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Contents

Draft Council directive for the harmonization amongst Member States of turnover tax legislation

(Proposal submitted by the Commission to the Council on 5 November 1962)

The Council of the European Economic Community,

Having regard to the provisions of the Treaty establishing the European Economic Community, and in particular Articles 99 and 100 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the Economic and Social Committee;

Having regard to the opinion of the European Parliament;

Whereas the aim of the Treaty is to create an economic union based on vigorous competition and having the characteristics of an internal market;

Whereas an essential prerequisite for this aim is that the turnover tax legislation of Member States should not distort competition nor hinder the free circulation of goods and services in the Common Market;

Whereas the existing laws do not meet the above-mentioned requirements since on the one hand the systems of multi-stage, cumulative taxation practised in five of the Member States are not neutral in their effects on competition, and on the other hand these same laws all permit in respect of intra-Community trade the application of compensatory taxes to imports and drawbacks on exports, thus maintaining tax frontiers between Member States;

Whereas it is in the interest of the Common Market to harmonize turnover tax legislation in order to eliminate as far as possible all distortions in the terms of competition, both nationally and at Community level, as well as to abolish the above-mentioned taxation measures affecting Community trade;

Whereas from studies in this field it is evident that harmonization must culminate in the abolition of multi-stage cumulative tax systems and the adoption by all Member States of a common system of added-value tax, to be applied at all stages of production and wholesale trade, leaving to the States the option whether to impose independently a supplementary tax on retail sales or to extend the system of added-value tax to retail trade;

Whereas the proposed harmonization must be carried out by stages as it will entail considerable modifications to the taxation structures of Member States and have far-reaching consequences in the budgetary, economic and social fields;

Whereas the replacement of the systems of multi-stage cumulative taxes by non-cumulative systems will remove the factors which distort competitions; and

Whereas it is therefore desirable that all Member States should during a preliminary stage adopt a non-cumulative system of their own choice;

Whereas during a second stage the Member States should mould their chosen non-cumulative systems into a common system of added-value taxation without, however, being obliged to adopt harmonized rates and reliefs;

Whereas the aim of the common system of added-value taxation must be to secure neutrality of effect on competition inasmuch as within each country the same goods will be taxed at the same rate irrespective of the number of stages in their production and distribution, and in international trade the amount of tax imposed will be known, so that it will be possible to fix an exact figure for compensation;

Whereas it is hardly possible at present to indicate by what time the necessary conditions for attaining the ultimate objective, which is the abolition of all tax frontiers, can be fulfilled; and

Whereas it is therefore preferable that the timing of the third and final stage and the measures pertaining thereto should be fixed at a later date on the basis of proposals made by the Commission to the Council,

Has adopted the present directive:

Article 1

Those Member States which for turnover taxes apply a multi-stage, cumulative system shall replace this, at latest by the

beginning of the fourth year reckoned from the end of the year of notification of this directive, by a non-cumulative system, under which tax will normally be imposed on goods and services at only one stage. Member States will, however, remain free to fix independently a supplementary tax at the retail stage superimposed upon the above-mentioned non-cumulative tax, or, if they have elected to apply an added-value tax system, to extend this system to cover retail trade.

As from the end of the above-mentioned period, standard-rate compensatory measures for imports and exports shall no longer be permitted in trade between Member States.

Article 2

The Member States shall inform the Commission at the end of each year of the period mentioned in Article 1 of any measures taken or contemplated to fulfil the obligation laid down in the said Article.

Article 3

The Member States shall introduce, at latest by the end of the transition period, a common system of added-value taxation embracing all stages up to and including wholesale trade. The form of this tax system and the methods of applying it shall be decided by the Council, acting on proposals of the Commission, before the end of the period referred to in Article 1. The Member States will be free to apply independently a supplementary tax on retail sales, or to make the common added-value tax applicable to this stage also.

