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THE PROBLEM OF SYNTHETIC NARCOTIC DRUGS

Compilation of the Views of Governments on the Use and Control of Synthetic Narcotic Drugs transmitted in accordance with resolution 505 C (XVI) of the Economic and Social Council

Note by the Secretary-General

1. The Economic and Social Council, at its sixteenth session, adopted a resolution on the problem of synthetic drugs (resolution 505 C (XVI)) reading, in part, as follows:

The Economic and Social Council,

. . . .

2. <u>Invites</u> the governments represented on the Commission on Narcotic Drugs and those of other important drug-manufacturing countries to furnish the Secretariat with such information on the following subjects as they may be able to provide:

(a) The question of the extent to which synthetic analgesics in general and synthetic opium alkaloids in particular are replacing or are likely to replace in the future natural narcotics made from opium and from poppy straw;

 (\underline{b}) The question whether the manufacture of synthetic drugs is desirable only when it presents economic or therapeutic advantages or whether such manufacture is desirable even where no such advantages exist;

(c) Their view on the provisional measures referred to in part II, section 2 of document E/CN.7/259/Rev.1 and on the applicability or inapplicability of the control measures

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referred to in part III: $*^{1/2}$

(d) The question whether, having regard on the one hand to the control problems involved, and on the other hand to the relevant economic and therapeutic considerations, it is desirable:

(i) to prohibit the use of synthetic drugs, or

(ii) to limit their number:

<u>Requests</u> the Secretariat to prepare compilations of the information so obtained and to submit them to the Commission for its consideration.
 The Secretary-General, by circular note C.N.114.1953.NARCOTICS of
 November 1953, transmitted the text of resolution 505 C (XVI) to the governments concerned and invited the governments to furnish him with the information sought by the Council. The circular note was addressed to the following governments:

(a) Members of the Commission

Canada	Netherlands $\frac{2}{}$
China	Peru
Egypt	Poland
France	Turkey
$Greece \frac{1}{}$	Union of Soviet Socialist Republics
India	United Kingdom
Iran	United States of America
Mexico	Yugoslavia
The following other	States listed as "manufacturing States" in

article 21 of the Opium Protocol: $\frac{3}{2}$

Belgium	Italy
Federal Republic	Japan
of Germany	Switzerland

^{*1/} Since Parts II and III of document E/CN.7/259/Rev.1 dealt with control measures as they had been proposed historically, at different times and by different authorities, the questions involved in those measures were consolidated in the interests of simplification and avoidance of duplication for the purposes of the questionnaire enclosed with circular note C.N.114.1953.NARCOTICS.

- 1/ Newly-elected Member
- 2/ Outgoing Member

(b)

3/ Protocol for Limiting and Regulating the Cultivation of the Poppy Plant, the Production of, International and Wholesale Trade in, and Use of Cpium, signed at New York, 23 June 1953.

3. By 8 March 1954, replies had been received from the following governments:

Belgium	Italy
Canada	Italy, for the Trust Territory of Somaliland
China	under Italian Administration
Egypt	Japan
France	Mexico
Federal Republic of Germany Greece ¹ /	Netherlands 2
	Switzerland
	United Kingdom
	United States of America
	Yugoslavia

4. The Secretary-General has the honour to submit to the Commission on Narcotic Drugs the views of the above-named governments on the use and control of synthetic narcotic drugs, together with the text of the questions submitted to the governments in circular note C.N.114.1953.NARCOTICS.

(A) The question of the extent to which synthetic analgesics
in general and synthetic opium alkaloids in particular are
replacing, or are likely to replace in the future, natural
narcotics made from opium and from poppy straw:

Belgium:

/Original text: French/

With the exception of pethidine, synthetic narcotic drugs were not subject to control in Belgium until November 1951 and no statistics regarding their use were therefore compiled until 1952.

It is not yet possible to determine the extent to which synthetic narcotic drugs other than pethidine are replacing natural narcotics.

1/ The permanent representative of Greece to the United Nations, in transmitting the observations of his Government, reserved himself the right to transmit any additional information that he might receive from his Government.

2/ The Government of the Netherlands concluded its observations with the following statement: "The above reply is based only on experiences in the Netherlands. In case the replies of other countries, or a change in the situation in the field of synthetic narcotic drugs would warrant it, the Netherlands Government reserve their right to reconsider the above".

In the case of pethidine, consumption in Belgium amounted to 42, 35 and 33 kilogrammes respectively in 1950, 1951 and 1952.

These figures appear to indicate that the tendency to use synthetic narcotics is not increasing. It is plainly still dependent on the extent to which medical practitioners recommend the use of such analgesics.

In the Belgian Congo, where imports of morphine have decreased by one kilogramme a year since 1950 despite the expansion of the hospital system, the consumption of synthetic drugs is increasing and seems likely to halve that of morphine.

Canada:

Up until the present time synthetic opium alkaloids other than papaverine have not been available in Canada. Moreover at the present time it would appear there is little if any possibility in the immediate future of the natural opium alkaloids being replaced by the synthetic opium alkaloids, taking into consideration cost factors and difficulties in the procedure of synthesizing. In spite of this, synthetic analgesics with addiction properties, and particularly pethidine, have been widely accepted and utilized by physicians as analgesics. As a matter of fact the routine use of the drug pethidine in preand post-operative procedures, as well as in connexion with obstetrical cases, is being widely followed by an ever-increasing number of physicians. This situation has resulted of course in a decrease The use of morphine and heroin. Present indications are that this trend will continue and our consumption of pethidine will reach even higher levels with a decrease in Canada's consumption of some optum alkaloids, particularly morphine. Factors closely related in this changing condition are advancement in medical science and medical thinking, rapid growth in population, and changing economic conditions.

China:

/Original text: Chinese7

The extent to which synthetic analgesics in general and synthetic opium alkaloids in particular are replacing, or are likely to replace in the future, natural narcotics made from opium and from poppy straw will depend upon further development of the economic and therapeutic desirabilities of the former as

against the latter. Since very little synthetic narcotics have been used and none of them has been manufactured in the Republic of China, no comprehensive information can be provided at present on this subject.

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Egypt:

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/Original text: French7

We are of the opinion that in certain cases synthetic analgesics should gradually be substituted for natural narcotics made from opium and from poppy straw although there is not yet any product which can effectively replace morphine in treatment. Natural narcotics may in future be replaced by synthetic analgesics.

France:

/Original text: French7

Synthetic analgesics in general are likely to replace morphine, but none of those at present in use could replace heroin, in so far as it is still used, or codeine or dionine.

The variety of factors involved makes it difficult to predict future developments. Furthermore, such replacement may depend largely on decisions taken by Governments.

Federal Republic of Germany:

/Original text: German7

... in the future the natural narcotics made from opium or poppy straw will to a large extent be replaced by synthetic substances. Developments in pharmaceutical chemistry will undoubtedly tend towards the production of more synthetic analgesics.

Greece:

(No comment).

Italy:

/Original text: Italian7

Synthetic analgesics in general and synthetic opium alkaloids in particular have not thus far been used in Italy in such quantities as to cause an appreciable decline in the consumption of natural narcotics.

There are two main reasons for this, namely:

(1) All the synthetic analgesics which have come into therapeutic use in recent years are generally regarded with some diffidence by medical practitioners, who, in addition to being accustomed to the use of natural narcotics, regard the synthetic drugs as novelties to be prescribed with caution because they have not yet been sufficiently tested from the point of view of their therapeutic effects and toxicity;

(2) all synthetic analgesics, including synthetic opium alkaloids, are prepared or imported and sold in Italy in the form of proprietary medicines at prices considerably higher than those of preparations with a natural alkaloid base. The latter are sold in Italy in the form of galenical preparations and cost less than the proprietary medicines, which, as is known, are burdened by higher production costs and by general research and advertising expenses.

Italy (Trust Territory of Somaliland under Italian Administration):

/Original text: Italian/

There is not sufficient evidence for determining whether and to what extent synthetic analgesics and synthetic drugs are likely to replace the natural narcotics currently in use.

Japan:

Some scientists are making researches into synthetic analgesics, such as methadone and the like. In the light of the fact that 3-dimethylamino-1, l-di-(2-thienyl)-l-butene, decided recently by the World Health Organization as a drug which falls under the regime laid down in the 1931 Convention for the drugs specified in article 1, paragraph 2, Group 1 of that Convention, is used in Japan as analgesic, it may not be altogether impossible that some synthetic drugs which will replace natural narcotics will appear in the future.

