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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 (Addendum)

Note by the Secretary-General

The Secretary-General has the honour to submit to the Commission on Narcotic Drugs the views of the Government of India on the use and control of synthetic narcotic drugs.

With reference to note C.N.114.1953. Narcotics, dated 3 November 1953, from the Secretary-General, United Nations, a note is enclosed incorporating the views of the Government of India on the points regarding the control of the production and distribution of synthetic narcotic drugs.

2. India has no synthetic (narcotic) drugs problem. Such drugs are not manufactured in the country, and only pethidine and methadone are imported into the country in limited quantities. These drugs, along with the fourteen others (and the salts of all except 'B-4-morpholinylethyl-morphine) which have been specified in the United Nations document E/NL.1953/84 dated 8 July 1953 are subjected in the country to all the restrictions laid down in the Convention of 13 July 1931.

3. In the matter of imports of drugs of all kinds, India exercises a very rigorous control under the Drugs Act, 1940, and the Rules made thereunder. No

new drug of any kind can be imported except under, and in accordance with, the permission in writing of the licensing authority appointed under that Act. The intending importer of any new drug, when applying for permission, is required to produce before such licensing authority, all documentary and other evidence relating to its standards of quality, purity, strength and such other information as may be demanded by that authority, including the results of therapeutic and pharmacological trials carried out on the drug in the country of origin, and a "free sale" certificate issued by the health authorities of each country. Trials are also conducted in this country before permission to import is given. No drug, the manufacture, sale or distribution of which is prohibited in the country of origin, is permitted to be imported under the same or any other name except for the purpose of examination, test, or analysis.

[Note - By a new drug is meant a drug which is not, for the time being, recognized by the Permanent Commission on Biological Standards of the World Health Organization or in the latest edition of the British Pharmacopeia or the British Pharmaceutical Code or any other pharmacopeia recognized by the Government of India and includes a patent or proprietary medicine containing such drug.]

4. In the absence of practical experience derived from the actual existence of an addiction problem arising from the consumption of synthetic narcotic drugs, it will be appreciated that any advice which India is in a position to give in this matter of the control of the production and distribution of these drugs, can only be of a very general nature.

NOTE INCORPORATING THE VIEWS OF THE GOVERNMENT OF INDIA
ON THE POINTS CONTAINED IN NOTE C.N.114.1953.NARCOTICS,
DATED 3 NOVEMBER 1953, FROM THE SECRETARY-GENERAL,
UNITED NATIONS, REGARDING THE CONTROL OF THE PRODUCTION
AND DISTRIBUTION OF SYNTHETIC NARCOTIC DRUGS

- (A) Views on 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

Pethidine and methadone are in use in India, not because these two drugs have been found to possess therapeutic properties immeasurably superior to those of natural narcotics but because they have properties which are believed to be different from those of natural narcotics. Introduced in India not many years ago, they have already replaced about 15 per cent of the natural narcotics made from opium, and there is a possibility of their making further inroads in this field if they were not subjected to quantitative import control. This control is being exercised with due regard to actual medical and scientific requirements.

- (B) 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

The manufacture of synthetic drugs is desirable only when they present economic and therapeutic advantages, and not otherwise. In India which produces opium and is, therefore, in a position to supply the internal demand and also, to a very limited extent, the external demand for opium alkaloids at economic prices, the manufacture of synthetic narcotic drugs is not likely to be encouraged except when it presents therapeutic advantages over opium alkaloids.

The two arguments which might, however, be advanced in favour of manufacture of synthetic drugs on an extensive scale are:

- (a) the cutting off of the supplies of raw opium from producing areas to manufacturing areas in the event of a world war, and
- (b) raising of the price of opium to an abnormally high level by the opium producing countries.

Similar objections were raised by some manufacturing countries when the present article 6 of the "Protocol for limiting and regulating the cultivation of the poppy plant, the production of, international and wholesale trade in, and use of opium" came up for discussion at the United Nations Opium Conference held at New York in May-June 1953, but the Conference rejected them as of comparative insignificance if not of no substance.

(C) 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 addiction-producing 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

The existing arrangements in regard to control over synthetic narcotics do not seem to be adequate. For the reasons mentioned in paragraph 20 under the heading "III. Inapplicability of certain control measures to, and need for additional control measures for, synthetic narcotics" of United Nations document E/CN.7/259/Rev.1, dated 20 March 1953, there appears to be a need for placing under national control, pending international examination, any synthetic drug which the national public health authorities have declared as likely to be dangerous to public health.

(2) If the existing arrangements are not considered sufficient, which of the following measures 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 addiction-producing or, although addiction-producing represents an important therapeutic advance, in which latter case the regular narcotics regime would apply:

(b) Regular narcotics control until it is found by the government that the drug is not addiction-producing:

- (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) Application of the import certificate and export authorization system as provided for in Chapter V of the international Opium Convention of 19 February 1925.

As a process of experimentation, by permitting general use of a new synthetic analgesic drug, may do irreparable harm by establishing the drug on the market, (a) and (c) seem to be the safest courses.

- (3) If any measures referred to under (2) appear desirable, to which synthetic drugs should they be applied:
 - (a) Synthetic drugs which by their chemical structure indicate probable addiction-producing properties; or
 - (b) All analgesic synthetic drugs; or
 - (c) All strongly analgesic drugs; or
 - (d) Any other type of drugs (to be specified).

Chemical structure may not be a reliable guide for ascertaining addiction-producing properties. Also, whether a new drug is a strong or a weak analgesic, would make a difference only in the degree of the danger involved in the use of one or the other. The safe course would, therefore, be to apply the control measures referred to in paragraph (C) (2) (a) and (c) above to all analgesics.

(D) Views on the measures 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.

India would favour the imposition of an obligation to prohibit the manufacture of, trade in, and use (except in small amounts for scientific purposes) of all synthetic drugs - as distinct from regulating these activities - until and unless they are certified by the World Health Organization to be non-habit-forming, and possessing therapeutical properties distinctly superior or significantly different from those of natural narcotics.

- (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.

The prohibitions referred to under (D) (1) should apply to all synthetic drugs and exceptions should be made only in cases where the drug in question represents an important therapeutical advance or has a distinct medical value which is not provided by existing drugs made from natural narcotics.

- (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.

The suggestion contained in paragraphs (a) and (b) will make for necessary security against misuse of the drugs. India has no other measures to suggest.

- (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?

An obligation should be placed on each government to report the composition and production of each synthetic drug manufactured in its territory to the Permanent Central Opium Board, and the Board or the Drugs Supervisory Body, assisted by the World Health Organization, should be entrusted with the task of ascertaining the world's requirement of narcotic drugs - both synthetic and natural. It should then be considered whether it would be possible to limit manufacture of each drug to such requirements, and to allocate manufacturing quotas to specified countries in a manner similar to that adopted to limit the production of opium in the "Protocol for limiting and regulating the cultivation of the poppy plant, the production of, international and wholesale trade in, and use of opium".

- (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 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.

(a) India has no strong views on the point, but it may be mentioned that the treatment accorded to drugs which are not themselves addiction-producing but are convertible into addiction-producing drugs, and falling in Group II of sub-paragraph (2) of Article 1 of the 1931 Convention is just as stringent as the treatment accorded in terms of the Convention, to addiction-producing drugs falling in Group I of that sub-paragraph.

(b) India concurs in the view that control over raw materials should be confined to factories using them for the manufacture of synthetic drugs.