

**Regulatory Affairs Journal, 2002, Vol.
13(8), 653-660**

The Position of Co-marketing and
Co-promotion Between EU Regulatory and
Competition Rules

**Carlo Piria explains the regulatory aspects and limitations of
co-marketing and co-promotion.**

Carlo Piria is a partner in Avvocati Associati Franzosi, Milano, Italy.

The purpose of this paper is to analyse the structure of co-marketing and co-promotion agreements in the pharmaceutical industry in the light of the regulatory provisions and competition law in force in the European Community (EC). The pharmaceutical legislation of the EC has consistently pursued two objectives: the protection of public health and the free movement of medicinal products. Therefore, the regulatory provisions cannot be read alone, but must always be interpreted in close connection with the general rules of the Treaty establishing the European Community and EC legislation which is intended to safeguard the free circulation of goods and competition among business organisations¹.

Defining co-marketing and co-promotion

Co-marketing and co-promotion are standard agreements and practice in the pharmaceutical industry. Co-marketing consists of the sale and marketing of a defined product, which is to be conducted independently and under different trademarks by each party in a defined territory in accordance with the terms and conditions of the agreement. Co-promotion consists of the sale and marketing of a defined product under a single trademark, where the parties co-operate in managing the overall process of commercialisation, from the manufacture through to sale to the ultimate consumer. In those countries where the promotion of a product under a single trademark by more than one company is permitted, co-promotion and co-marketing are sometimes interchangeable terms; in those countries where such a form of commercialisation is not allowed, co-marketing is generally referred to in opposition to co-promotion, and co-promotion describes the non-permissible activity.

Co-promotion does not require further description and comment, as it is sufficiently defined by the concentration of the promotional efforts of co-promoters on a single brand. In co-marketing, the contemporary presence of at least two trademarks requires some differentiation from those situations where more than one company are engaged in the commercialisation of identical products, distinguished by different tradenames, but there is no co-marketing agreement. The essence of co-marketing provides that all of the following conditions are met:

- There are at least two marketing authorisations identical in all respects but the tradenames, and all having a common origin as far as the registration dossier is concerned. (Where a dossier of common origin is lacking, even if there is identical product composition and the product constituents have a common origin in terms of manufacturing sources, the activity is not considered to be co-marketing. However where there is a common dossier, it is irrelevant whether or not there are supply relationships or other commercial agreements between co-marketers, even if these consist of licences under patents or know-how; the common registration dossier is of the essence).
- There is ownership by the originator of the dossier (or one of its affiliates) of the marketing rights (promotion and sale) in the contractual territory.
- There is contemporary enjoyment of similar marketing rights in the same territory by an unaffiliated company under a temporary agreement, such as that which may be obtained by means of consent to access the registration dossier or the assignment of a marketing authorisation or any other form of transfer of, or entitlement to, the regulatory situation which permits the promotion and sale of the product in the contractual territory.

Co-marketing may be put in place between subjects none of whom is a marketing authorisation holder (for instance, two companies, one being the national affiliate of a group to which the

company holder of all the centralised marketing authorisations belongs, while the other co-marketer is not a part of the group and both of them are indicated as local representative in the territory.) The contemporary presence of more than one marketer of a product, each one independent (i.e. not linked by an agreement) from the originator of the dossier is not co-marketing. On the other hand, an affiliation relationship between co-marketers implies that they are considered, from a competition point of view, as the same business organisation. Furthermore, a marketing authorisation generated by access to the dossier without any agreement with the originator (as, for instance, when the term of data protection has expired) is not co-marketing; nor does co-marketing generate the perpetual assignment of the marketing authorisation rights.

Regulatory framework

EC pharmaceutical legislation explicitly permits co-marketing. Chapter 1 (Marketing Authorisation) of Volume 2A of the Notice to Applicants expressly provides (paragraph 2.3) that:

in cases where companies wish to market the same medicinal product with a second trade name, then a separate application for a separate second authorisation must be submitted. The European Commission must be informed of this intention in advance.

Chapter 4 (Centralised Procedure) of Volume 2A of the Notice to Applicants states (paragraph 3.1) that a specific procedure has been agreed between the EMEA and the European Commission; under this procedure companies should submit, at the latest four months in advance, an explanation of the underlying motives of the multiple application and their intentions as far as exploitation of any authorisation granted.