Mexico:

/Original text: Spanish7

To date, the only synthetic analgesics used by the Mexican Medical Corps have been the products known as pethidine and methadone, the latter to a much lesser extent than the former, and the following alkaloids derived from the opium poppy: morphine, dihydrocodeinone, methylmorphine, ethylmorphine and

paracodine. It is estimated that the first group accounts for about 50 per cent of the drugs used, and that the other 50 per cent is accounted for by the second group; these percentages may be expected to vary in future.

Netherlands:

It must be assumed that the natural narcotic drugs will for some considerable time to come maintain their importance in the medical field and the Netherlands Government feels therefore that, although the possibility should not be ruled out that synthetic drugs will replace natural narcotics in the future, government policy need not be based yet on such a development.

Switzerland:

/Original text: French/

The question refers not only to synthetic opium alkaloids, but to synthetic analgesics in general. But not all synthetic analgesics are narcotic drugs and we have no way of controlling or estimating the extent to which non-narcotic analgesics are replacing or are likely to replace natural narcotics. Moreover, the question whether synthetic narcotic drugs are likely in the future to replace natural narcotics is contingent upon so many therapeutic, economic, purely local and even ephemeral factors that it is impossible to give a reasonable estimate.

United Kingdom:

In the opinion of Her Majesty's Government no conclusion can be drawn from the information available at the present time as to the extent to which synthetic analgesics in general, and synthetic opium alkaloids in particular, are replacing natural narcotics made from opium and from poppy straw, nor is it possible to forecast the extent to which this is likely to happen in the future. Statistics published by the Permanent Central Opium Board indicate a considerable increase in the use of most types of narcotic drugs, both natural and synthetic, and the position at the present time seems to be that synthetic drugs are not so much replacing opiates as supplementing them. There are a few cases in which replacement can be said to have occurred: thus pethidine is now generally used in place of tincture of opium in cases of child-birth (though here there is not merely replacement but greatly increased use); the use of methadone in place of morphine is occurring to some extent; and cocaine has largely been replaced by synthetic substitutes for certain purposes.

United States of America:

Of the synthetic analgesics which have been made subject to control under the narcotic laws of the United States, only four (Pethidine, locally known as meperidine, also Demerol; Methadone, local trade name Dolophine; alphaprodine, locally known as Nisentil; and Racemorphan, locally known as Dromoran) have been manufactured and distributed for nation-wide medical use. Total sales of pethidine (Demerol) have increased progressively and appreciably since 1945; there seems to be a falling-off in total sales of Methadone, of which the peak distribution was not significantly large; and total sales of alphaprodine (Nisentil) and of racemorphan (Dromoran) have not yet reached an appreciable extent, although it must be recognized that these two drugs have been introduced into medical channels comparatively recently. On the other hand, total sales of morphine for use as such (i.e., not for conversion into codeine) have rather sharply decreased over the same period although, considering for one factor the normal annual increments to general population, an appropriately progressive increase in total sales of morphine for use as such might have been expected. Therefore, there is some basis for the opinion that, as far as this country is concerned, the synthetic analgesics have to some extent replaced for analgesic use the natural narcotics (at least, morphine) made from opium and, without attempting a comprehensive analysis of all relevant factors, it is roughly estimated that this replacement may approach at present a degree of twenty-five per cent. On the question of the extent of future replacement of the natural narcotics for analgesic use by synthetic analgesics, no opinion is expressed, but scientists have repeatedly expressed the view that all uses of morphine, codeine and other products and compounds derived from opium for symptomatic relief may be replaced adequately by synthetic substances now known. (Minutes of Seventh Meeting, Committee on Drug Addiction and Narcotics of the National Research Council, 15 January 1951; confirmed by an opinion of same Committee in July, 1953.) Much depends, of course, upon whether the medical profession shall find it therapeutically advantageous to substitute one or more of the synthetic analgesics now available or to be available for one of the natural narcotics.

On the question of the extent of replacement of natural narcotics made from opium by synthetic opium alkaloids, it is understood that, at present, there are two drugs that fall within the latter category, synthetic papaverine and synthetic

morphine. There has been, of course, a considerable increase in the production of synthetic papaverine which has not replaced but has been sold for medical purposes in addition to those quantities produced from opium. The increase in production of synthetic papaverine is relatively unimportant, however, as this drug when it occurs in opium is one of the isoquinoline alkaloids of opium and has not been found to possess addiction liability nor, so far as is known, can it be converted into a drug possessing addiction liability. Synthetic morphine, while producible scientifically, is not commercially practicable, and, because of the difficulties involved, is not likely to be in the foreseeable future. However, it should be pointed out that racemorphan has been proven to represent structurally a partial synthesis of morphine which results in a product of like properties, fully capable of doing medically all that morphine does and, therefore, potentially a substitute for morphine, depending only upon general medical acceptance.

Yugoslavia:

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Synthetic analgesics, and especially synthetic opium alkaloids, replace only to a certain extent natural narcotics made from opium, morphine and codeine. In other indications these synthetic drugs which replace morphine as an analgesic are less suitable than morphine (i.e., when applied for general or local anaesthesia), owing to the lack of hypnotical effect and because the other effects of this alkaloid are far weaker, for example its effect upon the intestines. However, synthetic drugs in general and, synthetic opium alkaloids in particular, have the same, and sometimes even stronger, addiction-producing properties.

Synthetic opium alkaloids which replace codeine for the purpose of soothing cough, usually have stronger addiction-producing properties than this alkaloid.

It is difficult to say whether synthetic drugs will be able to replace completely morphine and codeine in all their modifications in the future, because those known up to the present, in spite of certain advantages, possess the same or even greater deficiencies than the natural alkaloids, and in particular addiction-producing properties. (B) Its views on the question whether the manufacture of synthetic drugs is desirable only when it presents economic or therapeutic advantages, or whether such manufacture is desirable even where no such advantages exist;

Belgium:

/Original text: French/

In view of the difficulties involved in controlling production, the manufacture of new synthetic drugs is desirable only in so far as these present appreciable economic or therapeutic advantages.

Canada:

Canada has not permitted up until the present time the manufacture of narcotic drugs, natural or otherwise, and therefore comments on this particular question are being withheld.

China:

/Original text: Chinese7

In view of the great danger which may result from the difficulties in controlling synthetic narcotics it is considered that the manufacture of synthetic narcotics is desirable only when it presents therapeutic advantages.

Egypt:

/Original text: French/

The manufacture of synthetic drugs is desirable only when it presents economic or therapeutic advantages.

France:

/Original text: French/

It is the French Government's view that the manufacture of synthetic drugs is desirable only when it presents therapeutic advantages.

In any event, economic considerations must be outweighed by the dangerous nature of such products. It is considered, however, that in the event of a possible shortage of opium and its derivatives a strictly limited production of synthetic drugs might be permitted.

Federal Republic of Germany:

<u>/</u>Original text: Germa<u>n</u>/

The manufacture of synthetic drugs seems desirable only when therapeutic

advantages may be expected. Economic advantages should be given weight in this connexion only if the new drug has equal therapeutic value and is cheaper to produce than the product it is intended to replace.

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Greece:

/Original text: French7

The manufacture of synthetic drugs would be desirable only if it presented economic or therapeutic advantages.

Italy:

/Original text: Italian/

The manufacture of synthetic drugs is desirable when it presents evident economic or therapeutic advantages, and even more so when it presents both kinds of advantages at the same time. Actually, even if a synthetic drug should present merely an economic advantage, the medical practitioners would inevitably be inclined to use natural drugs.

Italy (Trust Territory of Somaliland under Italian Administration):

/Original text: Italian/

The manufacture and distribution of synthetic drugs generally, apart from the possible economic and therapeutic advantages, should also be considered in relation to the possibility of greater control.

Japan:

The manufacture of synthetic drugs is desirable only when they have more therapeutical advantages and less addiction-producing properties as compared with natural narcotics.

Mexico

/Original text: Spanish/

The manufacture of synthetic drugs would be desirable, particularly if they should possess effective therapeutic and no addiction-producing properties.

Netherlands:

The manufacture of synthetic narcotic drugs is in general desirable only when it presents economic and therapeutic advantages. As it cannot be foreseen, when developing a new medicine, whether the manufacture of this medicine will present these advantages, its manufacture and the clinical research should not be hampered.

Switzerland:

/Original text: French/

The manufacture of synthetic drugs is desirable if the substances involved have medical or scientific value. On the other hand, it is not necessary that they should offer, when they are introduced, some economic or therapeutic advantages which apparently make them superior to the natural or synthetic narcotic drugs already on the market. It is a known fact that even after a very thorough clinical study, it is impossible to demonstrate finally and absolutely all the qualities, advantages and possible applications of a new product. Generally, these are not discovered until later, when the use of the products has become more widespread, and an excessively restrictive policy towards the introduction of new synthetic drugs might lead to the unfair rejection of very useful medicaments.

