COMMISSION OF THE EUROPEAN COMMUNITIES

COM(90) 597 final - SYN 316

Brussels, 18 December 1990

Proposal for a

COUNCIL DIRECTIVE

on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances

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(presented by the Commission)

Explanatory Memorandum

A. General observations

1. The proposed directive has as its objective to ensure that precursor chemicals are not diverted to the illicit manufacture of drugs and that there are not distortions of competition in the licit manufacture and placing on the Community market of these chemicals. To this end the proposed directive aims to lay down measures, as required by the 1988 UN Convention, to monitor the manufacture and placing on the Community market of precursors of psychotropic and narcotic substances. The 1988 UN Convention against illicit trafficking in Narcotic drugs and psychotropic substances was signed by the Community on 8 June 1989. This directive also complements the monitoring of Community's external trade in precursors as foreseen by the parallel proposed Council regulation*

2. The substances concerned are chemicals, some of limited licit trade (Annex Table I) others of substantial licit trade (Annex Table II). These are used as pharmaceutical intermediates or are chemicals either solvents and/or acids which are legitimately used in a wide range of chemical outlets. They are also important in the refining and processing of drugs and for this reason can be considered as precursor chemicals to the illicit manufacture of narcotic drugs and psychotropic substances.

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* COM (90) 215 20.06.1990
Proposal for a Council Regulation laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances

3. Monitoring of precursors worldwide and particularly in countries with a highly developed chemical industry is considered a necessary means of discouraging manufacture and limiting supply of illicit drugs and as such received primary attention in the Global Plan of Action adopted by the UN General Assembly on 23 February 1990. Adoption of measures to monitor precursors has been recognized by CELAD in its report, endorsed by the June 1990 Dublin Council, as one of the priority items in Community anti-drug action in the context of a single market.

4. The proposed directive foresees, as required by Art. 12 of the UN Convention, that operators maintain comprehensive commercial records of all transactions in the scheduled substances, except for minor quantities of solvents and acids sold at retail level. In addition the essential pharmaceutical intermediate chemicals (Annex Table I) will be required to be manufactured or placed on the market by and to operators possessing an authorization. As the overwhelming proportion of the legitimate transactions in Table I products are for pharmaceutical end-uses the authorization procedure foreseen makes use of the existing authorization system for the manufacture of pharmaceuticals. The need to obtain the fullest cooperation of the concerned economic operators to ensure efficacy of monitoring precursors is also recognized. In due consideration of areas covered by Member States' competence the proposal limits itself to the identification of certain objectives to be met by national legislation.

B. Contents of the Directive

1. In conformity with the UN Convention, the proposed directive distinguishes between two types of precursors (cf Table I and Table II in the Annex), i.e. those with limited use for licit purposes (Table I substances) and others with essential importance for legitimate commercial use (Table II substances). Both categories of precursors are subject to the general monitoring scheme laid down in this directive whereas the more stringent measures of Article 4 apply to Table I substances only[1)]

2. a) Article 1 determines the scope and lays down a number of definitions of terms.

b) Article 2 lays down the documentary requirements and ensures that competent authorities readily obtain access to documents and records for verification purposes (9d, e, UNC).

c) Article 3 requires Member States to appoint competent authorities for all matters relating to the implementation of the directive.

d) Article 4 (8a, b UNC) establishes an authorization system for substances of Table I that makes use of the system established under Art 16 of Directive 75/319/EEC.

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1) Numbers in brackets refer to corresponding paragraphs of Article 12 of the UN Convention (UNC)

e) Article 5 containing the centerpiece of the standard monitoring system reflects the cooperation-based approach by stimulating economic operators as well as other persons professionally involved to inform authorities of any circumstance indicating the possibility of diversion (9 a UNC)

f) Article 6 intends to facilitate the application of the directive by supplying monitoring authorities with sufficient powers such as inspection, search and seizure (9 b UNC).

g) Article 7 covering intra-Community cooperation between monitoring authorities refers mutatis mutandis to Regulation (EEC) 1468/81 on mutual assistance in customs and agricultural matters, thus providing not only for a well-established mechanism in administrative assistance but also for due protection of confidendiality with regard to all information obtained and circulated under this directive.

h) Final provisions

Article 8 while avoiding interference with Member States' competence in criminal matters, ensures that infringements of this directive be subject, Community-wide to appropriate sanctions.

Article 9 (12 UNC)[2] serves to fulfil the annual reporting obligations towards the UN with the Commission acting as coordinating body.

Article 10 requires Member States to report the implementing measures adopted.

