a could be construed as applying to national authorisations subsequently harmonised under Article 12, in the same way as those harmonised on grant by way of mutual recognition, then such competence could exist. Unfortunately, the wording of Articles 12 and 15a provides no clear guidance on this point.

The court therefore examined whether Article 12 imposed an arbitration procedure transferring competence from member states to the Community. If it did, then since variation, suspension or withdrawal of authorisations harmonised on grant under Article 10(2) necessarily fell within the scope of Article 15a, there would be no need to distinguish these authorisations from those harmonised by the same procedure after grant by amendment. On the other hand, if it did

not, then the Commission had no competence to adopt the decision following Germany's application. In that event, unless voluntary adoption[17] of the CPMP's advice could be placed on the same footing as a decision requiring such amendment, the purported withdrawal of the authorisations under the Article 15a applications could have no basis in law.

The court observed that Article 9 Chapter III requires member states to recognise authorisations unless, and exceptionally, they have grounds to decline under Article 10(1). Since it is the subsequent inability of member states to reach consensus that triggers referral to the CPMP, Article 10(2) must be interpreted as invoking both Article 13 and Article 14. This view is supported in recital 12 of Directive 2001/83/EEC which states that in the event of a disagreement between member states, a single decision, binding on the member states concerned, shall be reached.

The court then explored the possibility that the consultative procedure under Article 13 dictated by Article 12 impliedly imposed adoption of a decision under Article 14 in the same way that it would had reference been made under Article 10(2). In so doing it noted that Article 12 Chapter III Directive 75/319/EEC, before amendment by Directive 93/39/EEC, provided that only member states were entitled to seek the opinion of the CPMP before they reached a decision to grant, suspend or revoke an authorisation in specific cases where the interests of the Community are involved. As such it was expressly apparent from that version of Article 12 that the power to adopt a final decision lay with the national authorities of the member state concerned.

The court concluded that the broadening of the scope of Article 12 on amendment to permit applications, *inter alia*, by the Commission, did not permit the inference that amended Article 12 established an arbitration procedure transferring competence to the Commission. Rather, the Commission would only be competent to adopt decisions on national marketing authorisations following referral under Article 12 if that competence was clearly apparent from the purpose of the provision, or where it was expressly provided for in the system established by Chapter III.

Unlike Article 10(2), which explicitly relates to mutual recognition and must be interpreted in relation to the purpose of that procedure, Article 12, in common with Article 11, does not relate to mutual recognition governed by Articles 9 and 10 on grant, or Articles 15 and 15a on management. Consequently, since Article 12 does not contain any express definition of its scope, it must be taken to apply to the exclusive competence of member states only.

The Court found the Commission had no competence to adopt the Article 12 opinion of the CPMP. In relation to the effect that voluntary adoption of a non-binding opinion of the CPMP might have, the Court ruled, in accordance with the principle that the Community can act only within the powers conferred upon it,[18] that in the absence of express provision to the contrary, an application under Article 12 cannot act so as to deprive a member state of its future powers. Such application cannot therefore trigger Article 15a in relation to subsequent references in connection with the variation, suspension or withdrawal of an authorisation.

Reasons for decision on procedure

Article 11 Directive 65/65/EC provides that competent authorities of member states are to suspend or revoke authorisations where the product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, which means when it is established that therapeutic results cannot be obtained.

These conditions must be interpreted in accordance with the principle that the protection of public health takes

precedence over economic considerations.[19] The protection of health is considered first, then the risk/benefit balance of the product is re-assessed if there are new data that give rise to doubts as to efficacy or safety, and finally the application of the rules of evidence in accordance with the precautionary principle is brought to bear.[20]

The precautionary principle requires competent authorities to take appropriate measures to prevent risks to public health, safety and the environment. In the field of health, precautionary measures may therefore be legitimised without having to wait until the seriousness of such risks becomes apparent.[21] Where risk cannot be determined, competent authorities take such measures at their own discretion.

Authorisations may therefore be suspended or withdrawn where new data give rise to serious doubts as to safety or efficacy resulting in an unfavourable assessment of the risk/benefit ratio. Therefore, withdrawal can be justified only where there is new information and in particular, a shift in consensus in the medical community which results in new safety or efficacy assessment criteria cannot be justified unless based on new data.

