UNITED NATIONS

ECONOMIC AND SOCIAL COUNCIL

Distr.
GENERAL

E/CN.4/1172/Add.2
14 October 1975
ORIGINAL: ENGLISH/FRENCH/
RUSSIAN/SPANISH

COMMISSION ON HUMAN RIGHTS

HUMAN RIGHTS AND SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS

Protection of the human personality and its physical and intellectual integrity, in the light of advances in biology, medicine and biochemistry

Report of the Secretary-General (continued

Page

GE-75-13433

PART THREE: DEVELOPMENTS IN BIOCHEMISTRY

I. HUMAN RIGHTS PROBLEMS ARISING FROM THE RECENT PROLIFERATION OF NEW DRUGS AND INCREASE IN THE CONSUMPTION OF DRUGS

440. The "pharmaceutical revolution" - i.e., the recent proliferation of new drugs and increase in the consumption of drugs - is a result of accumulated knowledge of various disease processes and the way in which drugs act and also of new and improved facilities and resources for the manufacture of drugs.637/ The drug industry has been seen as "a major consumer industry in which research grows more and more expensive, manufacture more and more careful, and control more and more stringent, both internally and externally ... and the costs of publicity and information are high".638/

441. The WHO notes that:

> "For almost the whole of the millennial history of therapeutics, pharmacotherapy implied the administration of natural products, whether of animal, vegetable, or mineral origin ...
>
> "Today there is an entirely different situation, in that manufacture of new substances for therapeutic purposes has become a major industry. Thousands of such substances that never existed before are produced and exhaustively tested on animals for their pharmacological effects. Many, probably the majority, are rejected as not showing any promise of therapeutic effect or as being too toxic. Those that appear to be of potential therapeutic interest are subject to more exhaustive animal tests, about which recommendations have been made by a WHO Scientific Group on Principles for Pre-Clinical Testing of Drug Safety. Other WHO Scientific Groups have made recommendations on Principles for the Testing of Drugs for Teratogenicity, Principles for the Testing and Evaluation of Drugs for Carcinogenicity, and Evaluation and Testing of Drugs for Mutagenicity: Principles and Problems".639/

637/ Louis Lasagna, "The pharmaceutical revolution: its impact on science and society", Science, 166 (5 December 1969), pp.1227-1233; H. Mayer, "Excessive drug taking and the pharmacist", Journal Mondial de Pharmacie, No. 2, 1964, pp. 90-92.

638/ J. Cheymol, "Prevention of drug misuse", CIOMS Round Tables: Evaluation of Drugs: Whose Responsibility? (Geneva, WHO, 1968), p. 92.

639/ E/CN.4/1173, p. 18.

442. Professor Liljestrand of Sweden has noted that one of the problems arising from the proliferation of new drugs is how properly to evaluate them:

> "For the evaluation of a new drug it may be necessary to examine a considerable amount of data on the drug itself. The material may cover many volumes. Small details in it may be the only hint of future serious adverse reactions. The person who does this work has to have a thorough training and a good general knowledge of the actions and adverse reactions of similar substances. As many new drugs are introduced each year and each evaluation is time-consuming, quite a large number of well-trained persons are needed for this type of work. In order to maintain a certain standard, it is important that these persons should have some facilities for research work. As decisions not infrequently must be somewhat subjective, it is a considerable advantage if the authorities can have access to an independent advisory board of high scientific standing. In this connexion, I would like to stress the responsibilities of the academic professions; they have to support the authorities, helping them as well as the manufacturer, and act as an independent advisory board of high standard. It will of course be necessary for such an advisory board to have the data condensed, but such a synthesis will not really put too heavy burden on the scientists".640/

443. Nevertheless, certain new drugs are inadequately tested before they are released on the market - sometimes with tragic affects, as in the case of thalidomide. This drug was introduced to the general public, to the accompaniment of an advertising campaign, as being absolutely safe. In the case of humans, thalidomide proved to have a teratogenic effect and many malformed children were born to takers of the drug.641/

444. A publication notes that the rapid development of organic synthesis has made possible the production of many chemical substances which can be used as drugs. However, their introduction into the human body, while helping to achieve the immediate purpose of conquering a disease, frequently has undesirable consequences. Even a substance that has been duly tested clinically may later display an unfavourable action which it was difficult or perhaps impossible to foresee. For example, allergic consequences caused by certain antibiotics are well known.642/

445. There also appears to be a widespread tendency to use several drugs in combination, without evidence of the therapeutic value of such procedures, some drugs seemingly having been prescribed only to counteract the anticipated ill-effects

---

640/ P. Liljestrand, in CIOMS Round Tables: Evaluation of Drugs: Whose Responsibility? (Geneva, WHO, 1968), p. 35.

641/ T. Mann, "Sex, drugs and ethics", UNESCO, Impact of Science on Society, October-December 1970, pp. 256-257.

642/ Nauchno-Tekhnicheskaia Revoliutsiia i Sotsializm (The Scientific and Technical Revolution and Socialism) (Moscow, 1973), p. 46.

of others.643/ The interaction between drugs prescribed separately can sometimes produce quite unexpected and undesirable effects.644/

446. Another problem relating to the use of drugs is that

> "most psychoactive drugs including hypnotics can bring about modifications to the brain that need weeks for reversal. After stopping sleeping pills a patient may sleep worse than if /he/ had never had the pills, solely as a result of the drug itself. Correctly used, they should be prescribed not because of long-lasting neurotic personality disorders or environmental discord, but only when future termination of recent anxiety and insomnia can confidently be predicted so that, when the drugs cease, the drug withdrawal effects will be more than counter-balanced by the easing of life-provoked anxieties".645/

447. It has also been said that chemotherapeutic substances change the individual chemical environment in which our cells and organs live, function, and die. "Biochemically, we are to a large extent working in the dark and we still often judge the effects of drugs by broad and general so-called 'symptoms': Did she sleep better after taking this drug? ... Did the tension subside?"646/

448. It has been maintained that "people do not yet generally have a rational approach to drugs but a magic one. Also the type of information and promotion which have so far taken place seem to have given many people the feeling that they can lead a healthy life through chemical manipulation of their body and mind. In fact it seems to be a widespread feeling that chemical manipulation is a condition for health".647/

449. There also exists the problem of dependence, both physical and psychological. If an individual stops taking a drug, a set of specific symptoms may develop, ranging from discomfort or nausea to convulsions or delusions - the physical

---

643/ J. Klett, "Effects and implications of long-term maintenance chemotherapy", Journal of Drug Issues, vol. 2, No. 1, 1972, pp. 9-12.

644/ E. Cherry Doyle, "Drug interactions in a pill-popping age", Science News, vol. 99, 29 May 1971, pp. 365-366.

645/ I. Oswald, "Psychoactive drugs and sleep: withdrawal rebound phenomena", Triangle, 10, 1971, pp. 99-104.

646/ K. Evang, "Responsibilities of the governmental agencies in the dissemination of information on drugs", in CIOMS Round Tables: Evaluation of Drugs: Whose Responsibility? (Geneva, WHO, 1968), p. 66.

647/ Ibid., p. 70.

withdrawal state. Psychological dependence is established when the person derives feelings of well-being from the ingestion of a drug whereas its non-availability induces feelings of discomfort and anxiety.648/

450. The WHO Scientific Group on the Evaluation of Dependence-Producing Drugs has noted that "there are types of new drugs being developed continuously which induce effects that must be considered in connection with, but are not adequately characterized by, the current definition of addictiveness".649/

451. The Group also observed that "all drugs capable of inducing dependence may in higher dosage also be associated with psychotoxic effects leading to profound alterations in behaviour".650/

452. Occasionally drugs which were originally thought to have an entirely therapeutic purpose are discovered to have harmful applications. For instance, Methaqualone, which was initially developed as an anti-malarial drug and was afterwards used as a sedative, is widely used for non-therapeutic purposes.651/ Initially, Methaqualone was considered to lack a dependence-producing capability; later, reports of withdrawal symptoms started to appear; more recently it has come to be regarded as a drug with a great abuse potential and a low therapeutic use. Complications that may ensue from excessive consumption of Methaqualone include heart failure, convulsions and vomiting, which, in the case of unconscious patients, has caused deaths.652/

453. Further dangers arise from the indiscriminate medical use of powerful drugs, including the possible eliminating of protective organisms in the patient's body and the production of drug-resistant strains of bacteria.653/

454. Drug-taking to induce mood changes is becoming a method of dealing with daily life. Drugs of various descriptions have been used by man since ancient times, but it seems that only after the development of tranquilizers in the 1950s did drug-taking assume the role, not of curing a specific illness, but of making a reasonably healthy mental state more enjoyable.654/

648/ D.P. Young, A New World in the Morning: The Biopsychological Revolution (Philadelphia, The Westminster Press, 1972), pp. 49-50.

