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COMMISSION ON NARCOTIC DRUGS

Ninth Session

SUMMARY RECORD OF THE TWO HUNDRED AND THIRTY-SEVENTH MEETING

Held at Headquarters, New York,
on Wednesday, 28 April 1954, at 11.15 a.m.

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54-14299

PRESENT:

Chairman:	Mr. VAILLE	France
Rapporteur:	Mr. KRISHNAMOORTHY	India
Members:	Mr. SHARMAN	Canada
	Mr. CHUN	China
	Mr. ISMAIL	Egypt
	Mr. PANOPOULOS	Greece
	Mr. ARDALAN Mr. ESFANDIARY	Iran
	Mr. RABASA	Mexico
	Mr. LAZARTE	Peru
	Mr. FORYS	Poland
	Mr. OZKOL	Turkey
	Mrs. VASILYEVA	Union of Soviet Socialist Republics
	Mr. WALKER	United Kingdom of Great Britain and Northern Ireland
	Mr. ANSLINGER	United States of America
	Mr. NIKOLIC	Yugoslavia
Observers:	Mr. DANNER	Federal Republic of Germany
	Mr. GABRIELE	Italy
	Miss YAMANE	Japan
	Mr. van MUYDEN	Switzerland
Also present:	Mr. MAY	Permanent Central Opium Board
Representative of a specialized agency:		
	Dr. WOLFF	World Health Organization
Secretariat:	Mr. YATES	Director of the Narcotics Division
	Mr. PASTUHOV	Secretary of the Commission

THE PROBLEM OF SYNTHETIC NARCOTIC DRUGS (E/CN.7/260, 268, 277)(continued)

The CHAIRMAN invited the representative of the World Health Organization to explain the method followed by that Organization in selecting recommended international non-proprietary names for drugs moving in international commerce.

Dr. WOLFF (World Health Organization) recalled that the members of the Expert Committee on Drugs Liable to Produce Addiction had realized at its first session that the same drug often bore a great variety of names and that it would be advantageous if each of those substances and any other subsequently controlled could be given a recognized name by some authoritative body. The Committee had adopted a recommendation on that question. It was unnecessary to state that the carrying out of such a proposal had involved much work. Certain substances had for many years been given various names in different countries. The difficulty had been to find a name acceptable to all countries. The procedure to be followed in selecting recommended international non-proprietary names had then had to be determined.

The procedure adopted was described in the Chronicle of the World Health Organization (Volume 7, No. 10, pages 297-298). In accordance with that procedure proposals regarding recommended international non-proprietary names were submitted to WHO on a form provided for the purpose. The form was self-explanatory and was accompanied by general instructions. Proposals were submitted by the Director-General of WHO to a group of members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations set up for the purpose. As a rule, the name used by the person discovering or first developing and marketing a drug was accepted, unless there were compelling reasons to the contrary. All the names were published in the Chronicle of the World Health Organization and the Director-General of WHO duly notified Member States and national pharmacopoeia commissions. Member States were requested at the same time to take all the necessary steps to prevent the acquisition of proprietary rights in the proposed name during the period it was under consideration by WHO. Comments on, or objections to, the proposed name had to be forwarded to WHO

within six months of the date of publication of the name in the Chronicle of the World Health Organization. If a formal objection was filed, WHO might reconsider the proposed name or attempt to obtain withdrawal of the objection, but it did not recommend any international non-proprietary name as long as a formal objection was maintained. There was therefore a great difference between a proposed name and a recommended name. If no objection had been filed at the end of six months, WHO published the name as a recommended international non-proprietary name in the Chronicle of the World Health Organization and notified Member States of the decision, requesting them to take the necessary steps to prevent the acquisition of proprietary rights in the name.

As regards addiction-producing drugs, which was a more special concern of the Commission, WHO would try to expedite the procedure it followed in order to ensure that such drugs were rapidly placed under control. With that end in view the proposed name would no longer be published after the question had been studied by the Expert Committee on Drugs Liable to Produce Addiction, but as soon as a government proposal had been received. That procedure would save several months and, in addition, the experts mentioned above who would have to examine hundreds of different names, would be asked to grant top priority to the study of the names of addiction-producing drugs.

There were certain difficulties however. For example, bemidone was not yet included in the list annexed to the Expert Committee's fourth report and yet that name was commonly used. An objection had in fact been raised regarding that name and another name had been suggested. WHO had begun negotiations and hoped that the objection would be withdrawn, but no decision could be taken as long as it was maintained. There were other cases of a similar kind.