Article 4

The Commission will study by what means and within what period of time the harmonization of turnover taxes provided for in Article 3 shall attain its final object, namely the abolition of countervailing charges on imports and drawbacks on exports in trade between Member States, the neutral effect of turnover taxes on trade being safeguarded. The Commission will submit its proposals to the Council in sufficient time for the latter to take decisions before the end of the transition period.

Article 5

The present directive is addressed to all Member States.

Draft Council directive on the harmonization of laws and regulations governing pharmaceutical products

(Proposal submitted by the Commission to the Council on 5 November 1962)

The Council of the European Economic Community,

Having regard to the provisions of the Treaty and in particular Article 100 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Having regard to the opinion of the Economic and Social Committee;

Whereas the main purpose of legislation on the production and distribution of branded pharmaceutical must be to safeguard public health;

Whereas, however, this object must be attained by means that do not hinder the development of the pharmaceutical industry and trade in its products within the Community;

Whereas certain national arrangements constitute obstacles to trade in pharmaceutical products within the Community and therefore directly affect the establishment and functioning of the Common Market;

Whereas these obstacles must be overcome by harmonization of legislation on pharmaceutical matters in general;

Whereas, however, such harmonization of legislation can only be brought about gradually, priority being given to those

disparities which may most affect the functioning of the Common Market,

Has adopted the present directive :

CHAPTER I

Definitions and field of application

Article 1

For the purposes of the present directive, the following definitions shall apply :

1. Branded pharmaceuticals

Any medical preparation sold under a special name and put up in a special way.

2. Medical preparation

Any substance or mixture which is claimed to cure or prevent disease in human beings (or animals).

The term includes any substance or mixture administered to human beings (or animals) for purposes of diagnosis or in order to restore, improve or influence organic functions.

For purposes of health control, medical preparations are deemed to include surgical sutures, sterile dressings and materials which, for the purposes referred to in the foregoing paragraph, are permanently or temporarily introduced into the human (or animal) organism.

3. Substance

Any matter, be it of :

human origin, such as human blood and blood derivatives;

animal origin, such as micro-organisms, whole animals, parts of organs, microbial or animal secretions, toxins, extracts, blood derivatives, etc.

vegetable origin, such as micro-organisms, plants, parts of plants, vegetable secretions, extracts, etc.

chemical origin, such as natural elements and chemicals and compounds produced by chemical processes.

Article 2

The provisions of Chapters III to V of the present directive shall apply only to branded pharmaceuticals for human use intended for sale in the Member States.

CHAPTER II

Licensing of branded pharmaceuticals

Article 3

No branded pharmaceutical may be offered for sale in the member countries except under licence issued by the competent authority in the said countries.

Article 4

The licence referred to in Article 3 shall be withheld if, on the basis of the particulars and supporting documents listed in Article 6, the branded pharmaceutical does not have the therapeutic potency claimed for it or if such potency is not adequately substantiated by the applicant, or if the nature and quantities of the ingredients are not stated. The licence shall also be withheld if the data and documents submitted in support of the application are not in conformity with the provisions of Article 6.

Article 5

The competent authorities of the Member States may refuse to license the sale of a branded pharmaceutical for use as a contraceptive if under their legislation the sale of pharmaceuticals intended essentially for such purposes is prohibited.

Article 6

The licence referred to in Article 3 shall be issued by the competent authority of the Member States on application by the manufacturer and, where appropriate, the distributor.

The application must be accompanied by the following particulars and supporting documents :

1. Name or registered trading name and address of the manufacturer, and, where appropriate, name or registered trading name and address of the distributor.

2. Trade name of the preparation (brand name, or usual description accompanied by brand name or by name of manufacturer, or scientific description accompanied by brand name or by name of manufacturer).

3. Nature and quantities of ingredients, as usually described, without empirical chemical formulae, and internationally recognized common name as recommended by the World Health Organization.

4. Short description of method of preparation.

5. Therapeutical indications, contra-indications and secondary effects.

6. Formulation, directions for use, dosage; indications as to stability.

7. Tests applied (qualitative and quantitative analysis of ingredients and finished product; special tests, e.g. for sterility, pyrogenic property, presence of heavy metals, stability; biological tests and tests for toxicity).