649/ World Health Organization, Technical Report Series, No. 287 (Geneva, 1964), p. 4.

650/ Ibid., p. 5.

651/ WHO Expert Committee on Addiction-Producing Drugs, World Health Organization, Technical Report Series, No. 273, 1969, p. 7.

652/ E. F. Pascarelli, "Methaqualone abuse: the quiet epidemic", Journal of the American Medical Association, vol.224, No.II (2 June 1973), pp. 1512-1514.

653/ Cf. Nigel Calder, Technopolis: Social Control of the Uses of Science (London, 1969), pp. 14-15.

654/ D. P. Young, op. cit., pp. 44-46.

455. Some understanding of the particular dangers arising from the development of psychotropic ("mood-changing") drugs can be gained from an examination of relevant passages of four reports of the Commission on Narcotic Drugs: E/4140 (twentieth session), chapter VIII; E/4294 (twenty-first session), chapter VI and annex II; E/4455 (twenty-second session), chapter VI; and E/4606/Rev.1 (twenty-third session), paragraphs 255-290. According to these passages, the consumption of psychotropic drugs in recent years has increased greatly; this is true of drugs acquired with or without prescription. These drugs are being consumed increasingly as agents capable of procuring sleep, euphoria or relaxation, or of warding off fatigue and sleep, apart from their use as medicaments. In particular, many young people are attracted to certain of these substances because of their allegedly stimulating and thrilling effects or power to expand or intensify the experience of the user. Many of these drugs lead to physical or psychological dependence. Some, even in small doses, can cause serious psychological disturbance, including hallucinations which have resulted in deaths among drug-takers and others. Some adversely affect driving skills 655/ or the ability to work with complicated machinery. The drugs are often taken by injection, and the insanitary conditions under which this often happens cause infection, especially through hepatitis.

456. Dr. Quarton writes:

> "Drugs that 'expand consciousness', such as LSD, require close attention. These agents produce a subjective experience that combines an intensification of sensation with some confusion and with heightened emotions, including elation and fear. They have been used in combination with psychotherapy to treat various mental disorders. The most dramatic aspect of these 'psychedelic' agents is that they have escaped from the control of the scientific community and are distributed and used by sub-cultures within our society. The scientific use of LSD has recently been much curtailed by evidence that a prolonged psychosis can follow a single, very small dose. It is not possible to predict the future of these drugs because new scientific discoveries can radically alter utilization patterns, and because use of drugs for kicks is complicated by other very complex social phenomena."656/

655/ As regards the effect of psychotropic drugs on road safety, see also Dr. F. Goffioul in CIOMS, 6th Round Table Conference: Drug Abuse, Non-Medical Use of Dependence-Producing Drugs (New York, Plenum Press, 1972), pp. 144-145.

656/ Gardner C. Quarton, "Controlling human behavior and modifying personality", in Toward the Year 2000: Work in Progress, Daedalus, Summer 1967, p. 843.

457. Concern is aroused by the effects of the use of psychotropic drugs on public health and by its other social repercussions.657/ One of the social problems that arise on connexion with the use of such drugs is their tendency to promote criminal behaviour:

> "The increased self-confidence, the feeling of hyperability sometimes approaching a sensation of omnipotence, the heightened activity at the same time as difficulties and conflicts fade away and the inhibitions are reduced, have a criminogenic influence. Furthermore the hastened association of ideas make the addicts feel that they get a lot of new, and as they often think, deep thoughts as they describe it themselves. When discussing they believe they can ... commit a clever crime ... At the same time they ignore the difficulties and risks of being caught. This can lead to crimes of property, but also to crimes of violence."658/

458. Problems arising from the use of new drugs, including psychotropic drugs, have been exacerbated by their having become too freely available. In the passage quoted in paragraph 456 above, Dr. Quarton has referred to psychotropic drugs having "escaped from the control of the scientific community" and to their being "distributed and used by sub-cultures within our society". He has also written:

> "It seems likely ... that certain kinds of drugs which are easily and cheaply produced and which can be manufactured by relatively inexperienced chemists can be made and used by individuals in spite of disapproval by society at large and the institutions set up by the government to control use."659/

It has further been said:

> "Even more threatening /to health than tobacco smoking/ is the overuse of many different therapeutic agents sold ubiquitously by the billions and without prescription. This overuse constitutes a hazard even more widespread than the illegitimate use of narcotics or hallucinogens."660/

657/ D. C. Cameron, "Patterns of abuse of dependence-producing drugs - some research approaches and strategies", in CIOMS, 6th Round Table Conference: Drug Abuse, Non-Medical Use of Dependence-Producing Drugs (New York, Plenum Press, 1972), pp. 148-149.

658/ G. Rylander, "Central stimulants and criminal behaviour", Third World Congress of Medical Law, Ghent, Belgium, 19-23 August 1973, p. 1.

659/ Quarton, loc. cit., p. 849.

660/ Robert F. Rushmer and Lee L. Huntsman, "Biomedical engineering", in Science, vol. 167, No. 3919 (6 February 1970), p. 843.

459. The World Health Organization has said that:

> "As new therapeutic substances have become more numerous, and as their potential for doing good or harm has increased, the conditions under which /the final demonstration of the therapeutic efficacy and the safety of a new medicament (which demonstration can only be made on human subjects)/ should be made have in recent years been the subject of much discussion and, in some countries, of specific legislative provisions aimed at protecting the right of the ultimate consumer not to be exposed to unwarranted risks to health. As Sir Derrick Dunlop, first Chairman of the Safety of Drugs Committee of the United Kingdom, has said: 'Modern medicines are now such potent weapons that it is generally agreed that the sole responsibility for their safe production and use can no longer be left entirely to the manufacturer and prescriber.' This tendency for legislative bodies to intervene by defining conditions to be satisfied before new therapeutic substances are introduced into medical practice received considerable impetus from the consternation aroused by the teratogenic effects of thalidomide. The fact that such effects were entirely unexpected and, indeed, unprecedented, alerted the whole world to the need for the most scrupulous screening of new compounds before sanctioning their use for medical purposes. However, in 1967 a WHO Scientific Group on Principles for the Clinical Evaluation of Drugs expressed the opinion that a review of the purpose and design of a proposed trial of a new therapeutic substance 'by local research committees composed of physicians and experienced medical research workers ('peer groups') may actually be more effective than laws in protecting both the patient and the investigator'."661/

460. The International Association of Democratic Lawyers discussed the question of drug abuse at its Ninth Congress in 1970. Attention was drawn to such legal problems as the guilt of persons committing acts under the influence of drugs. "Different drugs affect different persons differently, and under dissimilar circumstances the same man /can have a different reaction/, as, for example, under the influence of drink, or according to the effects of time. The different responsibilities of the doctor, the drugtakers, the producer and the distributor may have to be determined".662/

461. The Council of the Pharmaceutical Society of Great Britain, an affiliate of the International Pharmaceutical Federation, approved a report by a Working Party on Human Rights and Drug Use that had been set up to consider the questions on which the Secretary-General had invited the Federation to comment. The report included the following passages on "the use - without the patient's consent - of a drug which is known to cause some damage to him while undergoing medical treatment":

661/ E/CN.4/1173, pp. 18-19.

662/ IXth Congress of the International Association of Democratic Lawyers, agenda item 4, The scientific and technological revolution and human rights, "Discussion points by Rudolf Bystricky", p. 3; communicated by the Association on 30 May 1972.

"The need to ensure the safety of medicines was now widely recognised throughout the world and many countries had set up regulatory bodies which have the responsibility of assessing whether or not a medicine satisfied accepted standards. However, most medicines showed a complex pattern of side-reactions and interactions with other drugs. It was possible that due to an idiosyncrasy a patient would be damaged by a drug which had been licensed by the regulatory body. While the consent of the patient was always obtained to a surgical operation, it was seldom obtained to the administration of a drug, although this administration could be more hazardous.

"The question then arose as to at what point was the damage to the patient sufficiently frequent and severe for the medical practitioner to discuss the matter with the patient and obtain his consent to its use. The Working Party considered the argument that the patient should be informed on aspects of damage which might occur to him from treatment with a medicine so that he could weigh this risk against the possible improvement which might result. However, it was doubtful if a medical practitioner could present to the patient a complete and balanced view of the action and uses of the drug in such a way that the patient could make a decision on whether or not to accept treatment by the drug. Such discussion could cause the patient unnecessary fear and worry. Only with a few licensed medicines was the risk of damage likely to be sufficiently high to require careful discussion with the patient and his written consent to the treatment.