2) The requirement to supply information on nature and origin of processing equipment seized is contained in Art. 13 of UNC.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission[1],

In cooperation with the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas some Member States have adopted measures to monitor the manufacture and the placing on the market of certain substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances; whereas other Member States are about to adopt measures of this kind; whereas it is therefore necessary to establish common rules at Community level in the perspective of the completed internal market in order to avoid distortion of competition in the licit trade and to ensure homogenous application of the rules established;

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Whereas on 19 December 1988, the United Nations Conference adopted in the effort to combat drugs a Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances; whereas the Community participated in the negotiation of this Convention, showing its political will to act within the limits of its competences;

Whereas the requirements of Article 12 of the aforementioned Convention, in respect of trade in precursors, i.e. substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances are implemented as far as trade between the Community and third countries by Council Regulation .....[4];

Whereas Article 12 of the convention envisages adoption of appropriate measures to monitor manufacture and distribution of precursors; whereas in order to trace possible illicit diversions of precursors in the Community or in view of a fraudulent export from the Community and to ensure that common monitoring rules are applied in the Community market, it is necessary to complement the aforesaid regulation;

Whereas the provisions of Article 12 of the Convention are based on a system of monitoring trade in the substances in question; whereas documentation and labelling as regards consignments of these substances have to be sufficiently clear; whereas it is furthermore important, whilst providing competent authorities with the necessary means of action, to develop, in compliance with the spirit of the Convention, mechanisms which are based on close cooperation with the economic operators concerned as well as on the development of the gathering, exchange and exploitation of intelligence;

Whereas it is also important, in this context, that Member States provide for sufficiently dissuasive sanctions;

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Whereas, to uncover illicit manufacture and distribution, measures have to be taken to encourage vigilance, by the various operators, in respect of suspect operations and their detection in cooperation with the competent authorities;

Whereas the licit trade in scheduled substances in Table I of the Annex is in fact restricted to the manufacture of medicinal products; whereas it is therefore possible to limit the manufacture and use of these products to persons holding an authorization to manufacture medicinal products granted in accordance with Article 16 of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products[5], as last amended by Directive 89/381/EEC[6];

Whereas it is important to provide mechanisms for administrative cooperation; whereas it is suitable in this respect, as far as the competent authorities in the Community are concerned, to seek inspiration from Council Regulation (EEC) No 1468/81 of 19 May 1981 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters[7], as amended by Regulation (EEC) No 945/87[8]; whereas particular attention has to be paid to the confidentiality of the information received and exchanged,

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5 OJ No L 147, 9.6.1975, p. 13.

6 OJ No L 181, 28.6.1989, p. 44.

7 OJ No L 144, 2.6.1981, p. 1.

8 OJ No L 90, 2.4.1987, p. 3.

HAS ADOPTED THIS DIRECTIVE :

TITLE I

General

Article 1

1. This Directive concerns the monitoring, within the Community, of certain substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances, with a view to preventing diversion of such substances.

2. For the purposes of this Directive :

   (a) "scheduled substances" means any substance listed in the Annex including mixtures containing such substances. This excludes pharmaceutical preparations or other preparations containing scheduled substances that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means;

   (b) "placing on the market" means any disposal against payment or free of charge to third parties of the scheduled substances manufactured in the Community or put into free circulation in the Community;

   (c) "operator" means any natural or legal person engaged in the manufacture, processing, trade or distribution of scheduled substances in the Community, or involved in other related activities such as broking or holding stock for third parties;

(d) "UN Convention" means the United Nations Convention against illicit traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988;

(e) "International Narcotics Control Board" means the Board established by the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol.

TITLE II

Monitoring of placing on the market

Article 2

Documentation, records and labelling

Member States shall take all the measures necessary to ensure that the placing on the market of scheduled substances is subject to the following requirements :

1. all transactions leading to the placing on the market of scheduled substances shall be properly documented.

   (a) In particular, commercial documents such as invoices, cargo manifests, administrative documents, transport and other shipping documents shall contain sufficient information to enable positive identification of the following :

   - the name, the quantity and the weight of the scheduled substance(s) as stated in the Annex, or in the case of mixtures, the name, the quantity and the weight of the substance(s) listed in the Annex.

- the name and address of the supplier(s) and the customer(s);

(b) the documentation must furthermore contain a declaration from the customer which shows the specific uses and which confirms that these substances are not used for the illicit manufacture of narcotic drugs or psychotropic substances.

(c) The obligations under (a) and (b) shall not apply to transactions concerning products of table II of the Annex when the quantities involved do not exceed those indicated in Table III of the Annex.

2. Whenever operators apply labels to scheduled substances in order to place them on the market such labels shall mention the names of these substances as stated in Tables I and II of the Annex;

3. Operators involved in the placing on the market of scheduled substances shall keep detailed commercial records necessary to fulfil the obligations under point 1 with regard to these activities;

4. The documents and records referred to in points 1 and 3 shall be kept for a period not less than two years from the end of the calendar year in which the operation referred to in point 1 took place, and shall be made readily available to the competent authorities upon request.