Relating to the mutual recognition procedure, Chapter 2 (Mutual Recognition) of Volume 2A of the Notice to Applicants states that the application for multiple marketing authorisations for an identical medicinal product with a different name by the same or a different marketing authorisation holder is possible. There is no provision in EC pharmaceutical legislation that explicitly prohibits or imposes restriction on the granting of separate marketing authorisations following multiple applications. The Mutual Recognition Facilitation Group (MRFG) has provided specific recommendations in order to facilitate and harmonise the regulatory issues for submission of duplicate applications in mutual recognition procedures².

Co-promotion is not at present explicitly provided for in the EC legislation. Co-promotion does not involve a multiplication of marketing authorisations and the establishment by the marketing authorisation holder of the scientific service in charge of information about the medicinal products pursuant to Article 98 of Directive 2001/83/EC is sufficient in order to have a responsible for the information about the products even if promoted by a third party other than the marketing authorisation holder³.

Lack of an explicit discipline for co-promotion has resulted in a different approach by the Member States. In Italy, for instance, promotion is permitted only for the marketing authorisation holder or the company that, under an agreement with the marketing authorisation holder, takes care of the distribution of the product across the whole national territory⁴. This rule, which was present in the Italian legislation well before the implementation of Directive 92/28/EEC on the advertising of medicinal products, in practice constitutes a prohibition of co-promotion and has been a determining factor in the significant development of co-marketing⁵.

The current draft of the proposal of modifications to Directive 2001/83/EC provides for the insertion of a paragraph 3 to Article 98, reading:

the Member States shall authorise the co-promotion of a medicinal product by the holder of the marketing authorisation and one or more companies named by him/her.

This would probably then lead to the removal of the prohibition of co-promotion where this practice is currently not allowed.

Competition issues

Co-marketing and co-promotion agreements undoubtedly pose problems with respect to the competition rules in the EU. Co-marketing and co-promotion by their very names express more than the simple fact of there being more than one player in the market place with the same product. They imply a co-ordination of policies that may include co-ordination of price policies to offer the same product, irrespective of the difference of trademarks, at the same price so as to be included in a reimbursed products list (especially where public healthcare systems are in a strong position because of the circumstance of the monopolistic manager of the healthcare services also being the regulator of the market.)

Articles 81(1) and 81(2) of the Treaty [formerly 85(1) and 85 (2)] prohibit and declare null and void¹:

all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;*
- (b) limit or control production, markets, technical development, or investment;*
- (c) share markets or sources of supply;*
- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;*
- (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.*

Pursuant to Article 81(3), the provisions of paragraph 1 may, however, be declared inapplicable in the case of any agreement or category of agreements, any decision or category of decisions and any concerted practice or category of concerted practices which contribute to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: impose on the concerned undertakings restrictions which are not indispensable to the attainment of these objectives; or afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

Regulation No 19/65/EEC as amended by Regulation (EC) No 1215/1999, empowers the Commission to apply Article 81(3) of the Treaty by regulation to certain categories of agreements and concerted practices falling within the scope of Article 81(1)⁶. This includes categories of agreements which are entered into by two or more undertakings, each operating, for the purposes of the agreement, at a different level of the production or distribution chain ('vertical agreements'), and which relate to the conditions under which the parties may purchase, sell or resell certain goods or services. It also includes categories of agreements to which only two subjects are party and which include restrictions imposed in relation to the acquisition or use of industrial property rights (in particular patents, utility models, designs or trademarks) or to the rights arising out of contracts for assignment of, or the right to use, a method of manufacture or knowledge relating to use or to the application of industrial processes.

The Commission has made use of this power by adopting, over the years, a number of regulations, commonly known as 'block exemption regulations'. The agreements falling in the scope of said regulations are automatically exempted, while the agreements which are not block exempted are to be expressly exempted by the Commission, if they meet the conditions provided for in Article 81(3) of the Treaty. The present situation of block exemption regulations, excluding the regulations specifically applicable to a particular industry (e.g. car manufacturing, brewing) consists of four regulations as follows:

Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices

This regulation is complemented by guidelines on vertical restraints^{7,8}. As mentioned above, 'vertical' means that the concerned business organisations operate at a different level of the production or distribution chain. The regulation has been applicable since 1 June 2000 and has replaced three block exemption regulations applying to exclusive distribution, exclusive purchasing and franchising agreements. As the Commission itself elucidates, the new rules embody a shift from the formalistic regulatory approach underlying the previous legislation towards a more economic approach in the assessment of vertical agreements under the EU competition rules. The aim of this new approach is to simplify the rules applicable to supply and distribution agreements and to reduce the regulatory burden, especially for companies lacking market power, such as small to medium enterprises, while ensuring a more effective control of agreements entered into by companies holding significant market power. The new policy is based on a single regulation with a wide scope of application, which block exempts supply and distribution agreements concerning final and intermediary goods as well as services.