The decisions to withdraw the authorisations were based on the negative assessment of the risk/benefit ratio of the anorectics in question. Since there had been no new evidence to justify an assumption that the risk of cardiac valve disorder was any greater than had previously been thought, those decisions were reached because of a change in the assessment criteria requiring long-term efficacy. However, this was due to a change in medical opinion as to best practice, as reflected in the CPMP's Note for Guidance and other national guidelines, but was not supported by new data. Article 11 therefore precluded the CPMP and the Commission from revising its previous findings as to the risk/benefit assessment for the drugs in question.

VARIATION OF THE TERMS OF COMMUNITY AUTHORISATION – ALTERNATIVE NAMES AND PACKAGE LAYOUTS

Summary

The Court of First Instance (Fifth Chamber) has ruled that there is nothing express or implied in the legislation concerning Community authorisations preventing variation of an authorisation to allow different product names and different package layouts to be used in different member states.

Where an authorisation holder can demonstrate the need for such variation to protect the public health, it is to be permitted, despite the fact that as a general principle, authorisations are to be uniform throughout the Community.

Background

In case 123/00 the applicant Dr Karl Thomae GmbH sought a Community marketing authorisation from the European Agency for the Evaluation of Medicinal Products (EMEA) under the provisions of Council Regulation (EEC) No 2309/93 for the anti-parkinsonism drug pramipexole under the brand name Daquiran™. It asked the German pharmaceutical company Byk Gulden Lomberg Fabrik GmbH (BG) for confirmation that it did not to object to the use of the mark but this was refused because of concerns that it might be confused with BG's mark Taxilan™ used for a neuroleptic drug.

Following a repeated request and grant of the marketing authorisation by the EMEA, BG asked the applicant to stop using Daquiran™. The applicant therefore applied to the EMEA for a Type I variation of its authorisation to change the name and package layout to Firol™ in Germany and the name to Sipnok™ in Denmark, Sweden and Finland. The EMEA refused the request.

Reasons for refusal

First, the EMEA complained that neither the conditions or requirements set out in

Annex 1 Commission Regulation (EC) No. 542/95, which concerns the examination of variations to the terms of authorisations, or the Commission's 'Guideline on Dossier Requirements for Type I Variations (November 1999) in the Notice to Applicants Volume 2C' had been fulfilled. Since the authorisation was to be valid throughout the EU, the EMEA argued that it was necessary that the product be marketed under one single mark. It explained that this principle was derived from the provisions of point 2, paragraph 3 of Article 4 Directive 65/65/EC and first indent Article 2(1) and Articles 2(1)(a) 7(1)(a) of Council Directive 92/27/EEC, defining the name of medicinal products in the chapters on Scope, Definition, Labelling of Medicinal Products and User Package Leaflet. The simultaneous use of Sipnok™ and Firol™ was therefore unacceptable.

Secondly, the EMEA explained that according to the Commission's 'Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Community (April 1999) in the Notice to Applicants, Volume 2C', the presentation of a medicinal product (logo, format, layout, style, colour scheme and pack dimensions) had to be identical throughout the Community. The altered trade dress proposed exclusively for the German packaging of pramipexole was therefore also unacceptable.

The applicant therefore applied to the court for an order annulling the decision or in the alternative a declaration that to the extent point 2, paragraph 3 of Article 4 Directive 65/65/EC and first indent Article 2(1) and Articles 2(1)(a) 7(1)(a) of Council Directive 92/27/EEC required use of a single trademark and package layout, they were unlawful.

Decision as to single name

The Court first considered whether the wording of the relevant legislation supported the view that, as a general rule, a Community authorisation may only be issued for a single name. It noted that point 2 paragraph 3 of Article 4, and point 1 of Article 4a Directive 65/65/EC, together with Directive 75/318, to which Article 11 of Regulation No. 2309/93 refers indirectly, all refer to the name of the product in the singular and none of which contemplates expressly the possibility of a community authorisation containing several product names. In addition, the provisions of Directive 92/27, relied on by the EMEA, to which Article 11 Regulation No 2309/93 also refers, use the word 'name' in the singular. Finally, so far as Type I variations of authorisations are concerned, Regulation No 542/95 also refers to the name in the singular.

The Court therefore concluded that as a general rule it was implicit that a Community authorisation contains only one name. Support for this interpretation could be found in that by making it easier to identify medicinal products, both the primary objectives of protection of public health[22] and the free movement of goods pursued by the general scheme of the Treaty were facilitated.