Article 3

In order to ensure the adoption of appropriate regulatory decisions concerning the manufacture of Table I products as set out in the Annex and the placing on the market of the scheduled substances, Member States shall designate a competent authority.

Member States shall inform the Commission of the competent authority thus designated.

Article 4

Additional requirements - Substances of Table I of the Annex

1. Member States shall take all appropriate measures to ensure that the manufacturing or putting into free circulation in the Community of scheduled substances of Table I of the Annex is subject to possession of an authorization granted in accordance with Article 16 of Directive 75/319/EEC.

2. Member States shall take all appropriate measures to ensure that operators holding the authorization referred to in paragraph 1 shall only make available scheduled substances of Table I of the Annex to operators who are themselves in possession of the authorization referred to in paragraph 1.

Article 5

Notification

1. Member States shall take, consistently with their own legal system, appropriate measures including the necessary legal protection of interested persons in connection with their own responsibility so as to encourage operators to immediately notify the competent authorities of any circumstances, such as unusual orders and transactions of scheduled substances, which indicate that such substances to be placed on the market or manufactured, as the case may be, are intended to be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

2. In addition to the measures to be taken under paragraph 1, Member States shall take, consistently with their own legal system, appropriate measures including the necessary legal protection of interested persons in connection with their own responsibility so as to encourage persons who suspect, as a result of information obtained by virtue of their professional activities, that scheduled substances which have been or are to be placed on the market or manufactured, as the case may be, are intended to be diverted for the illicit manufacture of a narcotic drug or psychotropic substance, to inform the competent authorities accordingly.

TITLE III

Measures of control

Article 6

Legal powers of competent authorities

1. In order to ensure the correct application of Articles 2, 4 and 5, Member States shall adopt, consistently with their own legal system, the measures necessary to allow the competent authorities :

   (a) to obtain information on any orders or transactions of scheduled substances;

   (b) to enter and search professional premises of operators and to obtain evidence of irregularities;

   (c) to seize any scheduled substance if there is sufficient evidence that such substance, which has been or is to be placed on the market or manufactured, as the case may be, is intended to be used in the illicit manufacture of a narcotic drug or psychotropic substance.

2. Without prejudice to the measures laid down in Article 4(1) and (2) and Article 6(1), the competent authorities of Member States may prohibit the placing on the market or manufacture, as the case may be, of scheduled substances, if there are reasonable grounds to believe that these substances are ultimately destined for the illicit manufacture of narcotic drugs or psychotropic substances.

TITLE IV

Administrative cooperation

Article 7

For the purposes of applying this Directive, the provisions of Regulation (EEC) No 1468/81 shall be applicable **mutatis mutandis**, in particular the provisions on confidentiality. Each Member State shall communicate to the other Member States and to the Commission particulars of the competent authorities appointed to act as correspondents within the meaning of Article 2(2) of Regulation (EEC) No 1468/81.

TITLE V

Final provisions

Article 8

Member States shall determine the sanctions to be applied for the infringement of the provisions of this Directive. The penalties shall be sufficient to promote compliance with those provisions.

Article 9

1. The competent authorities of Member States shall annually communicate to the Commission :

   - the amounts of scheduled substances seized and, when known, their origin;
   - any substance not included in the Annex which is identified as having been used in illicit manufacture of narcotic drugs or psychotropic substances, and which is deemed to be sufficiently significant to be brought to the attention of the International Narcotics Control Board;

- methods of diversion and illicit manufacture.
- the nature of processing equipment seized and where known, its origin.

2. The Commission, on the basis of the communications made pursuant to paragraph 1, shall, in consultation with Member States, draw up an annual report to be submitted to the International Narcotics Control Board.

Article 10

Member States shall adopt all the provisions necessary to comply with this Directive before 1 July 1991. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, For the Council

ANNEX

TABLE I	CAS Number	EINECS Number
Ephedrine	299-42-3	206-080-5
Ergometrine	60-79-7	200-485-0
Ergotamine	113-15-5	204-023-9
Lysergic acid	82-58-6	201-431-9
1-phenyl-2-propanone	103-79-7	203-144-4
Pseudoephedrine	90-82-4	202-018-6

TABLE II	CAS Number	EINECS Number
Acetic Anhydride	108-24-7	203-564-8
Acetone	67-64-1	200-662-2
Anthranilic acid	118-92-3	204-287-5
Ethyl ether	60-29-7	200-467-2
Phenylacetic acid	103-82-2	203-148-6
Piperidine	110-89-4	203-813-0

The salts of the substances listed in these tables whenever the existence of such salts is possible

TABLE III

	Threshold
Acetic Anhydride	1 litre
Acetone	1 litre
Anthranilic acid and its salts	100 grams
Ethyl ether	1 litre
Phenylacetic acid and its salts	200 grams
Piperdine and its salts	0,25 litre

Financial Statement

In respect of the proposal for a directive on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

1. Budget headings

N° A 130 Mission expenses
N° A 250 Meetings in general

2. Legal basis

Art 100 A of the EEC Treaty.

