EIGHTY-NINTH MEETING

Held on Tuesday, 24 May 1949, at 10.30 a.m.

Chairman: Mr. S. Krasovec (Yugoslavia)

Present: All members except Mr. A. W. Rudzinski (Poland).

Also present were Mr. H. L. May, Dr. N. B. Eddy, Mr. L. Steinig, Sir H. Greenfield and Mr. V. Pastuhov.

STATEMENT BY THE TURKISH REPRESENTATIVE CONCERNING A REPORT IN A SWISS JOURNAL ON MORPHINE RESEARCH IN ISTANBUL

Dr. OR (Turkey) wished to make a statement to clarify a point raised by the Netherlands representative at a previous meeting. That representative had referred to an article which had appeared in a German-language Swiss scientific journal, and which dealt with experimental work being carried out by a Government research station at Istanbul. The figures given in the article had been based on official figures supplied by the Government of Turkey for opium production from seed specially selected for the production of opium which would have an unusually high morphine content, amounting to as much as 28 per cent. Those figures should not create a misleading impression, as they referred solely to specially selected material; the morphine content of opium offered for sale by the Government monopoly was, of course, always standardized.

The CHAIRMAN said that the Commission would take note of the Turkish representative's statement.

RECOMMENDATIONS ADOPTED BY THE EXPERT COMMITTEE ON HABIT-FORMING DRUGS OF THE WORLD HEALTH ORGANIZATION (WHO/HFD/9, WHO/HFD/9/Corr.1) (continued)

The CHAIRMAN opened discussion on page 4 of the Expert Committee's report.

Mr. HUTSON (United Kingdom) summarized the views he had expressed at the previous meeting on the definition of drugs. He explained that he hoped to clarify the role to be played by the World Health Organization under the new convention which was to be drafted.

It seemed likely that a large number of new synthetic drugs would be referred to the WHO every year, many of which would never reach, or be intended to reach, the commercial market. If the WHO found that the drugs should be

/controlled,

controlled, much work of inspection and control would fall upon the signatory States, though, in fact, no control would be required, since the drug would not be in circulation. It was for consideration whether a State should allow a drug to be released to the commercial market at all before it had been referred to the WHO. Recently a drug known as "heptozone" had been prematurely released in the United Kingdom, and the probable recommendation by WHO for its control would come into effect only after a certain amount of harm had been done.

Since the Chairman of the WHO Expert Committee was present, he might be able to assist in clarifying another question which was arising in connexion with synthetic drugs, namely, at what point of manufacture drugs derived, for example, from coal tar, became dangerous and required to be controlled. At which stage, out of the many stages of manufacture involved, did the substance become habit-forming and likely to lead to addiction? An extreme case might be selected to illustrate the difficulty of defining a drug under those terms, the case of brandy, which, although hardly a drug in the accepted meaning of the word, might be described as habit-forming and likely to lead to addiction.

The point was of particular importance because, as things were, the legal control of drugs as narcotics in the United Kingdom was only possible in the case of substances which produced effects similar to those produced by morphine and cocaine.

Colonel SHARMAN (Canada) asked whether the United Kingdom representative proposed that a new drug which was not recommended for medical uses should be suppressed by the State in whose territory it had been invented, or on a universal basis. If the former, there was a danger that such a drug might be manufactured in some State other than that in which it had been invented.

In connexion with the question which the Canadian representative had addressed to the United Kingdom representative, Mr. ANSLINGER (United States) recalled the case of keto-bemidone, a drug whose suppression had been unanimously agreed upon by the authorities of the United States, where it had been invented, and by the manufacturer himself. The result had not been satisfactory, because a manufacturer in another country had seen fit to make the drug and distribute it throughout the world.

/At the invitation

At the invitation of the Chairman, Dr. EDDY (Chairman of the Expert Committee of the World Health Organization) amplified the reply made by the United States representative. He pointed out that the drug to which the United Kingdom representative had referred was included on the list of drugs condemned by the WHO Expert Committee, so that if the list were adopted it would be placed under effective control.