Although there are no express provisions in secondary legislation prohibiting the grant of authorisations for multiple names, the Court considered whether this was implicitly prohibited by such wording. Regulation No. 2309/93 provides that a variation may only be granted so far as it satisfies the criteria relating to quality, safety and efficacy and therefore the Court considered what impact an absolute prohibition would have on public health. It concluded that since brand names are frequently registered trademarks, there was a risk that following a trademark dispute it might become unlawful to market a product under a particular name in a particular member state and that this would jeopardise patients' access to that product, albeit on a temporary basis pending application for another Community authorisation under a different name.

In the Court's view this public health risk was more significant than any risk that might arise out of possible confusion

if multiple names were permissible. It drew attention to the fact that not only are name variations minor Type I variations, but that in the context of mutual recognition and national authorisations, one medicinal product may frequently have names which vary from one member state to another. On at least two occasions[23] in the past the Commission has permitted multiple names in variations of Community authorisations, following its own advice[24] on the interpretation of the appropriate legislation.

The interpretation of the legislation arrived at by the EMEA therefore conflicted with that already forwarded by the Commission. It had instead been based on the Commission's Guideline on dossier Type I variations (November 1999) which presented advice in tabulated form. From a practical perspective, this document only permitted substitution of a name with a single variation as opposed to the addition of a new one.

The Court held that in the absence of express prohibition to the contrary, where the holder of a Community authorisation can demonstrate that variation to add a name is necessary by exceptional circumstances to protect public health, and that the Commission is satisfied that such variation meets the required criteria of quality, safety and efficacy, then there are no grounds for preventing it.

Decision as to single packaging

Whilst the Commission's 'Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Community (April 1999) in the Notice to Applicants, Volume 2C' provides that the logo, format, layout, style, colour scheme and pack dimensions must all be identical for all versions of packs of a product throughout the Community, it should be noted that Regulation No. 2309/93 does not specifically dictate a single pack layout. Further, Regulation No. 542/95, which contemplates variations by way of change of name, is silent concerning changes in packaging. However, considering the unitary nature of the Community authorisation and the fundamental principle of the free movement of goods, it is implicit that, as with the use of a single name, an application for a Community authorisation must as a general rule have a single package layout.

The package layout, like the product name, is one of the formal aspects of a Community authorisation but variation in package layout is unlikely to carry the same risk of confusion. However, the rejection of an application to vary package layout in a particular member state is likely to pose a similar risk to public health, and for the same reasons, as would a prohibition on variation of authorisations to permit multiple names. Therefore the EMEA's decision in this regard was also annulled and such variations are to be permitted.

COMPETITION LAW

Further EC investigation of IMS

The European Commission has carried out a further investigation of IMS Health in the pharmaceuticals data sector under Article 82 EC, which prohibits abuse of dominant position. These proceedings were separate from the so-called '1860 Brick System' case in Germany in respect of IMS's refusal to license copyright in its structure for the ordering of regional pharmaceutical sales data in Germany. The result of the interim measures proceedings in that case was summarised in the Winter 2002 issue, and the substantive case continues, pending before the European Court of Justice.

In this further investigation, IMS was alleged to have abused its dominant position in the market for the collection of information on pharmacies' sales and doctors' prescriptions of pharmaceutical products, by anti-competitive discounting practices and tying the sale of some services to the purchase of others. Following investigation of complaints by new entrants Source Belgium and National Data Corporation of the USA,

much of IMS's conduct criticised in the Commission's statement of objections was found to have ceased. The Commission's remaining concerns were dealt with by the Belgian national competition authority ordered IMS to change its pricing structure in Belgium, on the basis of which Source Belgium withdrew its complaint.

Agricultural Crop Sciences: Acquisition allowed only subject to extensive divestment obligations

The European Commission has cleared Bayer's acquisition of Aventis Crop Science subject to stringent divestment commitments by Bayer. Bayer's agricultural business segment comprises crop protection and animal health businesses, and its crop protection business overlapped with that of the target businesses of Aventis Crop Science. The Commission's investigation showed that the transaction would have led to competition problems within the markets for agricultural insecticides, herbicides, fungicides, seed treatment, molluscides, professional pest control products and certain animal health products. In order to enable the Commission to conclude that no dominant position would be created or strengthened in any of these markets therefore prohibiting the transaction, Bayer undertook to divest Aventis Crop Science's entire European seed treatment business to a single undertaking. This included two insecticide products, Fipronil and Ethiprole, and five fungicide products. Bayer also undertook to divest other insecticides of a class in which it held the strongest portfolio, and various herbicide products. Further, Bayer agreed to grant a Europe-wide exclusive licence of a molluscide (a snail-bait product) and various herbicide products, and to grant exclusive licences to third parties for various products in one or more member states and to discontinue certain third party distribution agreements. The transaction was cleared only subject to fulfilment of these undertakings.