"It was recognised that the administration of a medicine to a pregnant woman could damage the foetus and that, as an additional safeguard, medicines used during pregnancy should be kept to the minimum necessary.

"While it would be possible to construct legislation to give the patient more protection, it would appear that in the complicated area of medication the best protection of the individual's physical integrity was the knowledge, judgement and professional standards of the medical practitioners, pharmacists and other health workers. Attempts to intervene by legislation between the patient and the health professions could lead to a more conservative attitude to the use of medicines and could deny many patients the relief which could be obtained from their use. It was felt that pharmacists, with their knowledge of the action and uses of drugs, performed a valuable service to the patient by carefully checking that the individual prescription for medicine was safe. Pharmacists not only considered the strength and dosage of the medicine, but also aspects such as drug interactions and they were prepared to draw the attention of the medical practitioner to these in the interests of the patient."

462. WHO has noted that a variety of methods of testing new drugs have been devised:

"At one extreme there are rigid, very detailed, and legally enforceable requirements covering not only the various phases by which a new medicament may be tested on humans and ultimately marketed but also specifying the type of information that should be included in labelling and advertising in respect of indications, contra-indications and possible adverse reactions. At the

other extreme, the highest medical authorities in the country nominate clinical investigators in whom they have confidence, and these are authorized by the government to conduct trials in accordance with their own conscience. An intermediate solution is that in which a panel of experts advises the responsible governmental authority what clinical trials should be authorized and what products should, after such trials, be licensed."663/

463. The situation as regards drugs control in different countries seems to vary widely. An author has stated that:

"At the national level the situation is ... highly confused. The ways in which governments have organized their control of and information on drugs differ widely. In fact I cannot think of two countries, even close to one another, with exactly the same system. In some countries the regulatory body in relation to drugs is an integrated part of the public health services and the information department of the health services, if such a thing exists, will be active in the field of information on drugs. In other countries the food and drug administration (or drug administration only) is partly or fully independent. The legal and fraud aspects may also dominate over the health aspects. In other countries again the governmental control laboratory for pharmaceutical specialities is the key government institution entrusted with some activities in the field of information.

"Some countries also have established state monopolies on the wholesale trade and importation of drugs, and these may have a role to play.

"Time will not permit me to go into detail in regard to the methods employed by and the authority vested in, these various types of administrative and organizational set-ups. I hope we will have a chance to listen to the experience from individual countries later.

"Generally, it may be said that in some countries government agencies of one or the other type already take a very active part in providing information on drugs, both to doctors and to consumers. Mostly this takes place through a system of critical control and appraisal before release of the information, which is produced by the manufacturing companies. Detailed rules have been worked out for the inclusion in information material to doctors of adverse reactions of the drug in question. The list of indications, etc. may have to be controlled, and so on. Some countries have gone further and as a general rule do not permit advertising to the public. The distribution to doctors of free samples of drugs which are not yet on the register (approved for marketing) has in some countries been abolished, on others strictly curtailed. Even free samples of drugs which are on the register may in many countries not be distributed to doctors in unlimited quantities.

663/ E/CN.4/1173, p. 20.

"Since drugs are commercial products of considerable economic 'specific weight', since there is keen competition between manufacturing companies, and since there will also frequently be highly diverging expert opinion in regard to the nature of an individual drug, what national government agencies can undertake in regard to information is strongly limited, especially for the public (information of doctors, in graduate and post-graduate education, has been dealt with by other speakers). Also, in some countries constitutional limitations exist in regard to the control or 'approval' of a written statement, in that this may be regarded as censorship.

"Nevertheless, national regulatory bodies all over the world are at present busy trying to find the extended role they feel they should play in regard to information. Since the detailed rules existing in the various countries may have important practical bearings on the type of labelling, package inserts, etc., the need for international co-ordination is already felt."664/

464. The WHO Expert Committee on Drug Dependence that met in Geneva from 8 to 13 October 1973 made the following recommendations concerning availability of drugs:

"1. Continuing attention should be given to (a) improving the effectiveness of controls on the licit production, distribution and use of dependence-producing drugs and suppressing the illicit traffic in such drugs; and (b) promoting further cooperation to this end at international (worldwide and regional), national, provincial, and community levels. The availability of a dependence-producing drug is a necessary precondition for its problem-related use.

...

"3. Physicians' prescriptions for dependence-producing drugs should be limited in amount, duration of validity, and number of refills. The accumulation of large amounts of dependence-producing drugs by individuals creates an increased risk of diversion for nonmedical use."665/

465. The same Committee also made the following recommendations concerning environmental conditions:

"5. Environmental conditions leading to undue stress should be alleviated as rapidly as feasible, particularly those conditions that are seen by most disadvantaged persons as being unfair (e.g. discrimination, blocked opportunity, slum conditions, certain business and labour practices).

664/ K. Evang, loc. cit., pp. 67-68.

665/ WHO Expert Committee on Drug Dependence, Twentieth Report, Technical Report Series, No. 551 (WHO, Geneva, 1974), p. 85.

'Any contribution that such stresses may make to engendering the destructive use of drugs is largely nonspecific. Concern over such drug use should not, however, be needed to remedy conditions that diminish any person's dignity or deny him a sense of worth, accomplishment, identity, integrity or hope."666/

466. The recommendations of the Expert Group on Drugs in Modern Society convened at Geneva from 4 to 9 December 1972, within the framework of the European Social Development Programme of the United Nations, with financial support from the United Nations Fund for Drug Abuse Control, included the following:

"4. In view of the new trends towards a psycho-social approach to the problems of drug-taking, and of the increasing urgency of considering the drug problem as only one aspect of social development in complex societies, it was stressed that it was important to see this problem as affecting the whole of society and necessitating a multi-disciplinary approach. It was strongly felt that any attempt to isolate the problem by assigning the exclusive responsibility for it to law-enforcement officials, to the medical profession or to any other professional group, should be opposed. It was also recognized that the prevention of drug abuse required over-all social planning directed to the general problem of the socially deprived and the maladjusted, among whom drug abuse was only a symptom.

"5. In view of the above consideration, and in order to prevent the harm resulting from traditional approaches to the drug problem, the meeting stressed the importance of integrated programmes of social action in preference to measures directed more specifically at the treatment of a single symptom (for example, special clinics for the treatment of heroin addicts). Partly with the same intention, it was suggested that governments should be encouraged to make available facilities for the analysis of black-market drugs, on an anonymous basis if necessary.

"6. Among the recommendations concerning information and education, the meeting stressed the following:

- the need for governments and other appropriate entities to stimulate the creation or strengthening of bodies responsible for improving the quality and accuracy of information given to the mass media; and for the mass media to make an effort to improve their own standards of accuracy and quality in the way they report matter relating to drugs and the behaviour of drug users:
- for more specific information, the importance of establishing a group of experts with powers to view and/or evaluate the impact of available media, for example films;
- for education, the usefulness of awakening the social awareness of children at a very early age and, in the context of the school, the advisability of integrating the subject in many other disciplines;

666/ Ibid., p. 87.

- for schoolroom education itself, the necessity of linking it with efforts aimed simultaneously at parents, teachers and the community at large whose attitudes were still too often derived from fear or ignorance."667/

467. A South American Plenipotentiary Conference on Narcotic Drugs and Psychotropic Substances was held at Buenos Aires from 25 to 27 April 1973. It was recommended in the Second Additional Protocol to the South American Agreement on Narcotic and Psychotropic Substances that:

"11. A special licence from the competent authority shall be required for any chemical or pharmaceutical establishment which manufactures, processes or purifies synthetic or extractive narcotic substances.

"12. Such substances and/or pharmaceutical preparations containing them may be acquired only by duly authorized establishments upon an application which has been signed by the responsible officer of the establishment concerned.

"13. The establishments referred to in article 12 shall be required to keep a file of the documents attesting to the acquisition and disposal of narcotic and psychotropic substances.

"14. Reports of the quantities of narcotic and psychotropic substances received, processed, consumed and stocked shall be sent to the competent authorities for every quarter expiring on the last day of March, June, September and December, made out in accordance with models previously adopted by the competent national authorities.

"15. Only legally authorized establishments shall be permitted to dispense narcotic and psychotropic substances to the public.

"Such substances shall be prescribed only by legally authorized professional persons, and their prescriptions must be kept by the pharmacies for checking and approval by the competent national health-control authorities.

"16. Every pharmaceutical establishment (drug-store, pharmacy or other) shall maintain a suitable system for registering all prescriptions so that the quantities acquired and the quantities expended can be compared.

"17. For narcotic drugs and other substances capable of producing physical or psychological dependence with a degree of risk equivalent to that of amphetamines and similar substances, an official prescription pad shall be introduced which shall be numbered, printed and distributed by the competent authority to each legally authorized professional person.