The new block exemption regulation allows companies whose market share is below 30% to benefit from a safe harbour under the Community competition rules. The share is referred to the supplier, but in case of exclusive supply obligations, the share must be referred to the buyer with respect to the market in which it purchases goods or services. The safe harbour below 30% market share, offers companies the freedom to create supply and distribution arrangements best suited to their individual commercial interests and to adapt to changing economic conditions. However, the block exemption regulation does not apply to the so-called hard core restrictions. Two of them are particularly relevant to the area of co-marketing and co-promotion:

- a producer may not impose on its distributors the price at which to resell its products (but maximum and recommended prices are normally permissible); *and*
- a producer may not restrict its distributors from selling to any customer if it is an unsolicited order (passive sales); this means that each distributor must be free to respond to a request for the product or service made by any customer inside the Community.

These particular restrictions to the competition game are prohibited in order to maintain free price competition between distributors for the benefit of consumers and to guarantee the consumers' right to purchase goods and services wherever they want inside the Community. These prohibition rules can also be applied directly by national competition authorities and national courts; violations can attract fines and give rise to claims of damages.

A second set of restrictions not covered by the new Regulation 2790/1999 concerns certain restrictions which are not exempted, but may under certain circumstances nonetheless be compatible with EC competition rules. The most important of these concerns non-compete obligations (requiring distributors to resell only the brands of one supplier) when their duration exceeds five years. Such agreements are not covered by the new block exemption regulation as they may have a strong foreclosing effect on the market. The guidelines describe under what circumstances long-term investments may justify a longer duration of non-compete obligations.

Above the 30% market share threshold, vertical agreements will not be covered by the new block exemption regulation, but nor are they automatically presumed to be illegal. They may require an individual examination under Article 81(3) of the Treaty which spells out the conditions under which agreements between companies may be exempted from EC competition rules. Companies in such a situation are asked to make a self-assessment of the possible consequences of their vertical agreements under the law. The guidelines assist companies in carrying out their own assessment under the EC competition rules by explaining which vertical agreements generally do not distort competition and therefore fall outside Article 81(1).

Regulation (EC) No 2658/2000 of 29 November 2000 on the application of Article 81(3) to categories of specialisation agreement

Regulation (EC) No 2659/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements

Regulations No 2658/2000 and 2659/2000 replace the former regulations on specialisation (Commission Regulation (EEC) No 417/85) and R&D (Commission Regulation (EEC) No 418/85)^{9,10}. In comparison to the old regulations, the new texts are designed to be more user-friendly, with greater clarity and an increased scope of application. The new block exemptions replace the system of specifically exempted 'white list' clauses by a general exemption of all conditions under which undertakings pursue R&D and specialisation agreements. This move away from a clause-based approach gives greater contractual freedom to the parties of such agreements and removes the 'strait-jacket' imposed by the old regulations. The combined market share threshold for exemption of all parties to an agreement is set at 20% for specialisation agreements and at 25% for R&D agreements. Beyond these market shares, R&D or specialisation agreements will not automatically be prohibited but will have to be assessed individually. However, hard core restrictions (price fixing, output limitation or allocation of markets or customers) will generally remain prohibited, irrespective of the parties' market power.

R&D agreements and specialisation agreements are horizontal agreements. The 'guidelines on the applicability of Article 81 of the Treaty to horizontal co-operation agreements' not only complement Regulations 2658/2000 and 2659/2000 referred to above, but also cover a wider range of the most common types of horizontal agreements, for which Regulation 19/65/EEC does not provide the possibility for a block exemption, and which therefore need to be individually exempted on a case-by-case basis^{11,12}. The guidelines are applicable to R&D and production agreements not covered by the block exemptions as well as to certain other types of competitor collaboration e.g. joint purchasing, joint commercialisation. The guidelines describe the general approach which should be followed when assessing horizontal co-operation agreements and set out a common analytical framework. This helps companies to assess with greater certainty whether or not an agreement is restrictive of competition and, if so, whether it would qualify for an exemption.