Full immunity from fines granted to Aventis SA in cartel cases

The European Commission found Aventis SA, Degussa AG and Nippon Soda Company Limited had participated in a price-fixing cartel in methionine, one of the most important amino acids used in compound animal feeds. The defendants had agreed price targets, implemented price increases and exchanged information on sales, volumes and market shares for the product, through regular meetings both at 'summit' and at 'managerial' staff levels. Degussa AG and Nippon Soda were fined respectively €118.12 and €9m. Aventis SA and its subsidiary were granted full immunity under the Commission's 1996 Leniency Notice, Aventis SA being the first undertaking to provide the Commission with decisive information identifying the infringements. The Commission stated that otherwise Aventis would have received a fine similar to the one imposed on Degussa. Nippon Soda and Degussa cooperated to a certain extent and were granted appropriate reductions in their fine. However, Degussa received a reduction of only 25 per cent of its fine because most information it provided was not provided voluntarily and it contested its participation in the cartel prior to mid-1992 and after 1997 despite evidence held on the Commission's file demonstrating the contrary.

Aventis SA also received total immunity from fines on the same basis in respect of the vitamins cartels case decided in November 2001 by the Commission, which involved total fines on eight companies of €855.22m, by far the largest fines imposed in any cartel case. However in that case, although Aventis received total immunity in respect of the vitamins A and E cartels, under the 1996 Leniency Notice, a fine of approximately €5m was imposed on Aventis because of its passive participation in the vitamin D3 cartel on which it provided no information to the Commission.

Both Hoffmann La Roche and BASF,

who were found to be the main instigators in the cartels, were granted 50 per cent reductions in their respective fines because they cooperated with the Commission at an early stage by providing crucial information on all of the individual vitamin cartels they were involved in.

It should be noted that a revised Leniency Notice was issued in February 2002, which is on similar lines to the 1996 Notice, will apply in respect of subsequent cartel investigations, giving incentives to cartel members to cooperate at an early stage with the Commission.

Guidance for businesses about changes to copyright law applicable from spring 2003

The Patent Office has issued guidance on a number of changes to copyright rules. The changes relate to the use of copyright material that will not infringe copyright. Such uses are referred to as exceptions and will not require a licence from the copyright owner. The area that will be most relevant to the life sciences sector is the copying of copyright material for commercial research.

The implementation of Directive 2001/29/EC, the Copyright Directive, requires a significant change to be made in English law. The new law will draw a distinction between research for commercial purposes and research for non-commercial purposes. Currently the law allows single copies of work to be made for research purposes and this will not constitute an act of infringement. The new rules will make such copying an infringing act where the copy is made for commercial research purposes.

This could create complications for both businesses and academic organisations that may begin research for non-commercial purposes and then the nature of the research may change to commercial research. This potential problem is taken into account in that what was appreciated at the time at which the copy is made will be the key to determining the nature of the research and therefore whether or not the copy falls within the continuing research for non-commercial purposes exception.

There may be a grey area for some in the life sciences sector where businesses are in collaborations with academic institutions and research may or may not be commercialised.

Review of the statutory maximum price scheme for generic medicines sold to community pharmacies and dispensing doctors

On 13th December, 2002, the Department of Health issued a response document in relation to the maximum price scheme consultation which reported that no fundamental objections had been voiced. The scheme was therefore rolled over on 12th December, 2002, because the Government's view that the scheme continued achieve the desired aim (of protecting the NHS from price increases) was not dispelled by the consultation process (required under the terms of Directive 89/105/EEC). The letter accompanying the consultation document highlighted the Government's further ongoing activity in that it is considering arrangements for the longer-term reimbursement of generic medicines and after further consultation will be announcing decisions. We expect further consultation will begin in the early part of this year.

Medicines and Healthcare Products Regulatory Agency (MHRA)

From April 2003 the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA) will be merged to form the MHRA. We are still some way from knowing exactly how this new entity will operate. The two entities have different structures including, fundamentally, the way in which they are funded. The MCA operates as a trading fund which is generally accepted as being a means of funding a public body which renders it

freer than those that are directly funded by the relevant government department on an expense-by-expense basis, as the MDA is. The consultation on the question of the funding structure has now closed.