United Kingdom:

This question appears to be based on the assumption that it is possible to say at a given time that a particular drug does not present (and presumably cannot be expected to present in the future) any economic or therapeutic advantage: This assumption is not borne out by experience in the United Kingdom. The economic or therapeutic advantages of a drug cannot be even provisionally assessed until it has been in use on an appreciable scale for some time and even then opinions are apt to be modified in the light of further experience. This has been the case with pethidine; its special value in child-birth was discovered after considerable use of the drug as a general analgesic and other uses are still being developed.

If the question relates to the continued production of synthetic drugs which sufficient experience has demonstrated to have neither economic nor therapeutic advantage, it is academic, since in such circumstances it is unlikely that manufacturers will persist in the production of drugs for which there is no effective demand.

United States of America:

As a general principle, the United States would not favour the manufacture for general medical distribution of a synthetic analgesic drug which was shown to possess addiction liability and which did not have economic, and particularly

therapeutic, advantages over other analgesics already in use. It has been noted that, unless preliminary clinical studies of a new synthetic analgesic drug demonstrate that it possesses some therapeutic advantages over other drugs of this type already in use, the producer of the new drug will not seek permission to manufacture and distribute the drug for medical use. It is expensive to introduce a new drug to the medical profession as the manufacturer must communicate to the thousands of physicians the alleged merits of the drug and very often this is done by means of visits to the physicians by trained representatives of the manufacturer. The manufacturer knows that if he does not convince a substantial number of physicians as to the therapeutic advantages of the new drug and if the trial of the new drug in medical practice by those physicians does not substantiate the claim of therapeutical advantages, he will lose his entire investment in the new drug not to speak of damage to his prestige among physicians. Most of the synthetic analgesics which have been subjected to control under the narcotic laws of the United States because they possess addiction liability have not been introduced or sought to be introduced into medical supply channels by the producers; it is fair to assume that the producers have not attempted to develop a medical market for these particular drugs because the producers are convinced that they do not possess any sufficient therapeutic advantage.

Yugoslavia:

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The manufacture of synthetic drugs is desirable only when these drugs present therapeutic advantages over natural narcotic alkaloids.

(C) Its views on the measures referred to in Part II, Section 2 of document E/CN.7/259/Rev.1, that is, provisional measures pending a decision on international control of a drug:

(1) In view of the inherent danger in addictionproducing synthetic drugs not being under control during the relatively long time necessarily required by the procedure by which such drugs are placed under international control, whether any obligation with regard to synthetic drugs should be placed on States prior to a decision of the competent international organ on the question of control, i.e., in most cases, at an earlier stage than at present; or whether the existing arrangements are sufficient.1/

Belgium:

/Original text: French/

The provisional measures referred to in document E/CN.7/259 would be capable of removing the inherent danger in synthetic drugs not being under control during the relatively long time between the date of their appearance and that on which they are placed under international control by decision of the World Health Organization.

Pending the application of international control, steps should be taken to prevent exports not covered by an import certificate issued in advance (See also below, (2).

Canada:

It is considered the present method of bringing synthetic narcotics under world-wide narcotic control is sufficient, providing adequate national control

1/ At present Governments are under no obligation to place a new synthetic narcotic drug under control whatever their views on its dangers (although they are of course free to do so if they desire) until the World Health Organization has decided that the drug should be subjected to one form or another of control or until the Commission on Narcotic Drugs of the Economic and Social Council has decided that Governments should provisionally control the drug pending the decision of the World Health Organization: Articles 1 and 2 of the Protocol of 1948 bringing under international control drugs outside the scope of the Convention of 13 July 1931 for limiting the manufacture and regulating the distribution of Narcotic Drugs, as amended by the Protocol signed at Lake Success on 11 December 1946. For drugs derived from opium and coca leaves see article 11 of the Convention of 13 July 1931 and article 14 (d) of the International Opium Convention of 23 January 1912.

is implemented in each country when a drug is discovered or appears with the possibility of addiction properties, for example national control could both prohibit the export from or the import into any country until it had been decided by the international means available the new drug had addiction properties or otherwise. In so far as Canada is concerned, immediate steps have always been taken to control any drug suspected of having addiction properties until it was or was not established by competent authorities as coming within the category of addiction-producing drugs. In some instances steps have been taken to prohibit supplies of a drug suspected of being a narcotic entering the country. (See also below, (D)(1)).

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China:

/Original text: Chinese/

The Government of the Republic of China favours the view that the obligation with regard to synthetic drugs should be placed on the States prior to a decision of the competent international control organ on the question of control.

Egypt:

/Original text: French/

Certain obligations with regard to synthetic drugs should be placed on governments before the competent international body has decided on the question of control.

France:

/Original text: French/

In theory, every synthetic drug should undoubtedly be placed under control as soon as it appears, in accordance with the intention underlying the drafting of the International Conventions on narcotic drugs and all national regulations.

It is obvious, however, that the immediate imposition of control involves certain practical problems, the solution of which largely depends on the different national regulations in regard to medicaments.

In France, where no new medicament may be made available to the public without a certificate of approval from the Ministry of Public Health, it can be ascertained whether or not a new product is a synthetic narcotic before it is used.

This procedure enables the French Government to list such a product in schedule B of poisonous substances before release to the public and thus to bring

it under the national and international provisions concerning narcotic drugs. This, clearly, is the ideal solution.

At the other end of the scale are countries which do not place such products under international and national control until the procedure laid down in the 1948 Protocol has been fully applied.

It must be recognized that there is no means of expediting that procedure.

For the last few years, the United Nations Secretariat has always transmitted communications received from different Governments to the Contracting Parties to the International Conventions, so that the aforementioned procedure may be put into effect. Governments have thus been informed as promptly as the competent international agencies.

This excellent system should make it possible for all the Contracting Parties to the International Conventions to take protective measures in regard to the products in question.

This would appear to be the appropriate course, since it is in the interest of all Parties to prevent the use of a narcotic drug from developing free of all control.

Federal Republic of Germany:

/Original text: German/

In view of the possibilities for the rapid and practically unlimited manufacture of such synthetic products, the existing agreements are... no longer adequate to prevent the dangers inherent in addiction-producing synthetic drugs. States where such drugs are placed on the market should be required to apply provisional control measures until international control comes into effect.

Greece:

(See below, (C)(2)).

Italy:

(See below, (C)(2)).

Italy (Trust Territory of Somaliland under Italian Administration):

/Original text: Italian/

Until these products are placed under international control, the Administering Authority of this Trust Territory will control the import (if any) and, generally, the use of synthetic drugs.

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Until practical arrangements for international control are worked out satisfactorily, it would be desirable to elaborate uniform transitional measures in order to avoid the possible indiscriminate distribution of products which are little known and, therefore, more dangerous.

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Japan:

The obligation to control should be placed on States prior to a decision under the existing convention.

Mexico:

/Original text: Spanish/

Any provisional measures to be put into effect should, above all, be subject to control in accordance with the 1925 and 1931 Conventions, and appropriate arrangements should be made to place that control in the hands of a competent body; in the meantime, the established measures should remain in force.

Netherlands:

The international control as at present existing is considered to be sufficient because a new drug could for a considerable period be a danger to public health in the country of manufacture only and not until much later be an international danger. This is subject however, to the observations under C.2.

Switzerland:

/Original text: French/

The provisional measures to be taken on the international level with respect to new products obtained from the phenanthrene alkaloids of opium or the ecgonine alkaloids of the coca leaf, referred to in article 11 of the Convention of 13 July 1931 and in article 14 of the International Opium Convention of 23 January 1912, are considered sufficient.

With regard to the provision of the 1948 Protocol bringing under international control drugs outside the scope of the earlier Conventions, we should like to describe how we have filled the gap to which your question refers, on the national level. Article 7 of the Federal Narcotic Drugs Act of 3 October 1951 provides that all substances and preparations chemically related to known narcotic drugs or presumably capable of producing similar effects are subject to restrictions pending the production of the evidence necessary for determining the nature of the substance. The article reads:

> "Substances and preparations not narcotic drugs as defined in article 2 but chemically related thereto and presumably capable of producing similar effects may be manufactured, imported for commercial purposes or used only by express leave of and subject to the conditions laid down by the Federal Public Health Service.