667/ Expert Group on Drugs in Modern Society, "Community reactions to drug use by young people", Bulletin on Narcotics, vol. XXVI, No. 2 (April-June 1974), pp. 6-7.

"18. For other drugs acting on the central nervous system, those States Parties which deem it necessary shall permit the use of a numbered prescription pad printed by the professional person himself, without registration with the competent health control department, provided that the name and address of the patient and the nature of the drug prescribed is recorded on the prescription counterfoil; in addition, particulars concerning the professional person signing the prescription shall appear on the pages of the prescription pad."668/

468. Although the Single Convention on Narcotic Drugs, 1961 669/ and the Convention on Psychotropic Substances, 1971 670/ contain detailed provisions concerning the control of the preparation, distribution, possession and use of drugs, and although by 11 October 1974, 671/ 98 States had become parties to the former Convention and 32 States had become parties to the Protocol (of 1972) Amending the Single Convention on Narcotic Drugs, 1961, 672/ it hs been thought useful to include in the present report some information on relevant measures taken or recommended on the national level.

469. The Government of Argentina has stated:

"The requirement of properly-regulated and correctly-performed clinicopharmacological experiments with comparable test and control groups before a new medicament is licensed, the improvement of national pharmacological services, education of the population concerning the desirability of abstaining from taking self-prescribed medicaments, a ban on press advertisements for medicaments and the requirement of medical prescriptions for dispensing them are all effective measures capable of mitigating the harm caused by the proliferation and mass consumption of medicaments."673/

668/ L. Olivieri, "South American Governmental Expert Meeting on Narcotic Drugs and Psychotropic Substances and South American Plenipotentiary Conference on Narcotic Drugs and Psychotropic Substances", Bulletin on Narcotics, vol. XXVI, No. 1 (January-March 1974), p. 14.

669/ United Nations publication, Sales No. 62.XI.1.

670/ E/CONF.58/6.

671/ See A/9707, para. 10.

672/ E/CONF.63/9. Forty ratifications or accessions are required for the entry into force of the Protocol, according to its article 18.

673/ Information furnished by the Government of Argentina on 30 May 1974.

470. In Costa Rica, Decree No.1869-SPPS of 27 July 1973 provides that: "Methaqualone and preparations containing it may be sold to the public only against a medical prescription and may be used only for medical and scientific purposes."674/

471. The Government of Ghana 675/ has expressed concern over:

> "... the laxity of drug control laws in Ghana which enables even dangerous drugs which should only be procured by a physician's prescription and taken under proper medical supervision to be sold without prescription.
>
> "Ghana is also concerned about the possibility of developing countries like Ghana becoming the dumping grounds for substandard pharmaceutical and biological products produced by unscrupulous and unethical pharmaceutical establishments in the developed countries. Ghana indeed entertains strong suspicions that this may already be happening.
>
> "This suspicion is based on the fact that in one developed country the standards for drugs produced for domestic consumption are known to differ from those for drugs produced for export.
>
> "It may be argued that the standards set for export are higher than those for domestic use.
>
> "This may be true, but the fact still remains that as long as facilities and resources for effective drug quality control in the developing countries remain primitive or non-existent, there will always be a potential danger of their being used as dumping grounds for substandard drugs and biologicals.
>
> "There is a strong case for protecting the consumer against the effects of substandard and inadequately tested drugs and Ghana recommends that steps be taken to get full enforcement of the code and guidelines recommended by the World Health Organization for the development of new drugs.
>
> "Ghana further recommends a strengthening and expansion of the global programme initiated by the World Health Organization for the monitoring and surveillance of the adverse effects of drugs.
>
> "In view of this situation in many countries, Ghana feels that the developed countries and international organizations should be urged to give support and assistance for the establishment and development of drug quality control programmes in such countries.

674/ International Digest of Health Legislation, 1974, vol. 25, No. 1, p. 62.

675/ Information furnished by the Government of Ghana on 21 March 1974.

"The establishment of an international body with responsibility for setting international standards for drugs and biologicals is considered to be desirable.

"It is envisaged that such a body would function like the FAO/WHO Codex Alimentarius Commission."

472. In Italy, the ministerial decree of 14 July 1973 concerning the sale to the public of products containing methaqualone "has been promulgated by the Minister of Health. It lays down that pharmaceutical products containing methaqualone may be sold to the public only on presentation of a medical prescription; the prescription must be renewed for each sale and must be retained by the pharmacist".676/

473. The Japanese Government has stated that:

"As for new drugs, safety and effectiveness of the drugs must be confirmed by the Government through strict examination, and a permission to produce and sell these drugs is given only to those who meet the necessary requirements.

"In addition, as for the drugs already in the market, production and sales may be suspended, if necessary, depending on a result of investigation on side effects, safety and effectiveness of these drugs.

"On the use of drugs, cautions on use must be described in detail to draw the consumers' attention to the correct use of drugs.

"The drugs which need special care in their use are obtained only by prescription.

"The description and advertisements of drugs are subject to strict control so that abuse and misuse of the drugs may be avoided."677/

474. In a paper prepared for the United Nations seminar on human rights and scientific and technological developments held at Vienna from 19 June to 1 July 1972, it was stated that

"the percentage of drugs (medication) accounts for 40 per cent of the total medical expenses in Japan. The drugs are extremely varied and used in a larger quantity compared to figures reported from other countries. Recently people who are concerned about this over-medication have begun to ask for complete assessments on main effects and side effects of drugs, and the government has established a system for collection of data and information in this respect".678/

676/ International Digest of Health Legislation, 1974, vol.25, No. 2, pp. 347-348.

677/ Information furnished by the Government of Japan on 22 March 1974.

678/ Kazuhiko Atsumi, working paper presented at the United Nations Seminar on Human Rights and Scientific and Technological Developments, Vienna, 19 June-1 July 1972 (WP/4), p. 12.

475. The Government of Luxembourg has stated that:

"Luxembourg possesses quite strict laws and regulations concerning medicaments accepted for sale in the Grand Duchy and concerning those which can be sold only against a medical prescription."679-680/

476. The Government of Norway has stated:681/

"As far as can be understood, this question refers to the problems of which the world has rapidly become more aware in recent years in connection with psychopharmacy. Human rights in relation to these problems are obviously connected with the sickness concept in psychiatry, something which again in the different societies has a cultural background. The general view on these questions in Norway does not diverge markedly from the prevailing view in the other countries of Western Europe. But it must be mentioned that, in regard to these questions, particularly among younger psychiatrists and social workers, there would be understanding for a point of view such as that expressed by the Norwegian psychiatrist, Svein Haugsgjerd: 'As well as the fact that ataraxica have their proper uses in psychiatry, they have nonetheless also become the object of unrestrained abuse on a large scale. Owing to their "normalizing" effect on unacceptable and disturbing behaviour, they have in a way replaced the mechanical restraints (such as foot-strap and belt, strait-jacket etc.) as the preferred means of preserving peace and maintaining order in the psychiatric hospitals and their supervised rooms and "disturbed departments". But this does not mean that it is not often best for a disturbed psychotic person that other people enter the picture to create structure and order, and that this must be achieved by technical aids when the instrument of environmental therapy - calm human companionship with straightforward acceptance of the situation - proves insufficient. But it is important not to forget why and for whose sake one gives medicine in such situations. Is it for the sake of society, or the department, or the family or the patient or the doctor himself?...' (quoted from "Nytt perspektiv på psykiatrien" ("New angles on psychiatry"), p. 294, Oslo, Pax Forlag, 1970).

"Perhaps it may be hoped that with a new realization (e.g. the tremendous developments in group dynamics now found in psychiatry) the need for ataraxica will diminish."

477. At the Third World Congress of Medical Law, which took place in Ghent, Belgium, from 19 to 23 August 1973, it was noted that in Poland:

679-690/ Information furnished by the Government of Luxembourg on 16 May 1974.

681/ Information furnished by the Government of Norway on 15 April 1974.

