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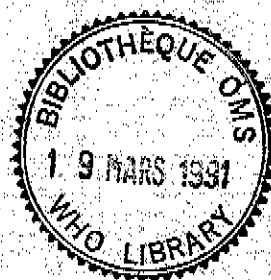
REGIONAL OFFICE FOR EUROPE

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Systems of Classification for Pharmaceuticals (ATC) and for Defined Daily Doses (DDD)

Report on the Second Consultation



Oslo
14 December 1990

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1991

EUR/HFA TARGET 31

This activity was organized by the WHO Regional Office for Europe to promote work aimed at achieving the following target in the health for all strategy.^a

TARGET 31

ENSURING THE QUALITY OF SERVICES

By 1990, all Member States should have built effective mechanisms for ensuring quality of patient care within their health care systems.

Index terms

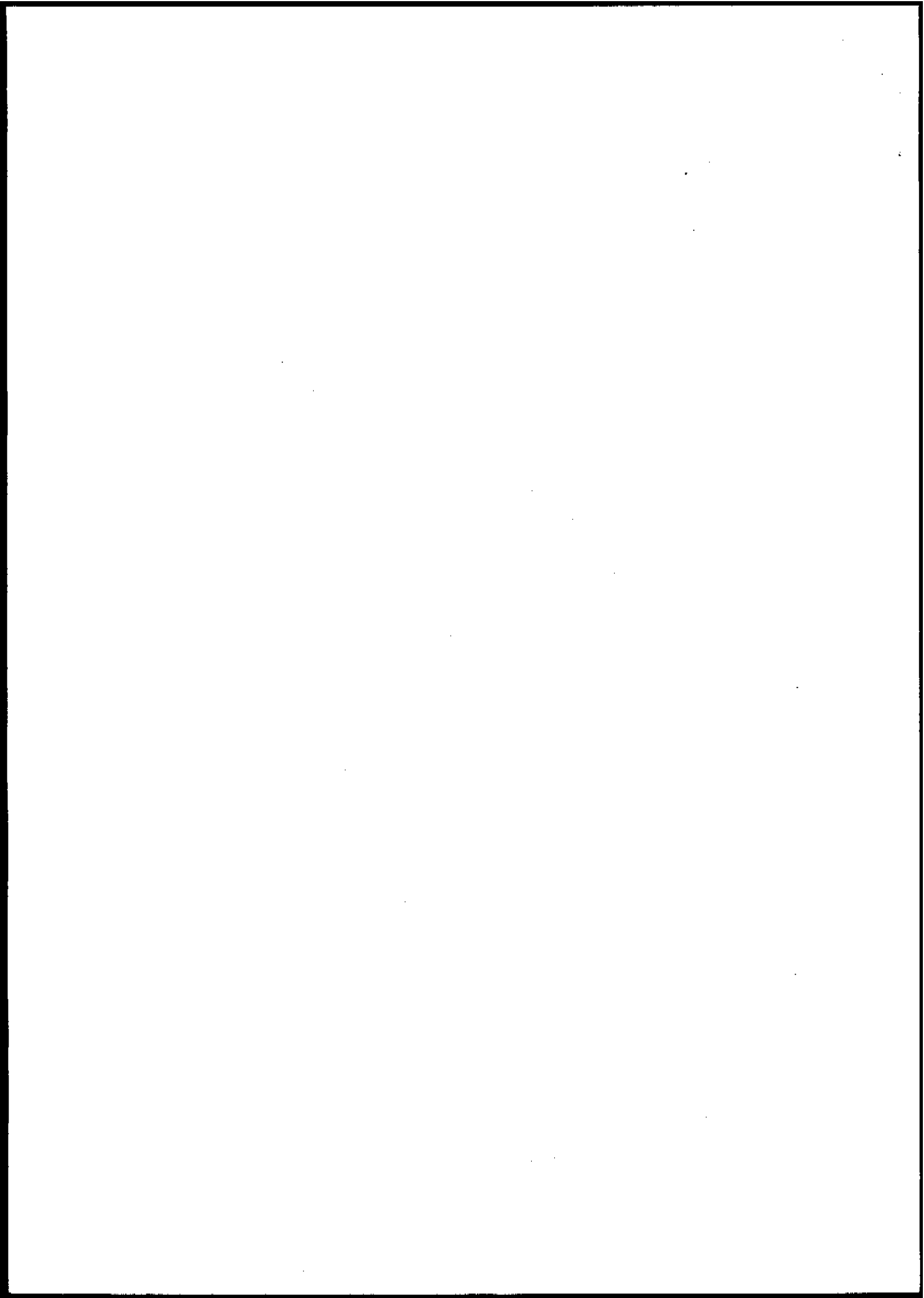
DRUGS - classification
DRUGS - administration and dosage
NET

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^a *Targets for health for all.* Copenhagen, WHO Regional Office Europe, 1985 (European Health for All Series, No. 1).