"Such leave shall be effective until the Federal Public Health Service determines whether the substance or preparation shall or shall not be deemed to be a narcotic drug."

We think that this provision may be considered sufficient for the transitional period.

This reply makes it unnecessary for us to state our position regarding points C(2) and C(3).

United Kingdom:

Her Majesty's Government recognize that the international machinery for placing new addiction-producing synthetic drugs under international control necessarily moves somewhat slowly and that it is at least possible that the delay in imposing control may involve dangers. In the view of Her Majesty's Government, however, the primary responsibility in this matter rests with the Governments of manufacturing countries, and it is indeed usually on the initiative of the Governments of manufacturing countries that the question of imposing international control on a new synthetic drug is brought up. If there is strong reason to suspect that a new drug may be addiction-producing the Government of the manufacturing country has a moral responsibility to ensure that the use of and trade in the drug is subject to adequate control pending a final decision on the question whether the drug is in fact addiction-producing and Her Majesty's Government doubts whether experience has shown that there has been any serious failure in this responsibility. The difficulty in the way of placing definite international obligations on Governments in this respect is that of defining the synthetic drugs to which provisional control measures should apply. Unless and until a satisfactory definition can be found it may be preferable to proceed by way of recommendation in respect of any type of drug which is known to be sufficiently suspect to justify the application of provisional control, such as the recommendation made in Economic and Social Council Resolution 246 G (IX) in regard to the chemical analogues of such drugs as dolantine, (pethidine) and

amidone (methadone). Her Majesty's Government can only say at the present stage that they will be prepared to give consideration to any proposals for provisional international control which can be shown to be practical and desirable.

United States of America:

After a new synthetic drug is discovered and found to have analgesic properties comparable, for instance, to those of morphine, it becomes necessary to determine by appropriate testing procedure whether the new drug also has addiction properties similar to those of morphine. It will take some time to complete this procedure and to make the determination, but when it is finally determined that the drug has addiction liability, in the opinion of the appropriate government authority of the State, that State should apply its regulatory narcotic controls to the new drug without unnecessary delay. Τn the United States, by statute, any drug found by the Secretary of the Treasury, after due notice and opportunity for public hearing, to have an addictionforming or addiction-sustaining liability similar to morphine or cocaine, and proclaimed by the President to have been so found by the Secretary, automatically becomes subject to the application of the narcotic laws of the United States. The finding by the Secretary is based upon scientific advice, and thirty days' public notice is given to afford any interested person an opportunity for a hearing with reference to the addiction liability of the drug. This plan is designed to apply the national narcotic controls to a new synthetic analgesic drug possessing addiction liability as promptly as possible after it is definitively determined that the drug does possess the described addiction liability.

Yugoslavia:

We consider it necessary that all states manufacturing synthetic analgesic drugs assume the obligation to subject these drugs to a control prior to a decision of the competent international organ on the question of control. (C) (2) If the existing arrangements are not considered sufficient, which of the following measures 1/ should be applied pending a decision of the competent international organ on the question of control:

> (a) Prohibition of the manufacture of, trade in and use of the drug (except in small amounts for scientific purposes) until it is found by the government concerned that the drug in question is either not addictionproducing or, although addiction-producing, represents an important therapeutical advance, in which latter case the regular narcotics régime would apply;

(b) <u>Regular narcotics control until it is found by</u> the government concerned that the drug is not addictionproducing;

(c) Prohibition of export pending the decision of the competent international organ on the question of control, and furthermore if the international organ decides to place the drugs under control, until legislation implementing this decision has been enacted by the exporting country;

(d) <u>Application of the import certificate and export</u> <u>authorization system as provided for in Chapter V of</u> the International Opium Convention of 19 February 1925.

(3) If any measures referred to under (2) appear desirable, to which synthetic drugs should they be applied:

(a) <u>Synthetic drugs which by their chemical structure</u> indicate probable addiction-producing properties; or,

- (b) <u>All analgesic synthetic drugs; or</u>,
- (c) All strongly analgesic drugs; or,
- (d) Any other type of drugs (to be specified). $^{2/}$
- $\underline{l}/$ The type of provisional measures will depend to a considerable extent on the type of permanent régime to be adopted under (D).
- 2/ Certain of the studies to be undertaken by the World Health Organization in consultation with the United Nations Secretariat (Economic and Social Council resolution 505 C (XVI), paragraph 1 (b) and (c) of the operative part) will be concerned with the practicability of such definitions.

Belgium:

/Original text: French/

(2) It seems clear that, under the existing arrangements, governments cannot be required to apply any of the measures mentioned.

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The measure referred to under (a), however, appears preferable to the others. (See also above, (C)(1)).

(3) This measure should be applied to synthetic drugs which by their chemical structure indicate probable addiction-producing properties, to all products having strongly analgesic properties, and to stimulating amines which unscrupulous firms induce the public to purchase, without medical advice and for other than therapeutic purposes, through advertising which trades upon the credulity of the public.

Canada:

(2) (a)(b)(c)(d) Answered in question (c)(1) above.

(3) (a) (b) (c) (d) It is considered complete control on a national level, even to the extent of limiting imports or exports of all potent new synthetic analgesics, should be initiated by countries until the recognized authority has ruled as to the addiction potentialities of the drugs.

China:

/Original text: Chinese/

(2) Prior to the decision of the international organ, the manufacture of, trade in, and use of the synthetic narcotic drugs (except in small amounts for scientific purposes) should be prohibited until it is found by the government concerned that the drug in question is either not addiction-producing or, although addiction-producing, represents an important therapeutic advance, in which latter case the regular narcotic regime would apply.

(3) Considering the difficulties of differentiating the analgesic from strongly analgesic drugs and of determining the addiction-producing properties by their chemical structures, the measures, therefore, should be applied to all analgesic synthetic drugs.

Egypt:

/Original text: French7

(2) Regular narcotics control should be applied until the Government concerned finds that the drug is not addiction-producing.

.(3) The measures should be applied to the following drugs:

(a) synthetic drugs which by their chemical structure indicate probable addiction-producing properties;

(b) derivatives of barbituric acid.

France:

/Original text: French/

(2) Having regard to the foregoing considerations (See above, (C)(1)) the questions under (2) may be answered as follows:

(a) Unless measures of prohibition are contemplated, it would appear difficult to forbid the manufacture of, trade in and use of such products;

(b) The application of regular narcotics control to such products, even on a provisional basis, serves to restrict their abuse;
(c) and (d) It appears essential to apply the international procedure for the import and export of narcotic drugs to such products as soon as they are notified to the Secretary-General of the United Nations. Steps must be taken to prevent a product from being freely exported from a country in which it is not treated as a narcotic drug to another in which it is so treated.

This has occurred on many occasions, in flagrant contravention of the spirit of the International Conventions.

.... In conclusion, it is the French Government's view that efforts should be made, on the basis of the 1948 Protocol, to convince the Contracting Parties that it is in their own interest to apply the national and international regulations concerning narcotic drugs on a provisional basis to every synthetic drug notified to the Secretary-General of the United Nations. In any event they should at once apply to such products the international procedure for external trade laid down in the Geneva Convention of 1925.

Lastly, no such product should be placed in circulation without a distinctive marking permitting its identification by the non-specialized services. (See also below, (D)(3)).

(3) Addiction-producing properties cannot be ascertained without physiological and clinical experiments. At the present stage of knowledge

therefore, it would seem difficult to establish a classification of synthetic products likely to produce addiction.

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Efforts should be made to induce all the Contracting Parties to notify the United Nations Secretariat as soon as possible of all products to which they consider the provisions of the 1948 Protocol to be applicable.

Federal Republic of Germany:

/Original text: German/

(2) (a) ... the presumption that a new drug is addictionproducing is not a sufficient ground for prohibiting the manufacture of, trade in and use of the drug.

(b) A government in whose territory a drug suspected of being addictionproducing is manufactured should, until it is determined whether the drug is addiction-producing or not, be required to ensure that in its territory the drug concerned may be supplied to consumers only against the prescription of a medical practitioner which must be renewed in each case.

(c) A general prohibition of export is not recommended.

(d) A government in whose territory a drug suspected of being addictionproducing is manufactured should, until it is determined whether the drug is addiction-producing or not, be required to inform the Secretary-General of the United Nations that the drug in question is presumed to be addiction-producing. This presumption would be brought to the attention of the Member States by the Secretary-General, and each State would be left free to decide whether it considered an import certificate necessary for the drug in question.

(3) The measures suggested under (2) should be applied to:

(a) Synthetic drugs which by their chemical structure indicate probable addiction-producing properties the existence of which has to some extent been confirmed by clinical observation.