3. Description of the action

3.1. General objectives

Implementation of common measures on the monitoring and control of certain chemical products in order to prevent their diversion to illicit drug manufacture.

3.2. Specific objectives

a) Introduction of a system of monitoring through specific documentation requirements on all but small retail transactions

b) an extention of the existing system of pharmaceutical authorization to products of Annex Table I

c) to fulfil periodic reporting requirements towards the competent bodies of the UN.

4. Reasons for the action

To fulfil the standard requirements on precursor monitoring that are contained in Art. 12 of UN convention. Community has to enact legislation of the internal aspects of precursor monitoring to complement the legislation already proposed for external trade and at the same time to avoid Member States taking individual legislation incompatible with the objectives of the Single Market.

5. Financial Impact

5.1. General

The main financial impact of these proposals will fall in the following areas :

- the periodic organisation of meetings with Member States' experts in order to continually monitor the correct working of the system
- the set-up, at Commission level, of a management structure ensuring liason with Member States, third countries and competent international organisations, in particular the UN and concerned industry associations
- drawing up guidelines (on labelling, on good distribution practice, on the treatment of mixtures, extention to other precursor chemicals) and report to the competent bodies of the UN.

5.2. Specific financial impact

a) Staff

The staffing requirements for carrying out the specific tasks described above are calculated as follows for the estimation of the expenses of personnel for Part A of the Budget

- from 1991 : 1 assistant (B5)
- from 1992 - 93 : 1 administrator (A7)
  1 secretary (C5)

The staffing requirements shown above must be met either by internal redeployment or under the budgetary procedure for the relevant years, in the context of the Commission decision on the programmation of resources.

The specific tasks to be performed include :

- collection, circulation and management of the information supplied by Member States and industry associations

- drawing up of guidelines with regard to

  . the labelling, particularly of mixtures
  . good distribution practice
  . extending the list of precursor chemicals, mixtures and processing equipment, requiring special monitoring

- drawing up of a report on the quantities and origin of precursor chemicals and equipment seized to the competent UN bodies.

Estimation of the attribution of costs of personnel to part A of the budget is as follows :

76.000 ecu in 1991
228.000 ecu in 1992 and 1993

b) Allowance for additional meetings :

A 250
Two meetings per year of Member States' experts

1991	ECU	18.000
1992	ECU	18.000
1993	ECU	18.000
TOTAL	ECU	54.000

c) Allowance for

Missions (A 130)

1991	ECU	6.000
1992	ECU	6.000
1993	ECU	6.000
TOTAL	ECU	18.000

Competitiveness and employment impact statement

Proposal for a
Council Directive (EEC)

on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances

I. What is the main reason for introducing the measures ?

The general objective is to comply with international obligations resulting from Art. 12 of the 1988 UN Convention against Illicit Traffic of Narcotic Drugs and Psychotropic Substances signed by the Community on 8 June 1989. The specific purpose of the proposal is to prevent the diversion of precursor chemicals to illicit manufacture of drugs by establishing a system of monitoring of all transactions except minor quantities sold at retail level in such chemicals. For the most sensitive chemicals of Table I, a system of authorization to manufacture and distribution is foreseen.

II. Features of the business in question

The measures apply to chemical and pharmaceutical companies as well as traders, dealers and brokers involved in the marketing and distribution aspects.

III. What direct obligations does this measure impose on business ?

Economic operators concerned with precursor chemicals must keep for at least 2 calendar years from date of transaction readily available commercial records. Furthermore those involved with substances in Table I are required to be in possession of an authorization accorded to pharmaceutical enterprises.

Since the overwhelming proportion of transactions related to Table I substance is in any case by and between pharmaceutical enterprises this would not impose in general a new obligation but an extention of the existing system.

IV. What indirect obligations are local authorities likely to impose on business ?

None foreseen

V. Are there any special measures in respects of SMEs ?

No

VI. What is the likely effect on

a) Competitiviness of business ?
None

b) employment ?
None

VII. Have both sides of industry be consulted on the proposals ?

Following interested parties were consulted :

- associations of chemical industry
- associations of pharmaceutical industry
- associations of chemical traders

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