PNC *Telecom plc v Thomas and another* [2002] All ER (D) 315 (Dec)

The claimant company applied for a declaration that the ability and entitlement of the defendants, who were registered holders of shares in the issued share capital of the company, to requisition and convene an extraordinary general meeting of the company, in reliance on a purported requisition notice dated 8th November, 2002, pursuant to s. 368(4) of the Companies Act 1985 had not arisen. The defendants contended that they had submitted a valid requisition notice to the company's board of directors by means of a fax transmitted to the company on 8th November, 2002, and in reliance on that document they had convened a meeting for 30th December, 2002. One of the issues for the court was whether for the purposes of s. 368(3)a of the Act it was permissible to 'deposit' a requisition notice on a company by fax. Section 368(3) states that 'the requisition must state the objects of the meeting, and must be signed by the requisitionists and deposited at the registered office of the company. . .'.

The Court held that for the purposes of s. 368(3) of the Act a requisition notice could be 'deposited' by fax. Accordingly a valid requisition notice was deposited and the meeting of 30th December, 2002, was validly convened.

Re Aitch Holdings Ltd and others [2002] All ER (D) 236 (Dec)

In October 2002, the applicant was disqualified for four years under the Company Directors Disqualification Act 1986. The order was made in respect of two companies that became insolvent as a result of mismanagement. No allegations of dishonesty were made against the applicant. Meanwhile, the applicant was also a director of 19 other companies. The companies were well run and there was no evidence of any of the companies defaulting on their obligations. The applicant then applied to the court, under s. 17 of the Act, for leave to continue to be a director of 17 of the property development companies, his interest in 2 of the 19 having ended. Subsequently, an interim order was made giving the applicant permission to act as a director on the conditions, *inter alia*, that each company had two directors in addition to the applicant, that all payments due were paid and two signatures be provided on the companies' cheques.

The Court allowed the application, stating that:

> 'In the circumstances, there was a clear need for the applicant to be involved in the management of the companies and it was clear from the evidence that the companies were well conducted, providing sufficient protection for the public. The court would grant leave to the applicant to act as a director of each of the 17 companies, with the same conditions as those attached to the interim order.'

References

1. Applicant: Artegodan GmbH.
2. Applicants: Bruno Farmaceutici SpA; Essential Nutrition Ltd; Hoechst Marion Rousel Ltd; Hoechst Marion Rousell SA (France); Marion Merell SA (Spain); Sanova Pharma GmbH ; Temmler Pharma GmbH & Co. KG.
3. Applicant: Schuck GmbH.
4. Applicants: Laboratórios Roussel Lda; Laboratoires Roussel Diamant SARL.
5. Applicants: Laboratórios Roussel Lda; Roussel Iberica SA.
6. Applicant: Gerot Pharmazeutica GmbH.
7. Applicant: Cambridge Healthcare Supplies Ltd.
8. Applicant: Laboratoires Pharmaceutiques Trenker SA.
9. As amended by Directives 83/570/EEC, 89/341/EEC, 89/342/EEC, 89/343/EEC, 89/381/EEC, 92/027/EEC and 93/39/EEC.

10. C(2000) 453, C(2000) 608 and C(2000) 452.
11. As amended by Directives 66/454/EEC, 75/319/EEC, 83/570/EEC, 87/21/EEC, 89/342/EEC, 89/343/EEC, 92/72/EEC, 92/73/EEC and 93/39EEC.
12. C(96) 3608.
13. Note for guidance on clinical investigation of drugs used in weight control, approved by the CPMP in December 1997.
14. C(2000) 453.
15. C(2000) 452.
16. C(2000) 608.
17. The decision purportedly adopted by the Commission to vary SmPCs was not challenged.
18. Article 5 EC first paragraph.
19. C-180/96 *R United Kingdom v Commission* [1996] ECR I-3903, C-183/95 *Affish* [1997] ECR I-4315.
20. Article 174(1),(2) EC.
21. C-180/96 *United Kingdom v Commission* [1998] ECR I-I2265, T-199/96 *Bergaderm and Goupil v Commission* [1998] ECR II-2805.
22. First recital Directive 65/65/EC.
23. Redfludin and Redfludan; Infergen and Inferax.
24. Point C of the Commission's Communication of 22th July, 1998.