The application of the measures referred to under (2) above to the drugs in sub-groups (b), (c) and (d) is not recommended.

Greece:

/Original text: French/

All new synthetic drugs which by their chemical structure are related to known analgesics should be placed under regular narcotics control until a

thorough investigation has established that they are not addiction-producing. The export of such synthetic drugs should be prohibited during that period.

Italy:

/Original text: Italian/

This Office¹/is of the opinion that it is not advisable to prohibit the manufacture and therapeutic use of new synthetic analgesics pending final settlement of the question whether or not they are addiction-producing, because it is difficult to decide in advance which substances are addiction-producing. Therefore, if a prohibition were imposed, substances with positive therapeutic effects but without addiction-producing properties might be barred from use.

This Office $\frac{1}{}$ accordingly believes that the use of such drugs should be allowed if they have first been placed under narcotic drugs control on the understanding that they will eventually be kept under or released from such control when the competent international organs have decided on the question of control.

With regard to the export of such drugs, this Office $\frac{1}{}$ considers that it would be better not to impose a prohibition, but to apply the import certificate and export authorization system as provided for in Chapter V of the International Opium Convention of 19 February 1925.

As to the synthetic analgesics to which the above-described restrictive measures should be applied, this Office $\frac{1}{}$ believes that attention should be given to all synthetic analgesics which by their chemical structure indicate probable addiction-producing properties.

Italy (Trust Territory of Somaliland under Italian Administration):

/Original text: Italian/

As control is recognized to be necessary, it is considered desirable that the measures referred to in point (d) (at present in effect in this Territory) should be applied; in other words, synthetic drugs should be subject to the control provided for in chapter V of the International Opium Convention of 19 February 1925 under the system of import certificates and export authorizations; as the adoption of control measures seems desirable, they should be applied as indicated in point 3 (b), in other words, to all products having an analgesic effect.

1/ The Office of the High Commissioner for Hygiene and Public Health.

Japan:

(2) Application of the import certificate and export authorization system as mentioned in (d). $\frac{1}{}$

(3) Of the synthetic analgesics mentioned in (b), those likely to have addiction-producing properties. $\frac{1}{}$

Mexico:

/Original text: Spanish7

Any new synthetic drug should be controlled as a narcotic drug until the Commission on Narcotic Drugs of the Economic and Social Council determines definitively that it is not addiction-producing, in which event the restrictions on its use would be removed and it could then be used freely.

Netherlands:

(2a) Every country should apply its regular narcotics regime to every new addiction-forming drug. Prohibition of the manufacture thereof is thus rendered unnecessary.

A government cannot undertake the responsibility to declare that one therapeutic drug obtains better results than another drug and on that basis forbid or allow new therapeutic drugs. Therefore the use of every new therapeutic drug should be tolerated as the use of every other new medicine. If any drug would show a marked danger however, it is desirable to have the authority to restrict further use of that medicine.

(2b) Before applying regular narcotics control the government should be convinced that a drug is addiction-forming and not - as the question assumes apply the control until it has been satisfactorily proved that the drug is not addiction-forming. Applying narcotics control to a number of drugs without knowing whether that serves any useful purpose would slacken the attention and diligence of the controlling officers, which in turn would endanger the close supervision of the strongly active drugs.

Drugs with unknown effect cannot be considered to constitute a social danger for a country with adequate administration, and therefore control of

^{1/} Note by the Secretariat: The context of the reply indicates that these measures are recommended by the Government of Japan.

those drugs does not seem justified from any point of view, including budgetary considerations. It goes without $\epsilon aying$ however, that the Netherlands Government gives its attention to all drugs which might possibly constitute a social danger, even if these drugs would not be covered by the regulations of any law.

(2c) There is no reason to subject new drugs - which might be of very innocent character - to more restrictions than necessary in order to ensure their use for therapeutic and scientific ends only. Absolute prohibition of export seems therefore undesirable. Although there are formal objections to applying legal precepts to drugs which are not yet covered by the laws concerned, these objections do not form any handicap in practice; it happens repeatedly that in international as well as in intra-national trade a drug is provisionally considered a narcotic drug even before the pertinent law has been amended. The control system is always being adapted to the actual situation and - as far as experience in the Netherlands is concerned - there is no reason to make detailed arrangements for new narcotic drugs pending their insertion in the laws and treaties.

(2d) The Netherlands Government deems it desirable to apply the import certificate and export authorization system without delay.

(3) It is not considered necessary to undertake far-flung international obligations based on speculative expectations as to the addiction-forming of groups of medicines because of their chemical and therapeutic properties only. If certain countries however, wish to classify these groups of medicines under their narcotic drug laws, it could be agreed internationally to honour this decision.

Switzerland:

(See above, (c)(1)).

United Kingdom:

(2)(a) and (b). If there is to be any change in the existing arrangements Her Majesty's Government in principle favour regulation rather than prohibition because in their opinion prohibition is likely to fetter medical and scientific

research and to impede developments which may be of great value to medicine. The exception for the manufacture of small amounts for scientific purposes would not be sufficient to secure the full exploration of the therapeutic properties and uses of a new drug. The regular narcotics control proposed in sub-paragraph (b) should be quite sufficient to deal with the possibility that the drug may have addiction-producing properties.

(2)(c) and (d) It is assumed that these are alternative to (a) and (b), since the import certificate and export authorization system would be one of the measures of "regular narcotics control" included in (b). Since in the view of Her Majesty's Government (see replies to D(1), (2) and (3)), the final form of control should be the regular narcotics control, they consider that provisional measures to control export should not go beyond the application of the import certificate and export authorization system.

(3) Her Majesty's Government prefer to defer final comment on this subparagraph until the result of the studies to be undertaken by the World Health Organization in consultation with the United Nations Secretariat about the practicability of such definition is known.

United States of America:

(2) In lieu of the measures stated under paragraphs (a) and (b) of this sub-heading, the United States is of the opinion that there should be prohibition of the manufacture of, trade in and use of a new synthetic analgesic drug (except in small amounts for scientific purposes) when the government concerned finds (1) that the drug possesses such a high degree of addiction liability as to outweigh any claimed merit as an analgesic (e.g. Ketobemidone), or (2) that the drug, although possessing some but not such significantly greater addiction liability, has no appreciable therapeutic advantage over analgesics already in use. If the competent international organ (which might be authorized to perform this additional function) should make the same finding it could be communicated to all the parties who would be bound by it; if the finding by the international organ were negative on both points, it would not be mandatory on the parties to apply the conditional prohibition but the original government concerned would not be bound to discontinue its conditional prohibition by reason of the decision of the international organ.

When the government concerned determines that a new synthetic analgesic drug possesses addiction liability it should prohibit the export of the drug (except for small amounts for scientific purposes under government supervision in the receiving country) pending the decision of the competent international organ on the question of control and, if the decision is to place the drug under control, until legislation implementing this decision has been enacted by the exporting country. In addition, in conformity with the procedure suggested in the preceding paragraph for findings with respect to two types of drugs, a country should be required or permitted to continue the export prohibition as to these two types, in accordance with an affirmative finding by the international organ or its own policy. Where any export is permitted, the import certificate and export authorization system should be applied.

(3) The measures suggested in paragraph (C)(2) above for consideration should apply to synthetic drugs shown to possess addiction liability, including application of the conditional prohibition against a synthetic drug shown to possess a relatively high degree of addiction liability. It is believed that there is not yet available sufficient scientific information on the basis of which a definite standard could be formulated equating a certain chemical structure to addiction liability properties. With respect to the question of applying narcotic control measures to all analgesic synthetic drugs - and certainly with respect to their application to all strongly analgesic drugs - it has been found possible in the United States to determine the addiction liability properties of such drugs within a reasonably short period, and where the drug is found to possess the requisite addiction liability the national controls can be applied without allowing significant opportunity for uncontrolled production and distribution during the intervening period.

Yugoslavia:

(2) Among the measures foreseen to be applied prior to the decision of the competent international organ on the question of control, we consider that the measure suggested sub (C) 2 (c) by the Secretary-General of the United Nations as the most convenient, i.e. the prohibition of the export

pending the decision of the competent international organ on the question of control, and, furthermore, if the international organ decides to place the drugs under control until legislation implementing the decision has been enacted by the exporting country.

(3) The measure r ferred to under (C) 2 (c) should be applied to all synthetic analgesic drugs (Part C (3) point (b) - Letter of the Secretary-General).