"drug addiction ... has been fought from the very moment the menacing danger was realized. The counteraction is founded on the coordination of the Departments of Health, Education and Home Affairs. The regulations regarding /narcotic drugs/ have been sharpened. New rules ordering a very careful protection of /narcotic drugs/ in the pharmacies have been introduced and the following requirements as regards the prescriptions for the /narcotic drugs/ have been made: they are valid for no more than two weeks; they are bound to contain the name and the address of the patient, a precise name of the medicine and the quantity desired (not bigger than ten times of the maximum portion for one dose), the precise doctor's indications, the way of application and the date of the issue of the prescription. Besides, the universal introduction of new patterns of prescriptions for /narcotic drugs/ different from others in colour and bearing special signs has been suggested. The wrappings of /narcotic drugs/ are different from others. Particular rules making it obligatory for the pharmacies to keep detailed records of accepted prescriptions for /narcotic drugs/ have been introduced."682/

478. The Government of the Republic of Viet-Nam has stated that "the proliferation of new medicaments does not constitute a danger if they are properly controlled and if their use is justified and supervised".683/

479. The Government of Romania has drawn attention to the necessity both for national institutes of drug control and for international co-operation through existing international institutes in the field, which should be accorded more clearly defined rights and more powerful enforcement machinery.684/

480. The Government of Singapore has stated that, in the light of human rights problems arising from the recent proliferation of new drugs and the increase in the consumption of drugs:

"the Misuse of Drugs Act 1973 was passed by Parliament on 7 July 1973. The purpose of the Act is to effect controls over the possession, sale, supply, and manufacture of drugs which tend to be misused and which are also subject to international surveillance under the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Drugs, 1971."685/

682/ T. Hanausek, Z. Marek and J. Widacki, "Crucial problems of the prevention of the drug addiction in Poland, paper prepared for the Third World Congress on Medical Law, Ghent, Belgium, 1973, p. 4.

683/ Information furnished by the Government of the Republic of Viet-Nam on 27 March 1974.

684/ Information furnished by the Government of Romania on 29 April 1974.

685/ Information furnished by the Government of Singapore on 13 March 1974.

481. The Government of Sweden has submitted the following information:686/

"As previously pointed out in several reports from the WHO, effective safeguards can be obtained by the impartial expert control of the experiments made with new drugs as well as by the documentation of the effects of drugs before they are approved for general use. Controls should be continued even after the drug has been put on the market and these should also comprise the registration and following up of any side-effects.

"In order to counteract the over-consumption of sedatives, a circular has been issued in Sweden to medical practitioners on the prescribing of hypnotic, sedative and ataractic drugs.

"When it comes to the increased consumption of medicines, Swedish psychiatry has very much concentrated its attention on the overdosage of drugs in hospitals, for such reasons as patients being considered troublesome. It is hardly likely that there is any over-consumption of drugs used in the treatment of psychoses.

"Drugs used in the treatment of psychoses probably never induce a state of dependence. On the other hand, this is a property of certain other kinds of drugs, e.g. some pain-killers, sedatives, appetite depressants and soporifics. Here there is a danger of prescriptions being written out too often and for too great quantities. The consumption of drugs inducing a state of dependence has gradually increased in Sweden. Public opinion has been aroused against the use of these medicines as their effects are only of short duration and not without risk. The Swedish Board of Health and Social Welfare has supplied widespread information to medical practitioners and the general public on these matters, and these efforts have resulted in a gratifying decline in the consumption of drugs for the relief of anxiety and sleeplessness.

"Work in this field is closely associated with the work done by the United Nations and the WHO on the control of psychotropic substances. (Cf. the Vienna Convention on Psychotropic Substances, 1971.)"

482. In Trinidad and Tobago, the Narcotics Control Regulations of 1965 prescribe various drug control measures:

"Thus, subject to certain exceptions, no pharmacist may dispense a narcotic to any person except on presentation of a prescription signed and dated by a physician, dental surgeon or veterinary surgeon (if the signature is unknown to the pharmacist it must first be verified). Detailed records must be kept of all transactions involving narcotics. Other provisions of the Regulations deal with the duties of physicians, etc., in respect of the

---

686/ Information furnished by the Government of Sweden on 12 March 1974.

/...

supply of narcotics, the duties of persons in charge of hospitals and other care establishments in respect of the use of narcotics and the keeping of records, the authorization of the possession of narcotics for research purposes, etc. It is further laid down that no person may in any advertisement to the general public advertise a narcotic or a preparation containing a narcotic."687/

483. The Government of the Ukrainian Soviet Socialist Republic has stated:688/

"Under the laws of the Republic only medicaments that are harmless and that present no danger to the patient may be used in medical practice; these are required to meet specific standards laid down by the competent authorities."

484. The Government of the Union of Soviet Socialist Republics has stated:689/

"The question of the use of narcotic and psychotropic substances for medical and scientific purposes, and the prevention of their use for other than medical purposes sanctioned by Soviet medical practice and international law, is at present dealt with at the international level in accordance with existing international agreements, and at the national level by legislation."

485. The United Kingdom has stated that:690/

"Under the Medicines Act 1968, all new medicines to be marketed in the United Kingdom must be licenced. The licensing authority is not, however, permitted to consider whether there are sufficient other drugs on the market which can be used to treat conditions for which the new drug is proposed; the field of its consideration is directed to the safety, quality and efficacy of the drug, though clearly efficacy has to be judged in relation to the other available remedies. Licensing does not concern itself with the cost of the drugs."

687/ International Digest of Health Legislation, vol. 21, No. 1, 1970, p. 204.

688/ Information furnished by the Government of the Ukrainian SSR on 23 October 1974.

689/ Information furnished by the Government of the USSR on 25 September 1974.

690/ Information furnished by the Government of the United Kingdom on 18 August 1974.

/...

II. TO THE EXTENT THAT PSYCHOTROPIC DRUGS HAVE A BENEFICIAL ASPECT, UNDER WHAT CONTROLS SHOULD THEIR USE BE PERMITTED?

486. The United Nations Conference for the Adoption of a Protocol on Psychotropic Substances adopted on 21 February 1971 the Convention on Psychotropic Substances (E/CONF.58/6). In its preamble, the States parties "noting with concern the public health and social problems resulting from the abuse of certain psychotropic substances", consider "that rigorous measures are necessary to restrict the use of such substances to legitimate purposes" 691/ and recognize "that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted."

487. Psychotropic drugs ("mood drugs") have come in recent years to be used widely as a means of helping individuals, by means of mood modification, to cope with various tensions, frustrations and other problems. One major factor contributing to this development has been the trend towards placing "mental" problems in a sense on the same footing as physical problems;692/ more and more, society is coming to regard psychological disorders on the same basis as physical ailments, i.e., as health problems which require treatment, with no stigma attached.693/

488. Tranquillizers have a number of beneficial applications, in particular in the treatment of mental disorders. It has been noted that, although the number of persons receiving some type of mental treatment is increasing, the number of persons resident in mental hospitals is decreasing owing to the use of tranquillizers, which permit patients to lead a relatively normal life and to live at home.694/ It has been said that

> "while until well into the nineteenth century persons judged to be of unsound mind were deprived of all rights and often even subjected to degrading physical restraints, there has since been a progressive tendency to regard psychiatric hospitals as centres for treatment and rehabilitation rather than for segregation. This tendency has been much favoured in recent years by the development of psychotropic drugs and the adoption of an 'open door' policy by psychiatric hospitals".695/

691/ Italics added.

692/ Young, op. cit., pp. 51-52.

693/ P. Pichot, "Disponibilité des drogues psychotropes et attitudes de la société envers des troubles du comportement" in R. H. Kung and H. Feher, eds., The Challenge of Life: Biomedical Progress and Human Values (Basel, Burkhäuser Verlag, 1972), pp. 291-292.

694/ Pichot, loc. cit., pp. 293-294.

695/ E/CN.4/1173, p. 32.

489. Tranquillizers are often resorted to in situations of tension and anxiety arising from minor, unresolved subconscious conflicts or from nervous hyper-excitability or tension resulting from excessive stimulation by one's environment.696/

490. Depressants (barbiturates such as Nembutal and Seconal) are another type of psychotropic substance with therapeutic uses, being used mostly to relieve insomnia and also some types of mental problems such as anxiety symptoms.697/

491. Hallucinogens, especially LSD, have also been found to possess therapeutic possibilities. The main use so far has been in the treatment of alcoholism in psychotherapy and for the relief of pain in terminal cancer.698/

492. Amphetamines are psychotropic drugs which have been found to have beneficial aspects; for instance, they have been used in reducing weight and relieving fatigue.699/

493. Speaking of drug treatment, Dr. Nathan S. Kline has written that:

> "It is the right of the consumer, i.e., the patient, to decide whether treatment is desired and to be allowed a choice if there are approximately equal alternatives. It is the function of professional societies to provide continuing education to physicians as to the availability and consequences of various types of treatment as well as to monitor the members of such professional organizations. It is the function of the government to attempt to meet the needs and demands of the general public in a manner that does not interfere with the appropriate practice of the best type of medicine possible."700/

696/ Young, op. cit., pp. 55-57.

697/ Ibid., pp. 59-60.

698/ Ibid., pp. 63-68.

699/ "Studies in bioethics, amphetamine quotas and medical freedom", Hastings Center Report, vol. 3, No. 6, December 1973.