8. Results of physio-chemical, biological or micro-biological, pharmacological, toxicological and clinical tests.

9. One or more samples or dummies of the product as proposed to be offered for sale, together with accompanying prospectus if any.

10. For foreign products: licence issued for sale in the country of origin or another country.

11. Document attesting that the manufacturer holds a licence in his own country to produce pharmaceuticals.

Article 7

The Member States shall make arrangements for the licensing procedure to take place within the following time-limits:

1. 30 days from the date of submission for the decision as to whether, having regard to the terms of Article 6, the application can be entertained;

2. 90 days from the date of the decision provided for in paragraph 1 for the decision to grant or withhold the licence having regard to the terms of Article 4.

In exceptional cases, the time-limit prescribed in paragraph 2 may be extended for a further 90 days. The applicant shall be notified to this effect before the expiry of the initial time-limit.

Article 8

The Member States shall take steps to enable the applicant to furnish proof that the tests on the finished product described by him as required by Article 6 have been made.

Article 9

The licence granted under Article 3 shall not impair the liability under ordinary law of the manufacturer or where appropriate the distributor.

Article 10

The licence shall be valid for five years and shall be renewable for five-year periods at the request of the licensee submitted three months before the end of any such period.

CHAPTER III

Suspension or withdrawal of licence

Article 11

The competent authorities of the Member States shall suspend or withdraw the licence to sell a branded pharmaceutical if the latter appears to be harmful under normal conditions of use, if it does not have the therapeutic potency claimed for it or if the nature and quantities of its ingredients are not in conformity with the statement made in accordance with Article 6, paragraph 3.

The licence shall also be suspended or withdrawn if the particulars supplied in the supporting documents submitted pursuant to Article 6 are found to be incorrect or if the tests on the finished product stipulated in Article 8 have not been made.

Article 12

Any decision taken under Articles 4, 5 and 11 shall state the precise grounds therefor. The person concerned shall be notified thereof and at the same time be informed of the remedies open to him at law and of the time-limit within which an appeal may be lodged.

CHAPTER IV

Labelling

Article 13

The containers and outer packing of branded pharmaceuticals must bear the following particulars:

1. Name of the product, which may be either a brand name or the usual description accompanied by a brand name or by the name of the manufacturer, or a scientific description accompanied by a brand name or by the name of the manufacturer.

If the product bears a brand name and consists of a single active substance with a common international name recom-

mended by the World Health Organization, such name shall appear in bold lettering underneath the brand name.

2. Nature and quantities of the active principles and the quantity of each per unit or expressed in percentages according to the formulation.

If any of the active principles has a common international name recommended by the WHO, this name must also be used.

3. Reference number for identification (batch number).

4. Licence number.

5. Name and address of the manufacturer or, where appropriate, the distributor.

6. Method of administration.

7. Latest date for use in the case of products with a period of stability of less than three years.

8. Special storage precautions where appropriate.

The formulation and the contents must be stated on the outer packing.

Article 14

For products put up in ampoules, the particulars mentioned in the first paragraph of the foregoing article are to be given on the outer packing. On the containers, however, only the following particulars need be given :

i) name of the product;

ii) quantities of the active principles;

iii) method of administration;

iv) latest date for use.

Article 15

As regards small containers other than ampoules, holding only one dose and on which it is impossible to give the particulars referred to in Article 14, the provisions of Article 13 shall apply to the outer packing only.

Article 16

In the case of narcotics, the outer packing and the container must bear in addition to the particulars stipulated in Article 13 a special mark consisting of two parallel red lines.

Article 17

Where there is no outer packing, all the particulars which in pursuance of the foregoing articles should appear on that packing shall be given on the container.

Article 18

The particulars stipulated in paragraphs 6, 7 and 8 of Article 13 must be printed on the outer packing and on the container in the language or languages of the country in which the pharmaceutical products are offered for sale.

Article 19

Nothing in the chapter shall prevent the publication on the other packing of other particulars required by regulation and not explicitly referred to in this directive.