(D) Its views on the measures $\frac{1}{referred}$ to in part III of document E/CN.7/259/Rev.1:

(1) Whether the Government, having regard on the one hand to the control problems involved and, on the other hand to the relevant economic and therapeutic considerations, would favour the imposition of an obligation to prohibit the manufacture of, trade in, and use (except in small amounts for scientific purposes) of synthetic narcotic drugs as distinct from regulating these activities and, if so, whether such prohibition should apply:

(a) To all synthetic narcotic drugs; or,

(b) Only to all synthetic narcotic drugs developed in the future; or,

(c) Only to all synthetic narcotic drugs developed in the future which prove to be particularly dangerous, such as the drug ketobemidone.

(2) Whether any of the prohibitions referred to under(D) (1) should be:

(a) unconditional; or,

(b) subject to exception where the drug in question

(i) represents an important therapeutical advance; or,

(ii) has a distinct medical value which is not provided by existing narcotic drugs; or,

(c) subject to any other conditions or exceptions to be suggested.

Belgium:

/Original text: French/

(1) As indicated under (B), it would be desirable to prohibit the manufacture of, trade in and use of all new synthetic narcotic drugs.

i.e., definitive measures to be taken in pursuance of a decision by an international organ that the drug in question should be placed under control.

(2) An exception should be made only where a new product has definite therapeutic or scientific advantages over narcotic drugs already in use. Canada:

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(1) (a) (b) (c) Once again it is felt that problems of control over the synthetics could be solved and in no way unduly interfere with the progress of the advancement in medical science if adequate measures are taken on a national basis to control the distribution and use of drugs considered to have addiction liability within the boundaries of a country until a decision has been reached as to whether such drugs fall within the classification of narcotics.

(2) (a) (b) (c) Answered in D (l) above.

China:

/Original text: Chinese7

(1) The Government of the Republic of China favours the prohibition of the manufacture of, trade in and use of synthetic narcotic drugs (except in small amounts for scientific purposes) should apply to all synthetic narcotic drugs developed in the future which prove to be particularly dangerous.

(2) The prohibitions referred to (D) (1) should be unconditional. Egypt:

/Original text: French7

(1) Governments should not be required to prohibit the manufacture of, trade in, and use of synthetic narcotic drugs, for such a measure might hinder scientific and therapeutic progress.

(2) See the preceding paragraph.

France:

/Original text: French/

(1) and (2) So far as this part of the questionnaire is concerned, the French Government has made it a general rule to prohibit synthetic narcotic drugs, exceptions being made for products of greater therapeutic value than the natural alkaloids of opium and their derivatives. This appeared to be the reasonable course.

Only one such exception has been made in France, in the case of pethidine hydrochloride, in order to meet the requirements of national defence.

Federal Republic of Germany:

/Original text: German7

(1) The imposition of an obligation to prohibit the manufacture of, trade in, and use of synthetic narcotic drugs is favoured.

The prohibition:

(a) should not apply to all synthetic narcotic drugs;

(b) should not apply to all synthetic narcotic drugs developed in future, but

(c) should apply only to narcotic drugs, e.g. ketobemidone, which appear from comprehensive clinical tests to be particularly dangerous from the point of view of producing addiction.

(2) The prohibitions referred to under (D) (1) should:

not be unconditional, but

be subject to exceptions if the drug in question represents an important therapeutical advance.

No other conditions or exceptions are suggested.

Greece:

/Original text: French/

The synthetic manufacture of new analgesics should in no way be prohibited. Enormous progress has been achieved in this connexion in recent years, and in all probability synthetic chemistry will eventually succeed in producing a powerful analgesic, of the morphine type, for example, that is not addiction-producing.

Italy:

 $\sqrt[]{Original text: Italian]}$ This Office^{1/}would be in favour of international action to prohibit the manufacture of, trade in, and use of particularly dangerous synthetic drugs, such as ketobemidone. It does not consider any exceptions advisable in this case.

Italy (Trust Territory of Somaliland under Italian Administration):

/Original text: Italian7

With regard to the applicability of certain measures discussed in the part III of document E/CN.7/259/Rev.1, the problem has no practical relevance to Somaliland because the manufacture of synthetic drugs, or the processing of the basic substance from which they are derived, is not even a remote possibility.

i.e., the Office of the High Commissioner for Hygiene and Public Health.

Japan:

(1) At the present stage, the Government does not have to be placed under the obligation to prohibit the manufacture of, trade in, and use of synthetic narcotic drugs.

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(2) Not applicable.

Mexico:

(No comment).

Netherlands:

(1) It is considered neither possible nor desirable to prohibit the manufacture of and trade in synthetic narcotic drugs, some of which already show a large world consumption.

A decision to forbid new narcotic drugs in the future is also considered undesirable because valuable medicines might be among them.

Although the principle to prchibit for general use certain marcotic drugs if they are particularly dangerous could be acceptable, their use under special control should nevertheless remain possible.

In these general remarks, the question whether ketobemidone is one of these drugs has not been considered.

(2) When the development of a medicine would mean an important therapeutical improvement, its use for medical purposes should not be restricted. An unconditional prohibition would therefore be incorrect.

Switzerland:

/Original text: French/

(1) and (2) In keeping with our comments on points B and C, we do not consider it desirable to prohibit all synthetic narcotic drugs or even merely new synthetic narcotic drugs. Such a prohibition would be contrary to medical and clinical science. So long as an analgesic drug has a distinct medical value, and so long as it is lawfully distributed, according to the rules prescribed by statute, we feel there can be no justification for prohibiting it. In our view, the first step to be taken in preventing abuse is to apply strictly the control measures now in force.

Consequently, until further notice, it will have to be decided in each case whether the measures which may legally be taken with respect to any one of those products are sufficient.

United Kingdom:

(1) and (2) As stated above, Her Majesty's Government are opposed in principle to prohibition as a means of control of synthetic narcotic drugs. The suggestion that all synthetic narcotic drugs should be prohibited is so plainly at variance with current experience as to call for no further comment. It would seem equally unreasonable to impose a flat prohibition on all synthetic narcotic drugs developed in the future. It appears to Her Majesty's Government that if the extreme measure of prohibition is to be adopted at all, it should only be in respect of a particular drug which has already been found to be particularly dangerous, and then only after full inquiry into both the risks and the advantages, if any, of its use.

United States of America:

As stated under paragraph (C)(2), the United States suggests (1) and (2)that prohibition of the manufacture of, trade in and use of a new synthetic analgesic drug (except in small amounts for scientific purposes) - as distinguished from regulating such activities - be applied if the government concerned finds (1) that the drug possesses such a high degree of addiction liability as to outweigh any claimed merit as an analgesic or (2) that the drug, although possessing some but not significantly greater addiction liability, has no appreciable therapeutic advantages over analgesics already in use. The exception permits further scientific research with either of these two types of drugs which may result in the development of a chemically variant form which is found to possess therapeutic advantages with relatively low addiction liability; in this event, the chemically variant form would not be prohibited but subjected only to the usual regulatory regime. With respect to any synthetic analgesic drug which represents an important therapeutical advance or has a distinct medical value not provided by existing narcotic drugs, and which possesses addiction liability to a degree no greater than that of morphine, for instance, only the usual regulatory regime should apply. A difficult question might be presented

if there should be developed a new synthetic analgesic drug which was found to have a distinct medical value not provided by existing analgesics, and a relatively high degree of addiction liability. The determination whether manufacture, trade in, and use of such a drug should be permitted under regulatory control instead of conditionally prohibited ought to depend upon whether its additional medical value in therapeutic use was deemed of sufficient importance to justify acceptance of the additional risk of spreading drug addiction, incidental to the high degree of addiction liability of the drug. The determination should be made by qualified experts, of course, who would require some time to give most careful consideration to all relevant factors before reaching a decision; pending this decision, the manufacture, trade in and use of the drug (except for scientific purposes) should be prohibited.

Yugoslavia:

(1) It is our opinion that the imposition of an obligation to prohibit the manufacture, trade in, and use of synthetic narcotic drugs (except in small amounts for scientific purposes) should be favoured so that this prohibition should be applied to all synthetic narcotic drugs (sub (a) - Letter of the Secretary-General).

(2) This prohibition should be subject to exception only in cases where the drug in question represents an important therapeutical advance or has a distinct medical value which the existing narcotic drugs do not provide (sub'(b) - Letter of the Secretary-General). (D) (3) Whether additional control measures, at present not required for narcotic drugs, should be applied to synthetic narcotic drugs which are not prohibited under the measures listed in (D) (2), such as:

> (a) Furnishing all packages containing synthetic narcotic drugs with a distinctive marking, e.g. with a double red line;

(b) Denaturing synthetic narcotic drugs which might in the future have an industrial use, i.e. a use other than medical or scientific; or,

(c) Any other measures to be suggested.