With regard to the question of internal control of drugs invented within the territory of a given State, he explained that there was a co-operative arrangement in force in the United States, whereby a manufacturer would submit a new drug, at a very early stage of its development, to the Public Health Service. That Service would give an opinion on its possible danger as habit-forming and make a recommendation to the Research Council. Until the Research Council had made a favourable recommendation in such a case, the Food and Drug Administration would not issue a permit for the manufacture of the product. The methods used for testing the substances submitted had been described in a symposium published in 1948 by the New York Academy of Sciences.

In his view, some such system of controlling a drug before its manufacture and sale had started was the only satisfactory way to ensure the necessary protection.

Mr. HUTSON (United Kingdom) asked whether, to clarify the limits of reasonable application of the 1948 Protocol, the Chairman of the Expert Committee could consider what action would be taken supposing brandy were referred to the WHO for examination as a dangerous drug.

Mr. ANSLINGER (United States of America) said that dangerous drugs were defined as drugs capable of producing addiction similar to that of opium and coca leaf derivatives, which would not appear to cover the case of brandy.

Dr. EDDY (World Health Organization) pointed out that all the substances on which the Expert Committee had made recommendations in the report under consideration had been shown to produce and sustain morphine-like addiction qualities. On the extreme example of brandy, he did not feel able to anticipate the action of the WHO.

Mr. HUTSON (United Kingdom) said that it might eventually be found necessary to define more clearly the meaning of the words "drug" and "addiction but that he would not press the point for the time being. /MR. KRUYSSE

Mr. KRUYSSE (Netherlands) urged that some distinction should be made between the few known synthetic narcotics and the mass which might be discovered in the future. The term "drug" was recognized to be hard to define, except in so far as it was a substance used therapeutically in medicine. However, the proposal that some public authority such as the Public Health Service should examine substances being developed by manufacturers to determine their properties appeared likely to lead to the exploitation of such an authority for the benefit of the manufacturers. In any case, some of the substances listed by the Expert Committee of the WHO were not drugs but only chemical substances.

The CHAIRMAN drew attention to the use of the word "substances" in the Expert Committee's recommendation under point 8 of its report (WHO/HFD/9 p.5).

Dr. EDDY (World Health Organization) expressed the view that the working arrangement in force in the United States regarding new synthetic drugs had been adopted as a matter of common sense by manufacturers, in order to avoid expensive preparations for the exploitation of a substance which would subsequently be declared dangerous. The way in which the system worked had been shown in the case already quoted, in which the manufacturer had agreed to suppress keto-bemidone.

The chemical substances under consideration by the Expert Committee had been regarded as potential drugs; they had been tested on human beings and all been intended for general use as pharmaceutical preparations.

The CHAIRMAN considered that there was little danger of the limits of reasonable application of article 1 of the 1948 Protocol being reached within the next two or three years, and at that time the Commission could reconsider the matter in the light of prevailing conditions.

He asked for observations directly concerning the Expert Committee's recommendation under item 8 of its report.

Mr. ANSLINGER (United States of America) strongly supported the recommendation. Two amidone-type drugs had already been placed on the world market without control. The practice of the United States Government, which might well be followed by others, was that no new drug, whether or not it would be covered by the 1948 Protocol, should be exported to another country without a notification being sent to that country's authorities and an import certificate being requested. In default of such a practice, however, new drugs would be put

/into circulation

into circulation and would cause addiction before they had been submitted to the Expert Committee and brought under control. The recommendation of the Expert Committee should therefore be endorsed and carried out by all countries to avoid serious addiction resulting from the production of new synthetic drugs.

Colonel SHARMAN (Canada) supported the view that a serious danger might be averted by the application of the recommendation.

Mr. HUTSON (United Kingdom) pointed out that the previous speakers had apparently assumed that the recommendation would have immediate effect, but that, in fact, it only required that provision should be made "in any new convention" for the control of the drugs in question.