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1. Introduction

A consultation on systems of classification for pharmaceuticals (ATC) and for defined daily doses (DDDs), funded by the Ministry of Welfare, Public Health and Cultural Affairs of the Netherlands, was convened in the WHO Regional Office for Europe on 5-6 October 1989. This consultation drew up recommendations for a possible broadening of the uses of the ATC system and the DDDs to areas other than drug utilization studies; e.g. cost-containment measures.

The Ministry of Welfare, Public Health and Cultural Affairs has now developed a cost-containment system for pharmaceuticals to be introduced in the Netherlands in April 1991 using the ATC/DD system in a slightly adapted form.

The aim of the Second Consultation was to present the new Dutch system to the Collaborating Centre for Drug Statistics Methodology in Oslo and to discuss the possibilities of adapting the present ATC/DDD system as developed by the Collaborating Centre in order to make it more suitable for cost-containment purposes.

The Consultation was organized by the WHO Collaborating Centre for Drug Statistics Methodology on the initiative of the Ministry of Welfare, Public Health and Cultural Affairs of the Netherlands.

2. The Medicines Reimbursement System (MRS) in the Netherlands

In the proposed Dutch MRS, the medicinal products are classified according to the following main principles.

1. The classification reflects the actual use of the medicines, thus making the classification applicable not only to cost-containment measures but to other purposes as well; e.g. research, promotion.

2. The classification groups together those products that have comparable therapeutic effects when given in the proper dose.

3. Standard daily doses (the average daily dose that will produce the expected therapeutic effect) are established for the various products within each therapeutic group, thus making it possible to change from one medicine to another within each group.

It is assumed that if drugs within a therapeutic group are equipotent when given in the standard daily dose, then the medicines within each group may be interchanged.

If medicines are classified according to such a system it is possible to introduce limits for reimbursement within each therapeutic group.

The following points are taken into consideration when classifying the medicines:

Therapeutic equivalence

Medicines are considered to be therapeutically equivalent only if they represent real therapeutic alternatives to each other with respect to indication, adverse effects, interactions and pharmaceutical dosage forms. In addition, it should be ensured that the groups reflect the way drugs are actually being prescribed and used.

Unequivocal classification

Each pharmaceutical dosage form should belong to one therapeutic group only.

For a pharmaceutical product that have more than one indication, the main indication is chosen as the basis for the classification and the establishment of the standard daily dose.

Standardized methodology

A uniform methodology should be used when classifying the medicines, and standard average daily doses for each class of drugs should be available.

Consensus on the methodology

The methods used for classifying the drugs and establishing the standard daily doses should be agreed upon by consensus to ensure acceptance by prescribers and the pharmaceutical industry as well as regulatory authorities.

Updating

A system for regular updating of the classification and the standard doses should be available.

The first proposal for a Dutch Reimbursement System was submitted to the Dutch Parliament in May 1990. At the same time it was sent to all relevant parties for comments.

Based on the results of the hearing the following criteria were established for considering medicines to be interchangeable:

- (a) the medicines should have the same or comparable main mode of action and be used on the same or a comparable main indication;
- (b) there should be no therapeutically relevant differences in the adverse reactions profile;
- (c) the medicines should be administered in the same way;
- (d) the medicines should be intended for the same age groups.

Comparison of the ATC/DDD system and the classification used in the MRS

The Dutch system uses the ATC/DDD system as a starting point when classifying their drugs. It has, however, been necessary to modify the system in certain therapeutic groups to fulfil the criterion of interchangeability set for the Dutch cost-containment system. The ATC classification and the Dutch classification do, however, run parallel in most groups.

Examples of differences between the ATC/DDD system and the MRS system

According to the criteria for the MRS classification all drugs within a group should have the same mode of action. This requirement does not apply in the ATC classification. Therefore, if groups in the ATC system at the fourth level contain active substances which have different modes of action, then the MRS classification will differ from the ATC classification.

The criterion of interchangeability includes the requirement that the medicines in each group should be administered in the same way. This criterion is not taken into account in the ATC system. It is, however, reflected in the system for establishing DDDs.

In the MRS classification there is a distinction between the various dosage forms; e.g. dosis aerosols and powder inhalation. In the DDD system this distinction is made for some dosage forms but not for dosis aerosols and powder inhalations.

The system for establishing DDDs for dermal preparations is weak in the ATC/DDD system and would benefit from further improvement.

The requirement that drugs in the same group should be intended for the same age group is at present not reflected in the ATC/DDD system.

Furthermore the ATC/DDD system does not reflect differences in side effects.

The MRS classification code

To illustrate the way in which medicines are classified according to the MRS system, the H₂-antagonists are taken as an example:

H₂-antagonists

ATC classification A 02 BA.

MRS classification 0 A 02 BA A 0 V (positions 9 and 10 are not indicated; the "V" is in position 11).

Positions 2-6 in the MRS system are identical with the ATC classification.

Position 1 in the MRS system indicates how many other groups exist that have the same mode of action but belong to different chemical classes. In the example the zero indicates that in this group there is only one chemical class and the whole class has the same mode of action.

Neuroleptics and NSAID drugs are examples of groups which consist of more than one chemical class. The different chemical classes can be recognized by their ATC code in positions 2-6.