700/ Nathan S. Kline, "Amphetamine quotas and medical freedom", Hastings Center Report, vol. 3, No. 6, December 1973, p. 9.

494. Some members of the medical profession believe that the problem of "on-the-spot" drug control should be left to the physician. The view has been expressed that: "we need to remove the issue of drug abuse from the realm of crusades and politics and to put it firmly under the public health and community medicine aegis where it belongs. The medical profession must again become involved in this problem. We must assert our right to do this, free of interference from the law enforcers."701/

495. The World Federation of Neurosurgical Societies has stated that the use of psychotropic drugs should be permitted only "under medical control".702/

496. The following view has been expressed concerning the proper relationship between patient and physician insofar as concerns drug taking:

> "The distribution of power in drug use or other decision making in the medical model exists on a continuum. On the one hand, the physician may make use of his own set of values at the expense of those of his patient. At the other extreme, the patient's judgments so dominate that the physician becomes nothing more than a technician advising his patient on what drugs will conform to a desired life style. The conflict of value perspectives between patient and physician is, perhaps, one of the greatest problems in medical ethics today. Yet, with the proviso that the physician has not only the right but the duty to withdraw from a case when his own moral standards are seriously violated, I see only two conditions in which the freedom of the patient to control his own internal body chemistry can justifiably be transferred to another individual. First, this could be done when there is a justifiable trust that sufficient consensus of value perspective or sufficient understanding of and respect for patient value orientation exists to permit the technically competent person to make such decisions. Secondly, in the countless day-to-day routine and trivial decisions in medical practice, we must recognize that patient consultation is logically and practically impossible. When such decisions can justifiably be considered trivial, most of us would have no problem with the transferring of such functions."703/

497. To some people, particularly of the younger generation, it is not self-evident that all self-induced abnormal mental states are necessarily harmful or to be condemned, or at any rate that they are more so than the abnormal states induced by socially accepted substances such as alcohol. Dr. Gerald Feinberg writes:

701/ D. Goldstein, "Drug abuse", in R. H. Kunz and H. Feher, eds., op. cit., p. 341.

702/ Information furnished by the World Federation of Neurosurgical Societies on 16 January 1974.

703/ R. M. Veatch, "Drugs and competing drug ethics", Hastings Center Studies, January 1974, vol. 2, No. 1, pp. 76-77.

"Regrettably most opponents of the use of psychedelic drugs have argued as if the ethics needed to evaluate the use of these drugs was quite clear and the only questions were the objective effects of the drugs. Proponents of the drugs could well argue that even if they have the bad effects cited by their critics, such as a loss of interest in the usual human activities or chromosome damage, the form of the psychic life they stimulate is worth the risk ...

"It must be admitted that the best known proponents of the use of LSD have made little effort to communicate their arguments in meaningful terms and therefore have not been taken very seriously by those for whom verbal communication is important ..."704/

498. While it may be held to be proper that society should impose certain limits on the production, labelling, access to and use of dangerous drugs, and inevitable that such restrictions should be based on prevailing moral standards, it has been argued that respect for individual freedom, including the right to control one's own body chemistry, should be observed in the adoption of legislation on the subject.705/

499. It has been stated that the most basic issue in drug control

"is whether or not the prohibition of behaviour whose direct effects are limited to the individual is within the function of the state. Those who feel it does not argue that the state has no more right to intervene with respect to the use of harmful drugs than it does with regard to harmful overeating. Those who take the contrary position argue that the harms are not limited to the individual, but burden society in a variety of ways: hence the state is entitled to prohibit its use in the public interest".706/

500. Although the Convention on Psychotropic Substances, 1971, 707/ contains detailed provisions relating to the control of the preparation, distribution, possession and use of psychotropic substances,708/ it has been thought useful to set out the following information regarding national measures to control the use of such substances.

704/ Gerald Feinberg, The Prometheus Project (Garden City, N.Y., Doubleday, Anchor Books, 1969), p. 107.

705/ D. P. Young, op. cit., p. 89.

706/ Veatch, loc. cit., p. 78.

707/ E/CONF.58/6.

708/ It should be noted that, as of 11 October 1974, only 19 of the 40 ratifications or accessions needed for the entry into force of the Convention had been registered, and that the most important countries manufacturing psychotropic substances had not yet ratified or acceded to the Convention (A/9707, para. 11).

501. The Government of Argentina has stated that:

"/The production of/ a medical prescription should be mandatory for every purchase of a psychotropic drug. The procedure would be more effective if such prescriptions were required to be made out on special forms issued by the health authority and subsequently recovered by the same authority from the pharmacies for verification".709/

502. The following account has been given of Egypt's policy in the matter:

"By and large, the Egyptian law in force, which dates from 1960, was already in full conformity with the recommendations which the United Nations adopted in 1971 in pursuance of the Convention on Psychotropic Substances (Vienna, 21 February 1971).

"First, Egypt had already increased the penalties prescribed for illicit trafficking in drugs, ... Indeed, the punishment for such trafficking has in some cases even been the dealth penalty. This severe legislative policy towards trafficking meets the provisions of the above Convention's article 22, which states the principle of adequate punishment in the following terms:

"'(a) "Subject to its constitutional limitations, each Party shall treat as a punishable offence, when committed intentionally, any action contrary to a law or regulation adopted in pursuance of its obligations under this Convention, and shall ensure that serious offences shall be liable to adequate punishment, particularly by imprisonment or other penalty of deprivation of liberty.'

"Secondly, the medical treatment which the Egyptian law had already prescribed in lieu of penal internment for drug users was an indication of progress in drug control at a time when the United Nations had not yet recommended that method of combating drug-taking."710/

503. The Government of Ghana feels

"that there is an urgent need for all Governments to adopt strict regulations for the control of all psychotropic drugs, particularly those with hallucinating effects.

"The need for an organisation and machinery for the effective enforcement of regulations for controlling the manufacture and sale of this group of drugs is strongly felt."711/

709/ Information furnished by the Government of Argentina on 3 June 1974.

710/ Ramses Behnan, "De l'abus et du trafic de drogues, paper prepared for the Third World Congress on Medical Law, Ghent, Belgium, 1973.

711/ Information furnished by the Government of Ghana on 21 March 1974.

504. The Government of Japan has stated that: "Psychotropic substances, ... including hallucinogens and stimulants, are handled only by those who have obtained license or designation."712/

505. Concerning control over the use of psychotropic drugs, the Government of Luxembourg has stated that "mention should be made both of the Act of 19 February 1973 concerning the sale of medicinal substances and the control of drug addiction, and of the regulations made under that Act."713/

506. The Government of Norway has stated that:

> "In Norway, by far the majority of the special preparations recognized pursuant to Section 16 in the Act concerning Medical Foods and Poisons, etc. are used under the supervision or control of some medical practitioner. In practice the question is closely related to economic circumstances, and it must be viewed in the light of the Administrative Provisions covering the refund of the costs of more important medicaments (including a number of psychotropic substances), laid down in pursuance of the National Insurance Act. This means that in practice the following rules will apply in respect of psychotropics for the use of: (a) Strong ataraxica (neuroleptica). Derivatives of phentiazin. Other strong ataraxica. The treatment should be instituted in a psychiatric hospital, department or polyclinic or by a specialist in psychiatry. For further prescription there should be a declaration from the primary treatment instance that it is indicated that the treatment shall proceed as ambulatory treatment. For continued prescription beyond one year there should be an annually renewed declaration from the primary treatment instance. (b) Anti-depressives. The same rules apply as under item (a)."714/

507. Concerning control over the use of psychotropic drugs, the Government of Romania has recommended that national professional medical organizations, since they benefit from the participation of a large number of specialists in their activities, should establish dosages, lengths of treatment, and the circumstances under which the drugs should and should not be given.715/

508. The Government of Singapore has stated that "Drugs are administered by a registered physician".716/

712/ Information furnished by the Government of Japan on 22 March 1974.

713/ Information furnished by the Government of Luxembourg on 16 May 1974.

714/ Information furnished by the Government of Norway on 15 April 1974.

715/ Information furnished by the Government of Romania on 29 April 1974.

716/ Information furnished by the Government of Singapore on 13 March 1974.

509. The Government of Sri Lanka has stated: "It is recommended that psychotropic drugs be dispensed on the prescription of a qualified physician."717/

510. The Government of the Ukrainian SSR has stated:718/

> "The Ukrainian SSR considers the existing international rules fully adequate to promote the use of narcotic and psychotropic drugs for medical and scientific purposes and to prevent their use for other purposes. It would therefore be premature to introduce any other international rules."