The necessity for control was clear, but definition was required if national laws were to be amended. It would be difficult for the United Kingdom delegation to endorse the recommendation, in view of the wide legislative amendments which would be required to implement it. In some such form as the following it would be possible for that delegation to support the recommendation:-

> The Committee recommends that Governments should endeavour to make such arrangements with their manufacturers that a drug which is analogous to those proved to be habit-forming, is not prematurely released to world trade.

All countries which manufactured drugs would probably be able to subscribe to such a recommendation, without being compelled to modify their entire narcotics legislation which would admittedly be necessary when the new convention came into force.

Mr. KRUYSSE (Netherlands) endorsed the argument advanced by the United States representative in principle. The potential danger of addiction-forming synthetics was real, and they should be very carefully watched. Ideally, all such potentially dangerous drugs should be controlled under a convention, but the legislation required would be almost impossible to frame. Moreover, inspectors for the control of synthetic drugs would have to be experts in organic chemistry, and be able to compare the effects of synthetic drugs with those of other narcotics. The inclusion of such synthetic drugs under the domestic control system might result in relaxing the attention given to narcotics as a whole. In his view, therefore, the wording of the recommendation was unacceptable, and would be better if it were expressed in the terms used in the body of the paragraph, namely:

/The Committee

The Committee considers that Governments should watch these compounds with extreme care and should take appropriate action immediately on the discovery of the addicting properties of any one of them.

Mr. STEINIG (Secretariat) remarked that the issue was one of considerable importance. There were three procedures for bringing under control new drugs considered dangerous from the social point of view. The first of those called for a modification of the convention in the case of each new drug to be placed under control. That system had been tried in the case of paracodeine and had proved both lengthy and inadequate. The second, embodied in article 10 of the 1925 Convention, was for the international control authority to recommend to Governments that they should place a given drug under control; that recommendation could be accepted or rejected by Governments, and only those Governments which accepted it were bound to carry it out. Thirdly, there was the principle embodied in the 1931 Convention that any finding by the international control authority to the effect that a certain drug was dangerous was immediately binding upon the Parties to the Convention. That procedure had been adopted for the purposes of the 1931 Convention because the scope of the latter had been clearly limited to two distinct groups of substances, namely those obtained from the Nenanthrene alkaloids of opium and the ecgonine alkaloids of the coca leaf, so that the control authority's decisions were restricted to drugs in those categories only. In view of the new situation resulting from the introduction of synthetic drugs, the 1948 Protocol had combined the methods of the 1925 and 1931 Conventions, so that while the initiative for bringing dangerous drugs to the attention of the international control authority rested with the Parties to the Convention, the decision taken on such notification by the World Health Organization was binding and could not be appealed against. However, some Governments might not be willing to undertake to apply the decisions of the international control authority with regard to all possible synthetic drugs. The Secretariat had therefore suggested that a new procedure might be adopted for the purposes of the new convention, whereby Governments Parties thereto might within a definite period -- say three months -- notify the international control authority of their rejection of its findings with regard to any particular drug. The control authority's decision would come into force only if it was accepted (i.e. not rejected) by twenty-five States, and would then be binding upon all States whether or not they were Parties to the convention.

/Under such

Under such a system the international control authority would not have unlimited power to enforce its decisions, and would consequently carefully consider whether all countries, and particularly those where drugs were manufactured, would be likely to accept them. On the other hand, Governments would hesitate to reject them in the face of world public opinion. If the same system were applied to other provisions of the new convention as well, that convention might become a truly flexible instrument; at the same time, constant amendments in the face of rapidly changing conditions might be avoided.

Mr. Steinig concluded by expressing the hope that further discussion of the matter would take place in connexion with the unification of the existing conventions, so that general principles would be thoroughly discussed before any definite decision was taken.

Colonel SHARMAN (Canada) felt that the practical point made by the United States representative was important in view of the fact that the new convention would not come into effect for some six or seven years. The Commission could not afford to disregard that interim period, and should make adequate provision against addiction to new synthetic drugs during that time. In that connexion, he drew attention to point 4, page 3 of the WHO Expert Committee's report. He believed that many consumer countries would, in the near future, also decide to proceed, for practical purposes, as if the Protocol signed at Paris on 19 November 1948 had already entered into force.