Belgium:

/Original text: French7

(a) To furnish packages containing synthetic narcotic drugs with a distinctive marking would facilitate import and export control.

This distinctive marking will, however, be of equal assistance to traffickers in detecting packages containing narcotic drugs.

(b) It would certainly be desirable to require the denaturing of synthetic narcotic drugs which might have a use other than medical or scientific.

Canada:

No further control measures on an international level are considered necessary, provided all countries are prepared to establish rigid national control measures for all synthetic analgesics as they are developed and in addition steps taken to enforce the measures until the new questionable chemicals have been established as narcotic.

China:

/Original text: Chinese/

Additional control measures, at present not required for narcotic drugs, should be applied to synthetic narcotic drugs which are not prohibited in (D) (1), such as:

(a) Furnishing all packages containing synthetic narcotics with a distinctive marking, e.g. with a double red line; and

(b) Denaturing synthetic narcotic drugs which might in the future have an industrial use, i.e. a use other than medical or scientific.

Egypt:

/Original text: French7

(a) All packages containing synthetic narcotic drugs should be furnished with a distinctive marking, e.g. with a double red line.

(b) We are in favour of denaturing synthetic narcotic drugs which might in the future have an industrial use, i.e. a use other than medical or scientific.

France:

/ riginal text: French

(a) It appears indispensable to furnish packages containing synthetic narcotic drugs with a distinctive marking, such as a double red line, since customs services cannot require their agents to know the chemical formulae of such products (see also above, (C) (2)).

(b) Consideration may be given to denaturing synthetic narcotic drugs which might in the future have an industrial use, but that process should in no circumstances take the place of the control which it is essential to apply to these products, regardless of their use.

Federal Republic of Germany:

/Original text: German/

Additional control measures for drugs not prohibited under (D) (2):

(a) The proposal to furnish all packages containing synthetic narcotic drugs with a distinctive marking is not advocated.

(b) The denaturing of synthetic narcotic drugs for industrial use is advocated.

(c) No other measures are suggested.

Greece:

/Original text: French7

It would be desirable to furnish all packages containing addiction-producing synthetic analgesics with a distinctive marking.

Italy:

(No comment).

Italy (Trust Territory of Somaliland under Italian Administration):

(No comment).

Japan:

Packages to be furnished with a distinctive marking, as mentioned in (a).

Mexico:

(No comment).

Netherlands:

A clear indication of the identity of narcotic drugs is urgently required but this requirement should not be restricted to the synthetic narcotic drugs. Use of a distinctive marking would be an improvement, but it might be better still, if narcotic drugs would be designated with internationally agreed names. In addition, locally known names and factory- or trade-marks could be indicated on the packing.

The industrial use of narcotic drugs has not yet been under discussion but in appropriate cases denaturation of narcotic drugs might be considered.

Switzerland:

/Original text: French7

Specifically, the solution suggested under (a) - furnishing all packages containing synthetic narcotic drugs with a distinctive marking - seems not only inadequate, but dangerous in that it attracts the attention of interested persons to the products in question. The solution suggested in (b) - denaturing synthetic narcotic drugs which might in the future have an industrial use - seems unnecessary on the international level inasmuch as narcotic drugs may not be manufactured and used except in accordance with the international agreements. If those synthetic drugs were capable of also being used for other than medical or scientific purposes, it should not be difficult for governments to take appropriate action, not necessarily by denaturing the drugs, so that their industrial use would not be dangerous.

United Kingdom:

Her Majesty's Government are not aware that the manufacture and use of and trade in synthetic narcotic drugs have so far revealed dangers calling for special additional control measures. The competent services in the United Kingdom are not satisfied that the imposition of a distinctive marking on all packages containing synthetic narcotic drugs would be of any assistance to them in maintaining control, and the proposal would have certain administrative disadvantages. Moreover, it is understood that some of the countries which see advantage in this marking wish it to be applied not merely to synthetic drugs but to other narcotic drugs. No case is known to Her Majesty's Government of a synthetic narcotic drug which has an industrial use, and Her Majesty's Government is unable to express any opinion on the likelihood of such use in the future or on the possibility of denaturing synthetic narcotic drugs so used, nor do they desire to suggest any other measure of control.

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United States of America:

As an additional control measure, to be applied to the synthetic narcotic drugs which are not to be prohibited, the Secretary-General suggests as a proposal that all packages of such synthetic drugs be furnished with a distinctive marking, e.g., with a double red line. Under the narcotic laws of the United States, all synthetic narcotic drugs subject thereto must bear a government tax-paid stamp which identifies the contents of the package - at least to the domestic trade - as narcotics. Under another law of the United States dealing <u>inter alia</u> with labelling requirements for all drugs intended for nation-wide distribution, it is made mandatory that the statement "Warning - May be habit forming" be placed on the labels of morphine, cocaine, and certain other drugs which, although not in the narcotic category are considered dangerous from the standpoint of habit formation (21 U.S.C.352(d)). A similar requirement might be considered for adoption with respect to synthetic narcotic drugs which would be permitted controlled distribution in national and international traffic, although the statement might be amended to read "Warning - May be addicting".

> The United States favours, in principle, the proposal for denaturing synthetic narcotic drugs which might in the future have an industrial use, i.e., a use other than medical or scientific. It is recognized, however, that there may be encountered practical difficulties in applying this solution of a future problem; it may not be possible to denature the particular drug to the extent that it is not readily reconvertible to its original form, and it may be found that the denatured form of the drug is not adaptable to that use in the non-medical industry that the original form has been found to serve. Certainly it is imperative that some special measures of control be provided before quantities of a synthetic narcotic drug are made available for use in a non-medical industry, and it should first be determined whether it is of sufficient importance that the dangerous drug be made available to the nonmedical industry in the light of the very important problem of preventing diversion of the drug to spread addiction. The drug should not be made available to the non-medical industry until (1) a decision is made on this first question, and (2) until some special measures are provided, in the case of an affirmative decision, to secure adequate supervision and control over the use of the drug in the non-medical industry, according to the circumstances, as will provide reasonable safeguards against diversion for the spread of drug addiction.

Yugoslavia:

To synthetic narcotic drugs not prohibited by measures listed under (D) (2) should also be applied the measure provided for sub (a) in the letter of the Secretary-General, i.e., all packages containing synthetic narcotic drugs should be furnished with a distinctive marking, e.g. with a double red line.

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(4) What, if any, additional measures against illicit traffic in narcotics would be desirable in view of the opportunities afforded to traffickers by the development of synthetic narcotics?

Belgium:

/Original text: French7

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Manufacture should not be permitted except by responsible firms under the control of a pharmacist, whose sales would be subject to control and would be made only to pharmaceutical wholesalers maintaining a register of narcotic drug transactions.

The system of supplying information to governments should also be made as efficient as possible in order to keep them constantly informed regarding the activities of traffickers and the smuggling methods they employ.

Canada:

Steps should be taken to ensure the manufacture and distribution of all new analgesics are closely controlled in each country. In addition close liaison should be maintained by narcotic authorities of all countries with the World Health Organization relative to the discovery of new analgesics.

China:

/Original text: Chinese7

Since there has been no illicit traffic in synthetic narcotic drugs in the Republic of China, no opinion can be expressed regarding additional measures against illicit traffic in narcotics.

Egypt:

/Original text: French/

We recommend that the penalties for illicit traffic in synthetic drugs should be strengthened.

France:

/Original text: French/

It is difficult to envisage any additional measures against illicit traffic in narcotics which would be of any specific value. The only fact which seems clear is that it would be particularly difficult to combat clandestine manufacture.

Federal Republic of Germany:

/Original text: German/

No additional measures against illicit traffic are suggested.

Greece:

(No comment).

Italy:

(No comment).

Italy (Trust Territory of Somaliland under Italian Administration):

(No comment).

Japan:

The existing control system is considered sufficient for attaining the objective.

Mexico:

(No comment).

Netherlands:

It seems not inconceivable that traffickers could in the future perform complete syntheses of synthetic narcotics. As there is no experience in this field however, it is difficult to indicate possible measures against it. It appears however, that synthetic drugs do not offer more possibilities for illegal trade than natural narcotics.

Switzerland:

/Original text: French7

The measures at present in force against illicit traffic in narcotics seem adequate in respect of synthetic narcotics also.