He pointed out that the Executive Board of WHO, after having examined the report of the Director-General on the application of the procedure for the selection of recommended international non-proprietary names, had considered that it was too soon to review the merits of the new system and had recommended that such a review should be postponed until a future World Health Assembly

Lastly, he emphasized that the question was a difficult one but progress had already been achieved. In some countries, certain names had been withdrawn in favour of proposed international non-proprietary names.

Mr. WALKER (United Kingdom) stressed the interest which his country took in the adoption of international non-proprietary names. When the competent authorities were notified that a certain product should be placed under control, the only name available was a lengthy chemical formula, difficult to pronounce, to remember and to use in current legislation and in administrative services. He realized that the task was difficult and therefore appreciated all the more WHO's efforts to simplify its procedure and make it more effective.

The CHAIRMAN, speaking as the representative of France, thought that the procedure followed by WHO was too slow and complicated. From the point of view of governments who were awaiting decisions, the system had functioned much better when it had first been applied than it did at present. Certain individual interests which conflicted with the general interest had been allowed to intervene. Such individual interests might always hamper the operation of an international system if the present procedure was maintained, which was regrettable.

WHO proposed a certain number of non-proprietary names and then had to wait six months before taking a decision. In any country a name might be immediately registered as a trademark and the manufacturer who had registered it might perhaps object to its adoption as a non-proprietary name. Such objection would paralyse any action by WHO. The Director-General, in proposing a name to governments certainly asked them to take the necessary steps to prevent the acquisition of proprietary rights over that name as long as it was being studied by WHO. But such a recommendation was useless since countries which had acceded to international conventions on the protection of trademarks were unable to give effect to the recommendation. If manufacturers had registered a trademark they could continue to use it. In practice, therefore,

any trademark already in use should not be proposed as an international non-proprietary name. The name which best suited a product, especially so far as narcotic drugs were concerned, should be adopted very promptly by WHO, and, as the Expert Committee suggested in its fourth report, the non-proprietary names applied to those products should be selected, at the latest, when the products were placed under control. It was regrettable that the question whether certain names used throughout the world were or were not trademarks was still being discussed, and it seemed unbelievable that it might one day be learned that such names could not be used as international non-proprietary names. The question would not arise if WHO acted more expeditiously. The working of the international control system must not be hampered merely because individual interests were being taken into consideration. The formulae of synthetic substances were too complicated and no one should try to impose them on administrative services throughout the world.

It would be advisable, therefore, for the Commission to adopt a resolution emphasizing that the current procedure was too complicated and slow and that it was desirable for such procedure to be simplified and expedited, particularly as regards narcotic drugs.

Mr. NIKOLIC (Yugoslavia) would support a draft resolution along the lines suggested by the Chairman, but would like it to give the World Health Organization definite indications as to what steps it should take.

The CHAIRMAN proposed that in order to meet the wishes of the representative of Yugoslavia, an article relating to non-proprietary names should be inserted in the single draft convention. At the present time, regardless of whatever recommendations might be made by WHO, a State could refuse to use the proposed names. The use of those names would, however, become compulsory for international purposes only and Governments could continue to authorize the use of trademarks to designate medical preparations.

Moreover the current procedure for the selection and publication of non-proprietary names recommended for drugs moving in international commerce, which was described on pages 297 to 299 of the Chronicle of the World Health Organization for October 1953 (vol. 7, No. 10), was much less expeditious than that previously employed by the WHO experts on nomenclature. The year's delay which that procedure often entailed was incompatible with the rapid progress of modern medicine. On the other hand, in many countries, such as France, the existing national procedure permitted a name to be adopted in less than a month.

He therefore proposed that the Committee should recommend a more speedy international procedure, which would, in particular, permit immediate consultation with the Berne Bureau, with which all trademarks of products moving in international commerce were deposited, in order to determine whether a proposed non-proprietary name was similar to a trademark already registered. If the Committee were to express a desire to that effect, it would certainly facilitate the work of the WHO experts.

Dr. WOLFF (World Health Organization) said that Member States had expressly asked for a time-limit of six months. Moreover while some countries might be in a position to adopt names quickly, that was not true of others. In point of fact, the WHO machinery for the election of international non-proprietary names was sometimes set in motion in the case of a particular proprietary name before the Organization had even received an official proposal on the subject, that is, before the Committee of Experts had met. Furthermore, WHO was in permanent contact with the Berne Bureau.