Commission Regulation (EC) No 240/96 of 31 January 1996 on the application of Article 85(3) [now 81(3)] of the Treaty to certain categories of technology transfer agreements

This regulation covers the classical patent and know-how license agreements and may be considered as the last survivor of the old formalistic approach; it will remain in force until 31 March 2006¹³.

Discussion

The first issue we have to deal with in comparing co-marketing and co-promotion agreements with the system of competition rules outlined above is whether they are to be considered horizontal or vertical agreements; that is, to decide whether co-promotion and co-marketing are agreements entered into by business organisations operating at the same or a different level of the production or distribution chain. But even before this, we have to ask ourselves if the two types of agreement really differ in their intrinsic nature. In other words, are the differentiation of trademarks and the fact that the normal common origin of a product in terms of manufacturing, so important as to put the co-marketers at a different level of the production/distribution chain, and, moreover, does the difference in trademarks create a competitive relationship between the co-marketers? 'Normal common origin of the product in manufacturing terms' implies that one of the co-marketers sells the product directly to the subsequent level of the chain (generally the wholesalers), while the other one purchases the product or the active ingredient from the first co-marketer before selling it (or before manufacturing and then selling it) to the wholesalers.

The following, for instance, has been the decision of the antitrust authority of Italy (a country where co-promotion is still not permitted) in a number of cases in 1999 where co-marketers were heavily fined because the public price of co-marketed products was the same. The Italian authority held that co-marketing was a vertical distribution agreement and the differentiation in trademarks generated a competitive relationship and so any concertation of prices was prohibited.

One proposal of interpretation may be that co-marketing and co-promotion do not differ in their essence and that the choice between co-marketing and co-promotion is a result of regulatory constraints, more than of a real dissimilarity between the economic nature of the agreements. In the recent *Evaluation of the operation of the community procedures for the authorisation of medicinal products*, the influence of regulatory rigidities on the conduct of business in the EU is well depicted¹⁴. For instance, according to the report it would appear that there would be greater use of the centralised procedure if it were more flexible in recognising the commercial context in which many products are developed. The degree of uniformity demanded to avoid partitioning of the market is viewed by companies as unnecessary or disproportionate in light of the objectives at issue. There continue to be major concerns about the requirement for a single trademark and about labelling practice. Recently, the Court of First Instance (Judgement 3 July 2002, Case T-179/00) held that the Commission erred in law in prohibiting the inclusion of the logo of the marketing authorisation holder's local representative in the blue box of the outer packaging of a medicinal product authorised by centralised procedure by virtue of Article 2(2), Directive 92/27/EEC^{15,16}. In fact this kind of restriction is viewed as making it impossible to reflect adequately the commercial interests of companies who have jointly developed products and intend to market them through co-marketing or co-promotion arrangements. On the other hand, the current regulatory prohibition of co-promotion, in countries like Italy, necessarily leads to organising co-operation as co-marketing.

It appears that the purpose of co-marketing, as well as of co-promotion, is the acquisition by the product originator of an additional force of penetration into the market, consisting of the promotional resources (typically the medical representatives) of the co-marketers, against a compensation leaving the co-marketer a sufficient profit margin. The purpose of co-marketing is the performance by the co-marketer of the promotional activity for the product which, even if characterised by a different tradename, is perfectly identical to that of the originator.

If providing door-to-door information to the physician were not considered to be the main sales driver, the originator would probably avoid a co-marketing arrangement. The economic desirability of a co-marketer arises when the incremental costs of an additional promotional force in the territory required to achieve a certain increment in sales allowed by the market potential of the product exceed the erosion of the margin on said additional revenues obtained through the co-marketer due to the compensation owed him. Externalising promotional costs allows the originator to be more efficient in connection with the additional revenues, and permits the co-marketer to allocate, again with an improvement of efficiency, available resources. This is conditional upon the price on which the profit margin for the co-marketer is measured (normally a function of public price) being not less than the efficiency level threshold. But said efficiencies, through the price control systems which characterise almost all the European countries, may be transferred to the last phase of the economic cycle. There are two interesting consequences of this way of looking at co-marketing. Firstly, all contractual relationships of a differing nature (license,

supply, technology transfer) are exclusively ancillary to co-marketing and aim at creating the legal-regulatory situation allowing the co-marketer to promote the product and the means by which the co-marketer is compensated for its activity. Secondly, even the enjoyment of marketing authorisation or any other transfer of regulatory rights is ancillary to the purpose of co-marketing; the originator does not want to transfer its regulatory and intellectual property rights surrounding the product, but entrust them with the co-marketer only for the co-marketing term.