511. The Government of the Union of Soviet Socialist Republics has stated that:

> "The requirements in regard to both control measures and legislation are laid down in international agreements and described in the documents of the 1961, 1971 and 1972 United Nations diplomatic conferences.
>
> "It would be premature to introduce any new international rules at present."719/

512. The United Kingdom has declared that:

> "Certain psychotropic drugs are controlled in the United Kingdom under legislation relating to poisons and to the misuse of drugs. The purpose of the legislation is mainly to control the distribution of these substances and they cannot, for example, be supplied for medical purposes except on a doctor's prescription. In order to be able to use controlled psychotropic drugs such as LSD (lysergic acid diethylamide) which are not in general medical use, a doctor must hold a licence from the Home Secretary. The licence enables him to possess a fixed quantity of a specified drug and is only granted upon the recommendation of the Chief Medical Officer who must be satisfied that the drug will be administered under conditions that ensure the welfare of the patient."720/

717/ Information furnished by the Government of Sri Lanka on 5 March 1974.

718/ Information furnished by the Government of the Ukrainian SSR on 29 October 1974.

719/ Information furnished by the Government of the USSR on 25 September 1974.

720/ Information furnished by the Government of the United Kingdom on 8 August 1974.

III. THE POSSIBLE ABUSE OF DRUGS, AS A MEANS OF CONTROL, FOR PURPOSES NOT CONNECTED WITH MEDICAL THERAPY AND INCONSISTENT WITH BASIC HUMAN RIGHTS

513. An earlier report of the Secretary-General, prepared as part of his study of human rights and scientific and technological developments, dealt with respect for the privacy of individuals and the integrity and sovereignty of nations in the light of advances in recording and other techniques; it covered, among other topics, invasion of the privacy of the individual by certain psychological and physical means, including the use of drugs (E/CN.4/1116, paras.179-277; E/CN.4/1116/Add.2; E/CN.4/1116/Add.4, paras. 3-4 and 8-32). These particular non-medical topics will not be touched upon again in the present report. Their scope may be seen from paragraphs 179-180 of document E/CN.4/1116, which read as follows:

> "179. The last several decades have seen the invention or development of various techniques of eliciting information from individuals by psychological and physical means such as personality assessment techniques ('personality tests'), polygraphs ('lie detectors'), narco-analysis and certain blood, breath and other bodily tests, the use of which may involve invasions of the privacy of the individual.
>
> "180. It should be kept in mind in this connexion that many of these techniques and devices have medical uses and when applied in the health and medical fields have as their exclusive objective the good of the person concerned, any invasion of his privacy being an incidental by-product.721/ The present study is concerned with the use of such techniques for non-medical purposes only."

514. There has been a growing controversy in recent years over the use of "behaviour modification" techniques involving drugs on groups which are not always in a position, or given the opportunity, to give their free and informed consent to such procedures. Concern has been expressed over inter alia the possibility that such techniques may be used mainly or exclusively to control dissidents, including political dissenters.722/ The three major groups involved at the moment are hyperkinetic children, the mentally ill and prison inmates.

515. Amphetamines and methyl phenidrate have been administered to children diagnosed as having "minimal brain dysfunction", a state characterized by hyperactivity, inattentiveness, diminished perception and physical and social awkwardness. It has been argued that such treatment has produced dramatic effects in alleviating these problems and enabling the hyperkinetic child to achieve greater success both academically and socially 723/:

721/ Cf. preliminary memorandum forwarded by the World Health Organization on 20 October 1970 (A/8055/Add.1) para. 24.

722/ See paras. 518 and 523-526 below.

723/ Paul H. Wender, "The case of MBD", Hastings Center Studies, January 1974, vol. 2, No. 1, p. 99.

"medication properly used is not a chemical straitjacket. It provides children with less distressing life experiences and thereby affords an opportunity for (statistically) more normal growth. It probably reduces the likelihood of an unhappy childhood and an unhappy life".724/

516. Another writer, however, admits that the long-term effects of medication cannot yet be known. Furthermore,

"ethical questions must be raised about the administration of such drugs to school children, about who should be making behaviour-controlling decisions, about whether in some cases school conditions make hyperactivity the only appropriate behaviour, and about whether nascent political leaders are being suppressed".725/

517. Dr. Quarton writes:

"One abuse of drugs that occurs today in some places is the use of tranquilizers in hospitals for the mentally ill and the aged primarily to keep troublemaking patients from annoying the staff. This use of drugs may actually prevent the life experiences necessary for social recovery, and in the future this type of abuse will be possible to an even greater extent."726/

518. Another writer states:

"As psychiatric treatments have become more effective, the tendency has grown to widen the definition of mental illness, particularly in the non-psychotic conditions whose only manifestation may be changes in emotional states such as increased anger, or depressive moods, anxiety states, or behaviour which deviates from social norms. There is likely to be a further blurring of boundaries between conventional definitions of social deviance and mental illness. We have already seen this process occur in alcoholism, in drug abuse, and increasingly in juvenile delinquency and criminal behaviour .... Many fear that the power of involuntary treatment will be granted to custodial facilities, in the name of 'mental health' and that psychotropic drug treatment will be used as a form of social control. ... political dissent and social nonconformity, it is feared, will be defined as mental illness and treated coercively with medication."726 A/

724/ Ibid., p. 100.

725/ Veatch, loc. cit., pp. 72-73.

726/ Quarton, loc. cit., p. 848.

726 A/ G. L. Klerman, "Psychotropic drugs as therapeutic agents", Hastings Center Studies, January 1974, vol. 2, No. 1, pp. 88-90.

519. One author states that it is necessary

> "to think for a moment of all the discussions and controversies on the subject of methods of treatment used in lunatic asylums in certain countries; to remember that in all existing social systems the authorities can take measures to change certain types of behaviour without endeavouring to ascertain or eliminate the external causes, or, what is worse, they can deliberately conceal them; to realize that the danger of violation of the personality is inherent in all psychopharmacological treatment and can always and everywhere become a reality; and to bear in mind that any action which affects the basis of a person's behaviour or, in a broader sense, his psyche, so bringing about changes in the noblest aspect of the human being, requires the utmost skill. Here again, the problem is complicated by the fact that the subjects are frequently children".727/

520. Drugs have also been used to modify the behaviour of prison inmates. In one state of one country, for instance, recalcitrant prisoners are said to have been injected with a gradually paralysing drug called Anectine.728/ Apomorphine, a drug inducing violent vomiting lasting between 15 minutes and one hour, has been used on disobedient prisoners in another state and, although the country's Court of Appeals recently ruled the prison programme of the state concerned to be "cruel and unusual punishment" - and hence unconstitutional - it did not ban the use of the drug entirely; it can still be administered with the authorization of a doctor and the written consent of the inmate.729/

521. This raises the question of "whether inmates can ever give a truly informed 'consent' to such /behaviour modification/ procedures, in view of the fact that inmates may believe that they will improve their chances for early parole if they cooperate with prison officials' requests to participate in a "special program".730/

522. Concern has also centred around the application of the drug Prolixin in Enanthate and of other phenotiazine derivatives to control prisoners. These drugs produce muscular distortion, nausea, loss of appetite, tachycardia and other side effects.731/ It has been considered of

---

727/ Andrea Bissanti, "The pharmacological basis of the control of human behaviour", Impact of Science on Society, vol. XXIII, No. 3, 1973, p. 4.

728/ Barbara Yuncker, "What is B-Mod", New York Post, 9 March 1974, p. 2.

729/ Ibid.; see also "Behaviour mod behind the walls", Time, 17 March 1974; and Leslie Oelsner, "U.S. bars crime fund use on behaviour modification", New York Times, 15 February 1974, p. 66.

730/ Oelsner, op. cit., p. 66.

731/ See article by Dr. Tom Murton of the Murton Foundation for Criminal Justice, Inc., reproduced in Medical Care of Prisoners and Detainees, Ciba Foundation Symposium 16 (Amsterdam, Elsevier, 1973), pp. 17-20.

"the utmost importance ... to call for a differentiation of medical or therapeutic interventions designed on the one hand to maintain or restore the well-being of patients and, on the other hand, /to promote/ the convenience or well-being of officers charged with the care of patients, whether captive or free. Medical personnel would be well advised, at all times, to deal honestly with their prisoner patients and to give adequate explanations as to the purpose and intended effect of any treatment administered."732/

523. Further problems arise from the possible abuse of drugs on the part of public authorities. At the International NGO Conference on Human Rights which met in Paris from 16 to 20 September 1968 it was stated, during the discussion of the report of Working Group 5 on rights affected by science and technology, that there was "not yet full awareness of all possibilities of affecting human behavior that already exist, as for example, the growth and nature of the consumption of tranquillizers".733/ In this connexion, Dr. Quarton writes:

"Recent developments in pharmocology and neurophysiology have focused attention on technological possibilities for controlling behavior and changing personality in radical ways. If a new technology of this type is developed, it could have a marked influence on the lives of some individuals. Systematic applications of these techniques would have broad social implications.