Article 20

If the provisions of the present chapter are not observed, and an order addressed to the person concerned has been ignored, the authorities of the Member States may suspend or withdraw the licence.

Any decision taken under the terms of the foregoing paragraph must state the grounds therefor. The person concerned shall be notified thereof and shall also be informed of remedies open to him at law and of the time-limit within which an appeal may be lodged.

CHAPTER V

Arrangements for application and transitional measures

Article 21

A licence may not be withheld, suspended or withdrawn except for the reasons set forth in this directive.

Article 22

The Member States shall put into effect any laws, regulations and administrative instructions needed to comply with the provisions of the present directive within twelve months of notification and shall inform the Commission forthwith of the action taken.

Article 23

Regulations made in pursuance of the present directive shall apply to products licensed for sale by virtue of the preceding provisions two years after the notification referred to in Article 22.

Article 24

The present directive is addressed to all Member States.

Draft Council regulation on the criteria to be observed in fixing target prices for agricultural products

(Proposal submitted by the Commission to the Council on 14 November 1962)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community and particularly Article 43;

Having regard to Regulation No. 19 concerning the gradual establishment of a common organization of the market in cereals and particularly paragraph 4 of Article 6;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Whereas in consequence of the closely interknit economic relationship and manifold interaction between the prices of all agricultural products, agricultural price policy forms a single whole and the prices for the various products must be fixed in accordance with a clearly defined concept of price policy;

Whereas in fixing the annual prices the Community's policy should avoid being unduly rigid, but prices and their interrelationship should nevertheless be determined in such a manner as to lay their sights on targets set for a number of years ahead;

Whereas the market and price policy should be aimed at securing for farmers and farm workers on efficiently managed and economically viable farms an adequate average income over the years;

Whereas in order to attain the objectives laid down in Article 39 of the Treaty for all persons engaged in agriculture, measures other than those relating to market and price policy must be taken notably under the policy for the improvement of agricultural structures, regional policy and social policy;

Whereas the level of farm prices has a considerable incidence on the incomes of persons engaged in agriculture and on the orientation of production in relation to demand, as well as on the development of the economy as a whole, including foreign trade, and whereas it is therefore advisable to establish in the light of such incidence three sets of criteria to be observed in the annual fixing of prices;

Whereas although it is not possible to draw up a rigid formula for the relative importance to be attached to each of these criteria, it is expedient that none should be applied without reference to all the others;

Has adopted the present regulation:

Article 1

1. As the Regulations of the Council on the gradual establishment of common market organizations for agricultural products lay down that basic target prices, guide prices or any other prices fixing the level to be attained for given agricultural products in the Member States or in the Community — hereinafter referred to as "target prices" — shall be fixed or brought into line, the institutions of the Community or of the Member States responsible for fixing target prices shall be guided by the criteria set forth in Articles 2 to 7 of the present Regulation.

2. In applying the criteria, all the following three sets shall be taken into account:

i) The criteria laid down in Articles 2 and 3 concerning the incomes of persons engaged in agriculture,

ii) The criteria laid down in Articles 4, 5 and 6 concerning the orientation of production in relation to demand,

iii) The criteria laid down in Article 7 concerning economic development in general.

Criteria concerning the income of persons engaged in agriculture

Article 2

1. Target prices shall be fixed in the context of a general farm price policy, based on the principles laid down in Article 39 and paragraph 4 of Article 40 of the Treaty, and designed to enable farmers

and agricultural workers on efficient and economically viable farms to obtain a fair average income over the years.

2. A fair income shall be taken to mean an income per full-time agricultural worker corresponding to that of a full-time worker in any comparable occupational group.

Article 3

1. In order to apply the criterion of agricultural price policy laid down in Article 2 (1) above, the following elements in particular shall be taken into account in the fixing of target prices:

a) The trend in producers' prices of farm products for which no target prices are fixed, having regard to the proportion of farm income derived from such products to total farm income within the Community;

b) The trend in the general level of prices in the context of paragraph 2 above;

c) The trend in prices paid by producers for major means of production in the context of paragraphs 3 and 4.