United Kingdom:

Illicit traffic is dependent on clandestine manufacture or import, or upon diversion from legitimate use. So far as this country is concerned there is no evidence of clandestine manufacture or import of synthetic narcotic drugs, and diversion from legitimate use is unimportant. The development of synthetic drugs has not created any special problem in the field of illicit traffic.

United States of America:

The United States at this time is not prepared to suggest additional measures against illicit traffic in narcotics that would be desirable in view of the opportunities afforded to traffickers by the development of synthetic narcotics (see also below, (D)(5)).

Yugoslavia:

One of the additional measures against illicit traffic in narcotics should be the obligation on the part of all member States to provide in their legislations stiff prison terms for smugglers. In cases of repeated violations these terms should be as rigorous as possible.

> (D)(5) Whether the Government agrees with the proposition that the following control measures should not be applied to synthetic narcotics in the future:

(a) Control of drugs which are not themselves addictionproducing but can be converted into addiction-producing drugs;

(b) Control of raw materials from which synthetic narcotics are manufactured, except for an account of the material obtained, held or used in the drug factory itself.1/

Belgium:

/Original text: French/

It is evident from the limitation Convention of 1931, which provides for the control of methylmorphine and ethylmorphine and for the prevention of clandestine manufacture by unauthorized firms for the purpose of supplying the clandestine trade, that control should also be applied to the products and materials specified in (a) and (b).

<u>l</u>/According to these proposals, control of synthetic narcotics would in general be limited to the finished product having addiction-producing properties but would include the manufacturing process.

Canada:

Where proper national control has been set up it is considered the suggested steps in question 5 (a) and (b) are not necessary and need not be initiated. As a matter of fact action as advanced could very well unnecessarily restrict and hinder internal trade and commerce in relation to common chemicals, particularly coal tar derivatives.

China:

/Original text: Chinese7

The Government of the Republic of China agrees with the proposition that the following control measures should not be applied to synthetic narcotics in the future:

(a) Control of drugs which are not themselves addiction-producing but can be converted into addiction-producing drugs.

(b) Control of raw materials from which synthetic narcotics are manufactured, except for an account of the material obtained, held or used in the drug factory itself.

Egypt:

/Original text: French7

We are of the opinion that control measures applicable to synthetic drugs should be applied to all drugs which are not themselves addiction-producing but can be converted into addiction-producing drugs.

France:

/Original text: French/

(a) If the use is permitted of all the synthetic narcotic drugs discovered in future, there is a risk of the list of substances likely to produce addiction becoming a lengthy one within the next few years.

The number of products subject to control has a direct bearing on the efficiency of that control. The obligation to add non-narcotic products to the list would seriously complicate the work of the responsible services.

(b) No control of the raw materials from which synthetic narcotics are manufactured would appear to be possible, since they are widely used in the chemical industry.

Nor would the suggested declaration by the manufacturers of pharmaceutical substances have any practical value.

Federal Republic of Germany:

/Original text: German/

The proposed control measures should not be applied to:

建碱糖糖糖糖酶原因 医结合 化氯化油酸医乙烯化化胆糖甙糖精酶胆碱 法有限问题处理 使变性不同性的现象

(a) drugs which are not themselves addiction-producing but can be converted into addiction-producing drugs;

(b) raw materials from which synthetic narcotics are manufactured. Only final products that are addiction-producing should be controlled.

Greece:

/Original text: French7

International control measures should be applied to all products which are not themselves addiction-producing but can be converted into addictionproducing drugs.

Italy:

/Original text: Italian7

So far as concerns the substances and raw materials from which synthetic narcotics are manufactured, this $Office^{1/}$ does not consider it advisable to place them under the control provided for narcotic drugs, because the same substances and materials are often also used for the manufacture of other pharmaceutical products which are not addiction-producing.

This Office[±]therefore feels that it would be sufficient to require firms holding or using such raw materials for the manufacture of pharmaceutical substances to account for the materials for the purposes of the necessary control.

Italy (Trust Territory of Somaliland under Italian Administration):

(No comment).

Japan:

The proposition may be agreed to. However, the agreement is based on the assumption that controlling measures, as mentioned in (a) and (b), technically involve practical difficulties. It is not meant that those controls should be eliminated.

 $\dot{}$ i.e. The Office of the High Commissioner for Hygiene and Public Health.

Mexico;

(No comment).

Netherlands:

It is considered desirable in the manufacture of synthetic narcotic drugs, not only to keep a check on the quantity of the final product, but also on the quantity of one of the principal raw materials in order to ensure a better inspection. It is very difficult however, to extend the control on these raw materials outside the place of manufacture of the narcotics as many raw materials are used in various other industries. Where semi-manufactured substances are concerned a certain measure of control is possible and desirable.

There does not exist any reason to treat medicines which can be transformed into synthetic narcotic drugs differently from those which can be transformed into natural narcotic drugs.

Switzerland:

/Original text: French/

It can be agreed for the present that the following control measures should not be applied to synthetic drugs at the international level:

(a) Control of drugs which are not themselves addiction-producing but can be converted into addiction-producing drugs;

(b) Control of raw materials from which synthetic narcotics are manufactured, except for an account of the material obtained, held or used in the drug factory itself.

At the national level, article 3 of the above-mentioned Act of 3 October 1951 stipulates that:

"The Federal Council may apply this Act to any substance which, though not causing addiction, may be converted into a product which does so."

United Kingdom:

(c) Her Majorty's Government agree that at the present time there is no eviden which would a tify the control of sympholic narcotic drug, which are not the producing but can be converted into addiction-producing drugs.

(b) Her Majesty's Government agree that general control of raw materials from which synthetic marcotic drugs are manufactured would be impracticable; the control of the manufacturing process which is suggested would only be justified where the finished product is intsalf subject to control.

United States of America:

(4) and (5) The United States at this tile is not prepared to suggest additional measures against illicit traffic in narcotics that would be desirable in view of the opportunities afforded to traffickers U_{σ} the development of synthetic narcotics. However, it does not find it possible to agree definitely with the proposition that the following control neasures should not be applied to synthetic narcotics in the future:

(a) Control of drugs which are not themselves addiction-producing but can be converted into addiction-producing drugs;

(b) Control of raw materials from which synthetic narcotics are manufactured, except for an account of the material obtained, held or used in the drug factory itself.

It is understood that the substance Diphenylacetonitrile, which is not subject to narcotic control in the United States, is an important chemical intermediate in the production of the synthetic narcotic drug Methadone. It is doubtful whether there are any other important uses for Diphenylacetonitrile in industry, and there is evidence of purchases of considerable quantities of this substance, primarily for export, by persons not qualified nor heretofore engaged in legitimate trade in narcotics. It is further understood that the production of Methadone from Diphenylacetonitrile does not present any unusual problem to a qualified chemist. There are, of course, chemical intermediates to the other synthetic narcotic drugs that have been subjected to the narcotic control regime, and a considerable number of these intermediates have wide commercial uses.

The United States is aware of the very logical arguments advanced in Chapter III of United Nations Document entitled "The Problem of Synthetic Drugs" (E/CN.7/259/Rev.1) against the possibility of control of these raw materials used in the manufacture of synthetic narcotics, e.g., the impossibility of subjecting to control raw materials which are commonly used in industry, and the impracticability of defining the word "convertible". It has also been suggested that any attempt to control any one or several of these intermediates will not stop an unscrupulous chemist, but will only make it a little more inconvenient for him; presumably, in the case of Diphenylacetonitrile for instance, the unscrupulous chemist would be compelled to obtain the uncontrolled constituent substances with which to produce Diphenylacetonitrile. Nevertheless, it is suggested that the World Health Organization might be requested to make a study of the important chemical intermediates used in the production of the known synthetic narcotic drugs to determine which of them, if any, have no significantly important industrial use other than such production of synthetic narcotics, and the same study could be made to determine the same question with reference to any synthetic narcotics discovered in the future. With respect to such intermediates, (and Diphenylacetonitrile may be found to come within this category) measures of control of manufacture, distribution and use could be applied. Even if, in the case of an intermediate like Diphenylacetonitrile, these measures would not stop but would only make more difficult the clandestine manufacture and distribution by the unscrupulous chemist, they would be valuable to the extent that they did obstruct the illegal activities of the said chemist, who would have to accept the additional risk of a charge of unlawful possession of the intermediate since his possession of the intermediate would then be unlawful.

Yugoslavia:

It is our opinion that the proposal according to which the control measures listed in the letter of the Secretary-General under (a) and (b) are not to apply to synthetic drugs in the future should be accepted, if, in accordance with the said proposal, the control of synthetic narcotic drugs comprises not only the control of finished products, but the control of the process of production also.

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