"...

"We can expect increasingly affective methods for modifying personality and controlling behavior. 'What will these techniques be? Who will use them? And for what purposes?'"734/

Professor Lewis B. Sohn, of Harvard University, has drawn attention to one possible purpose: "Drugs which can make ... the psychotic patient docile .. in the future can make the whole population docile. Again both the individuals and the people as a group have to be protected against giving to the government the power to do those things".735/

524. In a paper entitled "Technology and human rights" prepared for the Assembly for Human Rights, Montreal, 22-27 March 1968, Lord Ritchie-Calder of the University of Edinburgh writes:

732/ Ibid., p. 20.

733/ Human Rights: Final Report of the International NGO Conference (New York, 1969), p. 89.

734/ Quarton, loc. cit., pp. 837-838.

735/ Human Rights: Final Report of the International NGO Conference, p. 89.

"We have heard a great deal about psychochemicals or hallucinogens, the most notorious of which is LSD, lysergic acid diethylamide, which is odorless, tasteless and colourless. LSD may produce a wide range of psychopathologic reactions and psychoses, including the inability to concentrate, severe anxiety states and complete catatonic withdrawal - a trance-like state. These agents can be dispensed covertly in the air or orally ingested. An investigating U.S. congressional committee saw a film which showed that troops exposed to one of those agents were not even conscious of their abnormal condition, a state so changed that they were unable to follow the simplest command or perform normal tasks. One can say a great deal about the use of such agents ... in chemical warfare, but one does not need to have a battlefield to use such methods. One can foresee their uses as 'police gases', for example, against civil demonstrators, with individual consequences which psychopathologists cannot predict since people by physiology and temperament react differently to such agents and may suffer permanent mental and even genetic damage, so that offspring can be affected. Nor does one have to think of their use only on a mass scale. These can be used at the group and personal level ...".

525. Dr. Quarton writes:

"There are certain types of activity in which a high degree of efficiency by human participants is desired. The best example of this is in military efforts, but efficiency also leads to reduced costs in manufacturing and other similar activities. It is quite possible that managerial groups in the military or industry will encourage the use of behavior-manipulation techniques that increase the effectiveness of the human beings in the system. Since drugs are used to some degree in this way at the present time, some further experimentations are likely.

"Hostility to totalitarian forms of government does exist, however, and this suggests that most democratic societies will resist this type of use unless there is a radical change in our whole social structure."736/

526. Furthermore:

"The mere existence of a versatile armamentarium of psycho-chemicals that can bring pain or pleasure, sleep or wakefulness, sexual desire or impotence, feelings of heat or cold, thirst or hunger or satiety; that can offer greater insights and intellectual powers as easily as they can deaden or disorient the mind, that can, in brief, control human beings and therefore human behaviour in almost any desired way, holds out prospects that are not guaranteed to cheer us. Whose hands will they fall into? How can we insure that they will be used for our benefit, and not for the selfish or criminal purposes of private parties or of nations?"737/

736/ Quarton, loc. cit., p. 850.

737/ A. Rosenfeld, The Second Genesis: The Coming Control of Life (New York, 1969), pp. 223-224.

527. At the UNESCO Symposium on Science Policy and Medical Research held in Paris from 20 to 29 February 1968 it was stated:

> "But one topical problem which is as controversial as any is the use of psycho-drugs for insufficiently defined clinical objectives. Brain-washing by means of drugs perhaps arouses a little less horror nowadays than it used to when it was first described. This, however, has not changed its inhuman significance..."738/

528. The Union internationale des Syndicats de Police has stated:

> "The progress in the field of biology, chemistry and medicine reveals spectrelike features under the aspect to be investigated. Even today it is possible to control humans or human courses with medicaments ... From the medical standpoint this may be looked upon as a great progress. But what happens if these practices are used as the instruments of suppression or political control ...? Any safeguarding of human rights and the basic freedoms is then scarcely possible. To establish a safeguard here without excluding the positive results of research should be one of the greatest future tasks."739/

529. The Government of the Republic of Viet-Nam has stated that "the use of medicaments for non-medical purposes should be strictly prohibited".740/

530. The Government of Sweden has stated that "using psychoactive drugs for controlling the behaviour and radically changing the personality in a way that is of no benefit to the patient cannot be defined as medical treatment".741/

531. The Government of Singapore has stated that:

> "Mindful of /the possible abuse of drugs, as a means of control, for purposes not connected with medical therapy and inconsistent with basic human rights/ the Misuse of Drugs Act 1973 was passed by Parliament on 16 February 1973. This Act became operative on 7 July 1973. The purpose

---

738/ C. Chagas, "Problems of science policy and legislation arising from medical advances: the influence of medical sciences on man and society", Proceedings of the Symposium on Science Policy and Biomedical Research (Paris, UNESCO, 1969), p. 43.

739/ Information furnished by the Union Internationale des Syndicats de Police on 22 April 1972.

740/ Information furnished by the Government of the Republic of Viet-Nam on 27 March 1974.

741/ Information furnished by the Government of Sweden on 12 March 1974.

of the Act is to effect controls over the possession, sale, supply, and manufacture of drugs which tend to be misused and which are also subject to international surveillance under the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Drugs, 1971." 742/

532. The Government of the Ukrainian SSR has stated that "under the legislation of the Ukrainian SSR, narcotic and psychotropic substances may be used only for medical and scientific purposes". 743/

533. The Government of the Union of Socialist Republics has stated that:744/

"Under USSR law narcotic and psychotropic substances can only be used in accordance with a doctor's prescription for medical purposes and scientific research ... The degree of control and the list of preparations subject to control are determined by the Ministry of Health of the USSR in the light of the provisions of existing international agreements."

534. The Government of the United Kingdom has stated that:745/

"If the word control is used in the sense of subjugation, to facilitate detention or interrogation against the will of someone in custody by the use of medication not intended for that person's benefit, then the involvement of a medical practitioner in such a procedure, even if only to monitor the effect on the person in order that the medication does not endanger that person's life, is accepted in this country as unehtical."

742/ Information furnished by the Government of Singapore on 4 April 1974.

743/ Information furnished by the Government of the Ukrainian SSR on 29 October 1974.

744/ Information furnished by the Government of the USSR on 25 September 1974.

745/ Information furnished by the Government of the United Kingdom on 8 August 1974.

PART FOUR: EXPERIMENTS ON HUMAN SUBJECTS

I. PROTECTION OF THE INDIVIDUAL AGAINST UNJUSTIFIED EXPERIMENTS, INCLUDING THE QUESTION OF FREE AND INFORMED CONSENT TO EXPERIMENTS PERFORMED ON THE INDIVIDUAL

535. The question of the protection of the individual against unjustified experiments, including the issue of free and informed consent to experiments performed, was raised by the Secretary-General in his preliminary report.746/

536. The same problem has been dealt with by the WHO.747/

537. Further comments on the topic will appear in a later addendum to the present report (E/CN.4/1172/Add.3).

II. THE MORAL AND LEGAL POSITION OF THE PHYSICIAN WHO IS INVOLVED IN EXPERIMENTAL PROCEDURES

538. The question of the moral and legal position of the physician who is involved in experimental procedures was raised by the Secretary-General in his preliminary report.748/

539. The topic will be treated further in a later addendum to the present report (E/CN.4/1172/Add.3).

746/ See CN.4/1028/Add.2, paras. 186(v), 205, 252, 256-260 and 264-273; E/CN.4/1028/Add.5, paras. 80-82 and 84; and E/CN.4/1028/Add.6, paras. 39-42 and 44.

747/ E/CN.4/1173, pp. 3 and 15-20.

748/ See E/CN.4/1028/Add.2, paras. 196, 261 and 273 (i); and E/CN.4/1028/Add.5, paras. 63 and 83.

III. THE PROTECTION OF THE PUBLIC AGAINST HARM FROM CHEMICALS INTRODUCED INTO FOOD PRODUCTION, PROCESSING, PACKAGING AND STORAGE

540. The question of the protection of the public against harm from chemicals introduced into food production, processing, packaging and storage, which can sometimes be regarded as being experimental in relation to the general public, was raised by the Secretary-General in his preliminary report.749/

541. The same problem has been touched upon by WHO.750/

542. The topic will be dealt with in a further addendum to the present report (E/CN.4/1172/Add.3).

- - - - - - - - -

749/ See E/CN.4/1028/Add.2, paras. 262-263, 269 and 273(ii); and E/CN.4/1028/Add.6, para. 43.

750/ See A/8055/Add.1, paras. 67-70.