2. The trend in the general price level referred to in paragraph 1 *b* above shall be determined on the basis of the general cost of living index (not including rent).

3. The major means of production referred to in paragraph 1 *c* above shall be taken to comprise commercial fertilizers, pesticides, feed concentrates, machinery and tools, services, energy (motor fuel, coal, electricity) and the wages of farm labourers.

4. Changes in the prices of the major means of production referred to in paragraph 3 above by comparison with the preceding year shall be taken into consideration roughly according to the relative significance of each means of production for the particular product in respect of which the target price is fixed.

Criteria concerning the orientation of production in relation to demand

Article 4

1. In order to attain the objectives laid down for the orientation of production, account shall be taken of the fact that when target prices are fixed, their absolute level, as well the interrelation between target prices for the various products, contributes to the establishment or maintenance of a balance between production and imports of such products or groups of products on the one hand and demand for them (domestic consumption and exports) on the other.

2. On the basis of orientation forecasts, the Commission shall determine trends in production, domestic consumption and external trade in respect of products subject to target prices; it shall inform the Council thereof in the report referred to in Article 8 below and at the same time shall on the basis of such data set the targets to be decided by the Council with regard to the orientation of production.

Article 5

Target prices shall be fixed with due regard to the fact that their absolute level, as well as the interrelation between target prices for the different products, must help to promote specialization to suit economic structures and natural conditions within the Community.

Article 6

Target prices shall be fixed with due regard to the international trade situation and trends for the product under consideration or competing products.

Since world market prices are not always formed under normal conditions, they are to be compared with the prices at which the most efficient producers could supply the product concerned in sufficient quantity.

Criteria concerning general economic development

Article 7

1. Target prices shall be fixed with due regard to the fact that farm price policy should contribute to the gradual attainment of the objectives laid down in Article 2 of the Treaty.

2. In particular, account shall be taken of the fact that:

a) The level of the target price largely determines agricultural prosperity, which in turn contributes to the development of the economy as a whole;

b) The level of target prices may stimulate consumption and open up outlets for the

agricultural products of the Member States within the Community and in non-member countries;

c) The cost to the budgets of the Community or the Member States involved in the application of the target prices shall not jeopardize the harmonious development of the economy as a whole;

d) The level of a target price shall not impede the Community's contribution to the harmonious development of world trade.

General provisions

Article 8

1. On the basis of a report on the agricultural situation and the agricultural markets in the Community, of proposals for the fixing of target prices, and of the Commission's report to the Council referred to in Article 3 (3) of Council Regulation No. 25, the Council shall each year examine whether and to what extent the principle laid down in Article 1 (2) above and the criteria enumerated in Articles 2 to 7 above have been taken into account. In deciding on the new target prices the Council shall utilize the results of this examination.

2. The report on the agricultural situation and the agricultural markets in the Community shall contain all available numerical data required for an appreciation of the criteria enumerated in Articles 2 to 7 above during the year under review, and in particular:

a) Figures of the trend in income per full-time worker as defined in Article 2 (2) above;

b) Figures of the trend in the prices and price indices referred to in Article 3 (1 *a, b, c*) above;

c) Orientation forecasts for products subject to target prices; such forecasts shall also contain estimates of exports to non-member countries and of interventions on the Community markets;

d) Data concerning the regional trend in production, processing and consumption of products subject to target prices, and an analysis of intra-Community trade;

e) An analysis of the market situation in the Community and on world markets for products subject to target prices or competing products;

f) An analysis of the repercussions of the proposed target prices on general economic development, including foreign trade; such analysis to be made in conformity with Article 7 (2 *a-d*) above.

3. The Commission shall determine by a decision what data shall be published by the Member States for the preparation of the report, and the time at which they shall be notified.

Article 9

The present Regulation shall come into effect on the day following its publication in the official journal of the European Communities.

It shall be binding in all its parts and directly enforceable in all Member States.