The conclusion is that even if co-marketing encompasses supply or distribution arrangements, co-marketing as well as co-promotion, is a horizontal and co-operative agreement. Its evaluation under the competition rules must be made taking into account first of all the existing competitive relationship, if any; co-marketing under different tradenames is co-operation aiming at the joint promotion, not of the products respectively belonging to the parties, but all of them belonging to the originator, and some of which are entrusted for the promotion and sale with the co-marketer.

The core of co-marketing is promotion. Supply of the active ingredient or the product (which do not necessarily come from the originator, but may come from different subjects which also manufacture and supply them to the originator) are ancillary. Irrespective of the supply or distribution arrangements, co-marketers operate to the same level of the economic cycle i.e. the level at which the ex-factory price is formed. Construing compensation of the co-marketer as a direct compensation for the service (e.g. a percentage of sales generated by the co-marketer), instead of as a margin between the purchase and resale price, is not forbidden and is another way of arranging the business relationship.

According to the guidelines on horizontal agreements, those agreements closer to the downstream end of a product's economic cycle are commercialisation agreements dealt with by Section 5 of the guidelines¹². These agreements can vary widely in scope, depending on the marketing functions being covered by the co-operative efforts. At one end of the spectrum, there is joint selling leading to a joint determination of all commercial aspects related to sale of the product, including price. At the other end, there are more limited agreements that only address one specific marketing function such as distribution, service or advertising. Price fixing, the guidelines observe, can generally not be justifiable unless it is indispensable to the integration of other marketing functions and this integration will generate substantial efficiencies. The size of the efficiencies generated depends *inter alia* on the importance of the joint marketing activities to the overall cost structure of the product in question. Joint distribution is thus more likely to generate significant efficiencies for producers of widely distributed consumer products which are only bought by a limited number of users.

Of course, these statements from the guidelines can't be taken as a sort of general authorisation to price agreements. However, in the framework of a co-operative horizontal agreement which does not affect previous competitive relationships, aimed at the acquisition of promotional services on an undifferentiated product, is the common determination of price still to be considered anti-competitive? The product remains in the beneficial ownership of the originator and is just entrusted with the co-marketer in order to be promoted and, often necessarily as a regulatory constraint, distributed. Rather than a forbidden concertation, a unique price appears to be a transparency obligation in a regulated market, where the price regulation mechanism permits the transfer to the consumer of the benefits arising from co-marketing.

Further comments and conclusion

If there is an imperfection, we can find it not in the alteration of the competitive game, but in the substantial weakness of the co-promotion and co-marketing arrangements as they are generally practised in Europe, when looked at as tools able to strengthen the competitiveness of the European industry.

A report prepared in November 2000 for the Enterprise Directorate General of the European Commission by a group of scholars from leading Italian academies confirms that no company is now able to control and master internally all the knowledge required to discover and develop a new drug¹⁷. The ability to access and make efficient use of a network of collaborative relations and the underlying market for technology, the report says, has therefore become a crucial source of competitiveness. Such co-operation may take place between companies and academic institutions, pure research organisations or new biotechnology firms as technology suppliers, as well as between companies themselves engaged in all the phases of the economic cycle (research, development, manufacturing and marketing).

According to the report, US firms have consistently over time demonstrated the highest propensity to collaborate in the pre-clinical phase, whereas collaboration in marketing remains significant in the European countries. Furthermore, US firms act more frequently as licensors (originators) of new R&D projects as compared to European countries, which are typically

licensees (developers). Firms located in countries like Italy and, to a lesser extent, Sweden, have a high propensity to license-in in the latter phases of the R&D chain from the US, while UK and Swiss firms also collaborate extensively in the early stages of the R&D process. Moreover the role of 'originators' of US and Canadian companies is linked to the disproportionate share of licences which involve, largely as licensors, new biotechnology firms, universities and other research centres, as compared to the other major European countries (with the exception of the Netherlands, Denmark and Sweden) and Japan.

The report suggests that one major difference between the US and Europe is the presence in the US of an industry of technology suppliers, both new biotechnology firms and universities. In short, Europe and the US may not appear too different if one looks individually at the large drug multinationals; but they do appear different if one looks at the organisation of the industry. In the US there is not only a larger number of big innovative companies, but also a higher supply of new technologies and an extensive vertical specialisation between an industry that is specialised in the 'exploration' of new technologies and innovation opportunities and an industry that is specialised in their 'exploitation'.