Mr. ANSLINGER (United States of America) agreed with the representative of Canada. The United States had permitted the export of drugs such as amidone only after signing the 1948 Protocol, since it considered that, although that Protocol was not yet in force, it might be considered to be so for practical purposes. Until that time, it had exported such drugs only when the importing country had issued import licences in their respect.

Mr. STEINIG (Secretariat), replying to the representatives of Canada and the United States of America, stated that the Expert Committee's opinion with regard to the substances referred to in points 5, 6 and 7 of the report would be notified to the Secretary-General. As soon as the 1948 Protocol came into force, any Government Party to that Protocol would be bound to proceed with regard to those substances in accordance with the terms of the Protocol.

/Brigadier EL-KHOULI Bey

Brigadier EL-KHOULI Bey (Egypt) thought that the precautionary measure recommended in point 8 of the report was a very reasonable one, and observed that it was already being followed in Egypt in respect of all imported synthetic substances.

The CHAIRMAN having suggested that discussion of point 8 of the report should be deferred until the Commission proceeded to a later item of its agenda, Colonel SHARMAN (Canada) urged that it would be preferable to dispose of point 8 without delay, thereafter proceeding to the consideration of measures to be taken in the period between the coming into force of the 1948 Protocol and of the new convention.

The CHAIRMAN pointed out that the decisions of WHO, both with regard to existing substances, as in points 5, 6 and 7 of the report, and to possible future substances, as in point 8, were final and would become effective as soon as the 1948 Protocol came into force. The Commission could neither approve nor reject those decisions.

Mr. ANSLINGER (United States of America) observed that several months might elapse before the 1948 Protocol came into force. Moreover, the Commission would not have another session until the following year. It would therefore be advisable to ask the Secretariat to prepare a recommendation to be sent to all Governments Parties to the Protocol requesting them to carry out the recommendations of WHO as formulated in points 5, 6, 7 and 8 of the report. Such action would meet the Canadian representative's and his own objections.

Mr. KRUYSSE (Netherlands) did not grasp the meaning of the United States representative's suggestion. The decisions of the WHO would have to be accepted as law by all States as soon as the Protocol came into force If Governments were requested to bring under national control substances of a particular chemical type before that type was clearly defined, confusion would be bound to result.

Mr HUTSON (United Kingdom) agreed with the Netherlands representative. The possibility of informal arrangements whereby Governments might endeavour to control the manufacture of synthetic drugs was worthy of consideration. But in the field of synthetic drugs Governments would not be dealing only with already

/licensed

licensed manufacturers of narcotic drugs but with new manufacturers entering the field for the first time; the exercise of control would therefore be far more difficult. Mr. Hutson stressed that his objection should not be interpreted as an indication of the United Kingdom Government's unwillingness to bring under control possible new types of synthetic drugs; however, it did not wish to undertake lightly an obligation which it might not be able to fulfil.

Mr. ANSLINGER (United States of America) felt that a recommendation such as he had suggested, which would be sent out to all Governments, would serve the purpose of putting those Governments on their guard against substances referred to in point 8.

The CHAIRMAN requested the United States representative to submit his proposal in writing.

Point 9

The CHAIRMAN noted that the reports of the Permanent Central Board and the Supervisory Body stressed the same point as that contained in paragraph 2 of point 9 (page 6 of the report).

Mr. KRUYSSE (Netherlands) drew attention to the remarks concerning Finland contained in Annex II of the report, third paragraph, page 13. He wished to know whether those remarks were merely a supposition or a statement of fact. If the former was the case, he expressed serious concern about the practice described, and wondered whether the Secretariat or the WHO were in a position to make inquiries leading to a clarification of the matter.