WHO would endeavour to speed up its present procedure and any wishes the Committee might express in that connexion would be well received.

Mr. NIKOLIC (Yugoslavia) pointed out that since a formal objection to a proposed name might be filed by any interested person, any individual in any of the eighty States, which belonged to WHO, had, in effect, a right of veto on international names. He wondered how that difficulty could be overcome.

Mr. ANSLINGER (United States of America) agreed with the French representative. The same difficulty arose in connexion with all pharmaceutical products and not only with narcotics.

Mr. van MUYDEN (Observer for Switzerland) considered that it would be desirable to include in the clause on international non-proprietary names which it was proposed to insert in the draft single convention a detailed provision on the time-limits to be observed by signatory Governments in adopting those names.

The CHAIRMAN put to the vote the two proposals which had been put forward in the course of the discussion.

The Commission decided by 12 votes to none, with 2 abstentions, to request the World Health Organization to speed up its procedure for the selection of international non-proprietary names.

The Commission decided by 12 votes to none, with 2 abstentions, to insert in the draft single convention a clause defining the conditions for the adoption of international non-proprietary names for the purpose of applying international conventions.

Replying to a question by Dr. WOLFF (World Health Organization), the CHAIRMAN explained that the Committee's desire for the adoption by WHO of a more speedy procedure for the selection of non-proprietary names would be expressed in a draft resolution; members of the Committee could submit amendments containing details, in particular, of the procedure to be suggested to WHO.

Compilation of the views of Governments on the use and control of synthetic narcotic drugs (E/CN.7/277) (continued)

The CHAIRMAN invited the members of the Commission to continue its study of document E/CN.7/277 and to discuss question D.

Mr. KRISHNAMOORTHY (India) put forward his Government's views on the various paragraphs of that question:

1. An obligation should be imposed on Governments to prohibit the manufacture of, trade in and use of all synthetic drugs, as distinct from regulating those activities, until and unless they were certified by the World Health Organization to be non-habit forming and to possess therapeutical properties distinctly superior to and significantly different from those of natural narcotics.

2. 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 represented an important therapeutical advance or had a distinct medical value which was not provided by existing drugs made from natural narcotics.

3. The suggestions contained in paragraphs (a) and (b) would make for the necessary security against misuse of the drugs. India had no other measures to suggest.

4. The 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 WHO should be authorized to ascertain the world's requirements of narcotic drugs, both synthetic and natural. It should then be considered whether it would be possible to limit the 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 1953 Protocol.

5. The treatment accorded to drugs which were not themselves addiction-producing but were convertible into addiction-producing drugs and which fell into group II of article 1 (2) of the 1931 Convention must also be accorded to synthetic drugs. Furthermore, control over raw materials should be confined to factories using them for the manufacture of synthetic drugs.

Mr. OZKOL (Turkey) said that an obligation should be imposed on governments to prohibit the manufacture of, trade in and use of all synthetic drugs except of course for the small amounts required for scientific purposes. The existing control provisions should perhaps be reviewed and redrafted for that purpose. The only exceptions that might be contemplated should apply to synthetic substances which were of considerable therapeutic value and less habit-forming than natural drugs.

Mr. DANNER (Observer for the Federal Republic of Germany), describing the position of his Government, said it was to be assumed that new pharmaceutical chemical compounds, including synthetic analgesics, would be produced in coming years. That process could not and should not be checked. However, the same did not hold true for compounds manifestly capable of producing addiction, the use of which must be severely restricted if not prohibited altogether. That was why the Government of the Federal Republic of Germany, by a decree of 15 July 1953, had applied the relevant provisions of the 1931 Convention to the thirteen synthetic narcotic drugs in respect of which the Secretary-General had recommended such action. The Government of the Federal Republic of Germany did not consider it possible to prohibit the manufacture of a new compound merely because it was presumed to be addiction-producing; such prohibition was justified only when the compound in question presented an immediate danger. The following provisional measures might, however, be applied to a synthetic narcotic drug, the chemical structure of which suggested that it might be addiction-producing: the Government on whose territory such a compound was manufactured should be required to take steps to ensure that it was not supplied except on the prescription of a medical practitioner; it should also be required to inform the United Nations officially that the compound was presumed to have addiction-producing properties. That information would be transmitted to the Governments of all States, which could then decide on the basis of the facts whether or not to apply the system of import certificates to the product. It should be possible to induce governments to prohibit narcotic drugs which were particularly dangerous and which did not represent a therapeutic advance.