The European research system needs not only to be strengthened in terms of its ability to produce more and better research, but also to exploit its innovation potential by translating this potential into economic performance. The US competitiveness in drug innovation appears to be the sum of these two effects of better in-house capabilities and more effective use of the market for technology; European firms lag behind their US counterparts in terms of their in-house capabilities and, moreover, in the extent of their use of the market for technology.

Co-operation among European companies appears to be a necessity in order to develop a domestic research system through a division of innovative labour and to increase the productivity of their research as well as to gain access to external knowledge from specialist technology suppliers without the mediation of US companies. Co-operation may involve the early phases of research and development or it may be more marketing oriented.

The typical format of an agreement between a technology supplier and a pharmaceutical company is a technology transfer, whereby the consideration for the technology supplier is in terms of lump sum or royalties or a combination of both. When the co-operating companies are fully engaged in the entire stream of the product life, down to the marketing phase, they tend to have their reward from the market in terms of revenue from sales. In such cases, the co-promotion or the co-marketing of the product by the companies engaged in the co-operative agreement is the result and the contents of their agreement. A co-marketing or a co-promotion agreement made at the earliest stages of product development not only appears to be a key success factor in the competitive game, but it is more likely to fall under the scope of the block exemption regulation No 2659/2000 as it is related alternatively to:

- joint research and development of products or processes and joint exploitation of the results of that research and development; *or*
- joint exploitation of the results of research and development of products or processes jointly carried out pursuant to a prior agreement between the same parties.

The efficiencies generated will not simply be the avoidance of the 'cost of competition', but, as the EC guidelines require, real savings resulting from the integration of economic activities.

The environment of the pharmaceutical industry has been rapidly changing since the last decade of the last century. Co-marketing and co-promotion as a tool for non-European companies to gain access to those national markets particularly protected from a regulatory point of view are no longer in line with the new environment. Innovation is confirmed as the arena in which the competitive contest will be decided. The future of co-marketing and co-promotion may be co-research and co-development between European companies.

References

1. Consolidated version of The Treaty establishing the European Community as amended by The Treaty of Amsterdam (signed 2 October 1997), *OJ*, 1997, **C340**, 173-308
2. MRFG, Recommendations on Multiple Applications in Mutual Recognition Procedures, Final Version, 28 May 1999, available via website <http://heads.medagencies.org/>
3. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, *OJ*, 2001, **L311**, 67-128
4. Legislative Decree No 541/1992, *Gazzetta Ufficiale della Repubblica Italiana (GURI)*, 11 January, 1993, 7, supplement, as amended by Legislative Decree No 44/1997, *GURI*, 6 March, 1997, 54, supplement
5. Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use, *OJ*, 1992, **L113**, 13-18

6. Council Regulation (EC) No 1215/1999 of 10 June 1999 amending Regulation No 19/65/EEC on the application of Article 81(3) of the Treaty to certain categories of agreements and concerted practices, *OJ*, 1999, **L148**, 1-4
7. Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices, *OJ*, 1999, **L336**, 21-25
8. Commission Notice 2000/C 291/01, Guidelines on vertical restraints, *OJ*, 2000, **C291**, 1-44
9. Commission Regulation (EC) No 2658/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of specialisation agreements, *OJ*, 2000, **L304**, 3-6
10. Commission Regulation (EC) No 2659/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements, *OJ*, 2000, **L304**, 7-12
11. Regulation No 19/65/EEC of 2 March of the Council on application of Article 85(3) of the Treaty to certain categories of agreements and concerted practices, *OJ*, 1965, **P036**, 533-535
12. Commission Notice Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements, *OJ*, 2001, **C003**, 2-30
13. Commission Regulation (EC) No 240/96 of 31 January 1996 on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements, *OJ*, 1996, **L031**, 2-13
14. Cameron & McKenna and Andersen Consulting, 'Evaluation of the operation of the community procedures for the authorisation of medicinal products', November 2000, <http://dg3.eudra.org/F2>
15. Court of First Instance, Judgement: Case T-179/00, 3 July 2002, <http://www.curia.eu.int>
16. Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets, *OJ*, 1992, **L113**, 8-12
17. Gambardella A, Orsenigo L and Pammolli F, *A global competitiveness in pharmaceuticals – A European perspective*, November 2000, <http://dg3.eudra.org/F2>