Dr. EDDY (World Health Organization) explained that the statement in question was part of a memorandum by Dr. Fischer. The only action which the Expert Committee had been able to take on the matter was to note that it did not have sufficient information with regard to diacetylmorphine, and to suggest ways in which further information might be obtained. The Committee had not, however, been able to express an opinion of its own on the matter.

Mr. STEINIG (Secretariat) stated that the Executive Board of the WHO, had, in March 1949, adopted the Expert Committee's report, and had submitted that report to the Economic and Social Council. Accordingly, the recommendation contained in point 9 would be acted upon.

/Mr. MAY

Mr. MAY (President of the Permanent Central Board) having stressed that the accuracy of the statement in question with regard to Finland could not be doubted, Mr. KRUYSSE (Netherlands) explained that he had not intended to cast doubt on Dr. Fischer's statement; it was not clear from the wording of the sentence in question whether it stated or merely supposed a fact.

The CHAIRMAN said that it would be mentioned in the Rapporteur's report that the Commission would be greatly interested in further information connected with the subject matter of point 9 of the report.

Mr. BOURGOIS (France) observed that the views of his Government which he had expressed at a previous meeting, had been based upon information supplied by Mr. Bouquet, Mr. Aubertin and the Académie de Médécine.

Point 10

Dr. EDDY (World Health Organization) drew the Commission's attention to the fact that additional information had been received on the compound mentioned in paragraph (a), which should be named morphinan (WHO/HFD/9/Corr.1). A report on that compound (E/CN.7/154) showed that it was more powerful than morphine and that its progress must be carefully watched. That item had been included in the report for information.

Mr. HUTSON (United Kingdom) said that he had understood that amphetamine was very similar to benzedrine. In the United Kingdom benzedrine was not regarded as causing effects similar to those of morphine, although it was covered by certain clauses in the poison laws.

Dr. EDDY (World Health Organization) explained that the Expert Committee did not consider that amphetamine was similar to morphine. It was known to have been used to excess, but it did not come within the definition of habit-forming drugs. It would not, therefore, be appropriate to take any action at that stage.

Point 11

Colonel SHARMAN (Canada) was strongly in favour of the Expert Committee's recommendation. It was essential that a standardized nomenclature for synthetic drugs should be established as soon as possible. So many different names were given to such drugs that constant reference to a key list was necessary when reading technical journals.

/Mr. KRUYSSE

Mr. KRUYSSE (Netherlands) thought that there might be difficulties. Manufacturers generally wished to retain their proprietary names for marketing purposes. Moreover, the use of chemical names in international commerce might give rise to errors in transcription and, thus, in control. He cited a case in which a shipment of two and a half kilogrammes of demerol from Switzerland -- where that drug was not covered by the Swiss opium law -- had reached a wholesaler in the Netherlands without an import permit because an error had been made in transcribing the full chemical name in the customs manifest. The Permanent Central Board had requested the Commission on Narcotic Drugs to examine the possibility of recommending to Governments the adoption of a uniform nomenclature for the drugs commonly known as "demerol" and "amidone" (E/CN.7/160, page 29). The Expert Committee's recommendation might be regarded as carrying that recommendation a stage further. It might be advisable to make a beginning with the two drugs mentioned by the Board, since they were those most widely employed.

Mr. HUTSON (United Kingdom) observed that it was essential that trade names should not be used for international purposes. Under United Kingdom law, the container of a habit-forming drug might bear a proprietary name, but in addition it must be labelled with the name under which it had been scheduled. The legal description was the essential requisite. The Commission, therefore, should endorse the Committee's recommendation, but also add a recommendation of its own to the effect that the Secretary-General should be requested to initiate the study of measures whereby a single name, not being a trade name, should be used for all international purposes.

Mr. KRUYSSE (Netherlands) wondered whether such a study by the Secretariat might not duplicate the work of the Expert Committee on the Unification of Pharmacopeias of the World Health Organization.

In reply to Colonel SHARMAN (Canada), Dr. EDDY (World Health Organization) confirmed the fact that that question had been referred to the Committee on the Unification of Pharmacopeias.