Mr. RABASA (Mexico) wished to supplement the information furnished by his Government in its reply to the questionnaire. Although Mexico did not manufacture synthetic or other narcotic drugs and had to import all it used, it felt that in the interests of technical progress research and experiments should continue with a view to the discovery of new synthetic products superior to corresponding products and to the improvement of the quality and manufacturing processes of the synthetic analgesics already known. The manufacture of synthetic narcotic drugs was desirable, provided that they had definite therapeutic qualities and were not addiction-producing. However, their manufacture should be placed under a double control - national and international. The provisions of Mexico's health and penal codes were strictly enforced within the general framework of international conventions and the Higher Board of Health, which had the power to prohibit or bring under control dangerous and narcotic drugs, was responsible for the implementation of the recommendations of the international organs of control.

Mr. SHARMAN (Canada) said that he favoured the prohibition of certain synthetic compounds, provided that their dangerous addiction-producing power had been demonstrated.

Dr. WOLFF (World Health Organization) pointed out that, in its reply to the questionnaire, the United States Government had 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 had no important industrial use other than the production of synthetic narcotic drugs, as well as similar studies in respect of any such drugs discovered in the future. WHO would be happy to make such studies, if they were considered permissible under WHO's constitution. He doubted, however, whether that was the case and whether WHO was competent to undertake research more closely connected with industrial chemistry than with medical science.

The CHAIRMAN proposed that the Commission should take note of document E/CN.7/277.

It was so agreed.

The Commission also took note, without discussion, of document E/CN.7/260 (Survey of the Synthetic Narcotic Drugs, their Salts and Preparations Placed under National Control in the Various Countries and Territories).

The CHAIRMAN invited the Commission to consider document E/CN.7/268 (Chemical Aspects of Synthetic Substances with Morphine-like Effect).

Dr. WOLFF (World Health Organization) presented the study he and Dr. Braenden had prepared on synthetic substances with morphine-like effect which was the first of a series in preparation according to resolution 505 C XVI of the Economic and Social Council. It was soon to be published in the Bulletin of the World Health Organization. It described four groups of synthetic compounds, to which in the future science might add others, and gave the formula, synonyms and methods of synthesis of each substance in those groups.

Mr. van MUYDEN (Observer for Switzerland) congratulated the authors on their study. It clearly demonstrated that a relatively minor change in molecular structure of an addiction-producing drugs could completely eradicate its habit-forming properties. That was sufficient proof that general or partial prohibition would be prejudicial to the development of new substances of proved therapeutic value.

The CHAIRMAN felt that he was interpreting the wishes of the Commission in thanking the authors of the study, of which he proposed that the Commission should take note.

It was so agreed.

The CHAIRMAN proposed that the Commission should request the Rapporteur to prepare a draft resolution summarizing the Commission's work on synthetic narcotic drugs and the conclusions it had reached.

The draft resolution might propose that the Council should take note of documents E/CN.7/259, 260, 277 and 268, note the rise in the consumption of synthetic narcotic drugs, that 43 States had ratified the 1948 Protocol and that medical circles had not given enough attention to the addiction-producing power of new narcotic drugs, drawing attention in that connexion to the special responsibility which the right to give prescriptions imposed upon the medical profession.

The draft resolution might then propose that the Council should recommend Governments:

(a) to make the control of the manufacture and use of synthetic narcotic drugs as strict as possible;

(b) to adhere to the 1948 Protocol, if they had not already done so; and

(c) to warn the medical profession of the addiction-producing power of synthetic narcotic drugs.

The draft resolution might further indicate that it would be in the interest of each Contracting Party:

(d) provisionally to place under national control the synthetic narcotic drugs which had been brought to the attention of the Secretary-General as being addiction-producing;

(e) to extend the control provided for the 1925 Convention to exports and imports of such drugs; and

(f) where necessary, to keep under observation certain intermediates required for the manufacture of synthetic narcotic drugs.

It was so agreed.

The CHAIRMAN proposed that the Commission should decide at the beginning of its next meeting whether to recommend the prohibition of ketobemidone.

It was so agreed.

Mr. YATES (Secretariat) confirmed that 43 States had ratified the 1948 Protocol and added that on 12 March 1954 the Italian Government had informed the Secretary-General that, in accordance with General Assembly resolution 211 (III), it had extended the application of the Protocol to Somaliland under Italian administration.

The meeting rose at 1.5 p.m.