Colonel SHARMAN (Canada) thought that, in that case, such a technical question should be left to WHO, whose decision on that matter would be final.

/The CHAIRMAN

The CHAIRMAN pointed out that such a procedure was not clearly stated in the Committee's resolution.

Mr. KRUYSSE (Netherlands) proposed that the WHO Committee on the Unification of Pharmacopeias should be requested, when making any decision on a new synthetic drug to be covered by the 1948 Protocol, to invite Governments to use a single name adopted by that Committee. That Committee would therefore automatically be asked to decide upon the nomenclature of the drugs concerned. Admittedly, that Committee was frequently faced with disputes even political in character and thus tended to work slowly. A purely technical question such as that under discussion should not, however, entail any great delay. The advantage of such a procedure was that it would necessarily exclude the possibility of a proprietary name being used for international purposes.

Mr. ZAKUSOV (Union of Soviet Socialist Republics) could see no reasonable alternative to the use of the chemical names. That was the basic principle in all pharmacopeias. Furthermore, the Geneva nomenclature was generally accepted. That did not necessarily exclude the use of proprietary names, but they should be used as subsidiary titles, as had been done in point 5 of the report (WHO/HFD/9). It might also be desirable that the chemical formula should be specified in addition to the chemical name.

Dr. EDDY (World Health Organization) observed that there was a general consensus of opinion that the USSR representative's proposal was desirable. The example cited by the Netherlands representative, however, showed the risk of errors occurring unless some shorter name were also used. The chemical name should, therefore, be the basis, but a shorter description could be used if it were recorded as being synonymous with the longer chemical name.

Mr. STEINIG (Secretariat) pointed out that it would be improper to amend a recommendation of the WHO, but the proposals advanced could be included in the Commission's report in the form of comments.

The CHAIRMAN proposed that, in the absence of any objections, the Commission should endorse the Expert Committee's recommendation.

It was so decided.

/The CHAIRMAN

The CHAIRMAN put to the vote the proposal of the United Kingdom representative to the effect that it should be specified that the names used for international purposes should not be trade names. He pointed out that the United Kingdom and USSR proposals were not mutually exclusive.

Colonel SHARMAN (Canada) opposed the United Kingdom proposal because he felt that no limitations should be placed upon WHO's freedom of decision.

The United Kingdom proposal was adopted by 9 votes to 3.

The CHAIRMAN put to the vote the USSR representative's proposal that the chemical name should be used exclusively.

The USSR proposal was adopted by 5 votes to 3.

Colonel SHARMAN (Canada) explained that he had voted against the USSR proposal for the same reason as he had opposed that of the United Kingdom. WHO, however, might take the USSR proposal as its basis. With regard to the Netherlands representative's proposal, the procedure suggested by him would entail most undesirable delay. The WHO Committee on Habit-Forming Drugs would be expected to take a decision on drugs eligible for control as speedily as possible and inform Governments without delay. The question of the name of the drug could not arise until the Committee had made such a decision. To refer the subsidiary question at that stage to the Committee on the Unification of Pharmacopeias would mean that rapid action would be deferred.

Mr. BOURGOIS (France) said that he had abstained from voting on grounds similar to those advanced by the Canadian representative.

Mr. KRUYSSE (Netherlands) accepted the Canadian representative's argument. He therefore suggested that WHO should recommend that the names concerned should be established as soon as possible with a view to a subsequent decision under the 1948 Protocol.

Dr. EDDY (World Health Organization) agreed with the representative of Canada. To refer to the Committee on the Unification of Pharmacopeias would be impractical. The Expert Committee would inevitably report on the drugs involved under their chemical names, although it might for subsequent convenience use a shorter form.

/Mr. KRUYSSE

Mr. KRUYSSE (Netherlands) withdrew his proposal in view of the explanations of the Canadian and WHO representatives.

Points 12 and 13

The CHAIRMAN said that no action was needed on point 12. He proposed that the Commission should take note of point 13.

It was so decided.

The meeting rose at 1.15 p.m.