Position 7 connects the MRS classification to the ATC classification. It is used to separate active substances with the same mode of action but with a different adverse reaction profile. Position 7 is also used for separating substances, such as vitamins, and for subdividing ATC classification groups which have an "X" in position 5.

Position 7 is also used when the ATC classification at the fourth level contains substances with the same mode of classification, but different indications, or when it contains substances with different modes of action.

In the example position 7 is filled with an "A". This "A" indicates that the classification of the group corresponds completely to the ATC classification. Any other letter than "A" indicates that modification of the ATC classification has been necessary.

Position 8 indicates route of administration. The "O" in position 8 indicates oral use.

Positions 9 and 10 are for administrative purposes.

Position 11 indicates the age groups for which the medicines in the group are intended. The "V" in the example stands for adults.

Establishment of standard daily doses

The defined daily dose (DDD) system is the standard for the determination of the standard daily dose in the MRS. The DDD values correspond well with the doses that are normally used in the Netherlands for the great majority of drugs, particularly for the more recently introduced ones. The DDD system does not, however, follow shifts in main indications, but this has not been a problem for the MRS. In a few cases the DDD values are very different from the doses used in the Netherlands.

The establishment of standard daily doses needs a different approach if the quantity of an active substance prescribed per day will influence the period of treatment. This problem should also be considered also when establishing DDDs.

Discussion

Basically it would be desirable to have a classification system which serves the following purposes:

- (1) price comparisons
- (2) adverse reaction monitoring
- (3) regulatory purposes
- (4) research.

The ATC system has been developed for drug utilization surveys and research. When using the system for other purposes, there may be problems.

It was agreed that the Dutch classification system was more suitable for price comparisons than the ATC/DDD system. It was, however, felt that it would

be extremely difficult to obtain international agreement on a classification as detailed as the one used in the MRS, since there will always be differences between countries in the way drugs are being prescribed and used. It was therefore recommended to try to reach international agreement on a main classification according to the ATC system but that the more detailed adaptations of the system should be made at national level. The ATC system should be kept as an international core, and the fifth level could be used to modify the system for various purposes.

It was also agreed that certain classifications in the ATC system should be reconsidered to see whether they could be improved thereby reducing the differences between this system and the MRS.

Action. An overview of the MRS classifications that differ from the ATC classification will be sent from the Ministry of Welfare, Health and Cultural Affairs in the Netherlands to the Collaborating Centre for Drug Statistics Methodology in Oslo. The Centre will consider these classifications and see if it will be possible to change the present ATC codes.

3. Use of the ATC/DDD system in price comparisons

The participants agreed that when presenting the use of the ATC/DDS system for the purpose of price comparisons, a positive approach should be taken, e.g. by giving clear instructions as to how the system could be adapted to serve that particular purpose.

4. Classification of drugs and establishment of DDDs for new drugs released in the Netherlands

The number of new substances introduced per year in the Netherlands is very low (approx. 10) and should not represent a problem to the Collaborating Centre in Oslo.

The classification of combination products is, however, problematic and it will be carried out at national level in the Netherlands, as recommended by the Collaborating Centre.

The establishment of DDDs is a problem when the total treatment dose is constant whilst the number of days used for the treatment may vary (e.g. iconazole) and harmonization of the DDDs for such substances should be reconsidered.

The establishment of DDDs for dermatological products is also difficult and may need further refinement. At present, the consumption of these products is calculated on the basis of grams of active substance sold.

5. Handling of classification requests by the Collaborating Centre

If a new drug belongs to an established drug group and the classification is straightforward, the Collaborating Centre will decide on the code. If the new drug belongs to a completely new therapeutic class, the classification will be decided upon in consultation with an International Advisory Board which meets twice a year. In urgent cases the Board may be consulted in writing.

It is important that the necessary background documentation is submitted to the Collaborating Centre together with the request for classification. The documentation should preferably come from independent sources, e.g. articles from recognized medical journals, etc. and not only from the manufacturer. To establish new DDDs it is necessary to submit results of studies where the drug in question has been compared with a recognized drug.

The Netherlands will need relatively quick decisions on their requests for ATC classification and establishment of DDDs.

6. Third consultation on the ATC/DDD system

A third consultation will be organized at the Collaborating Centre in Oslo on 26-27 February 1991.

The aim of the meeting will be to:

- (1) define the various purposes and uses of the ATC/DDD system
- (2) reach a consensus on a core classification
- (3) decide on recommendations for the various uses of the system.

Proposed participants:

Dr I. Trolin, Sweden
Dr G. Battaglino, and
representatives from the
Collaborating Centre
Ministry of Welfare, Health and Social Affairs of the Netherlands, and
WHO, Copenhagen.

The cost of the meeting will be covered by the Netherlands.

The meeting will be organized by the Collaborating Centre in Oslo.

Action. Mr K. Öydvín will send a budget proposal for the meeting to Dr de Vos.

7. Establishment of a new Advisory Board assisting the Collaborating Centre

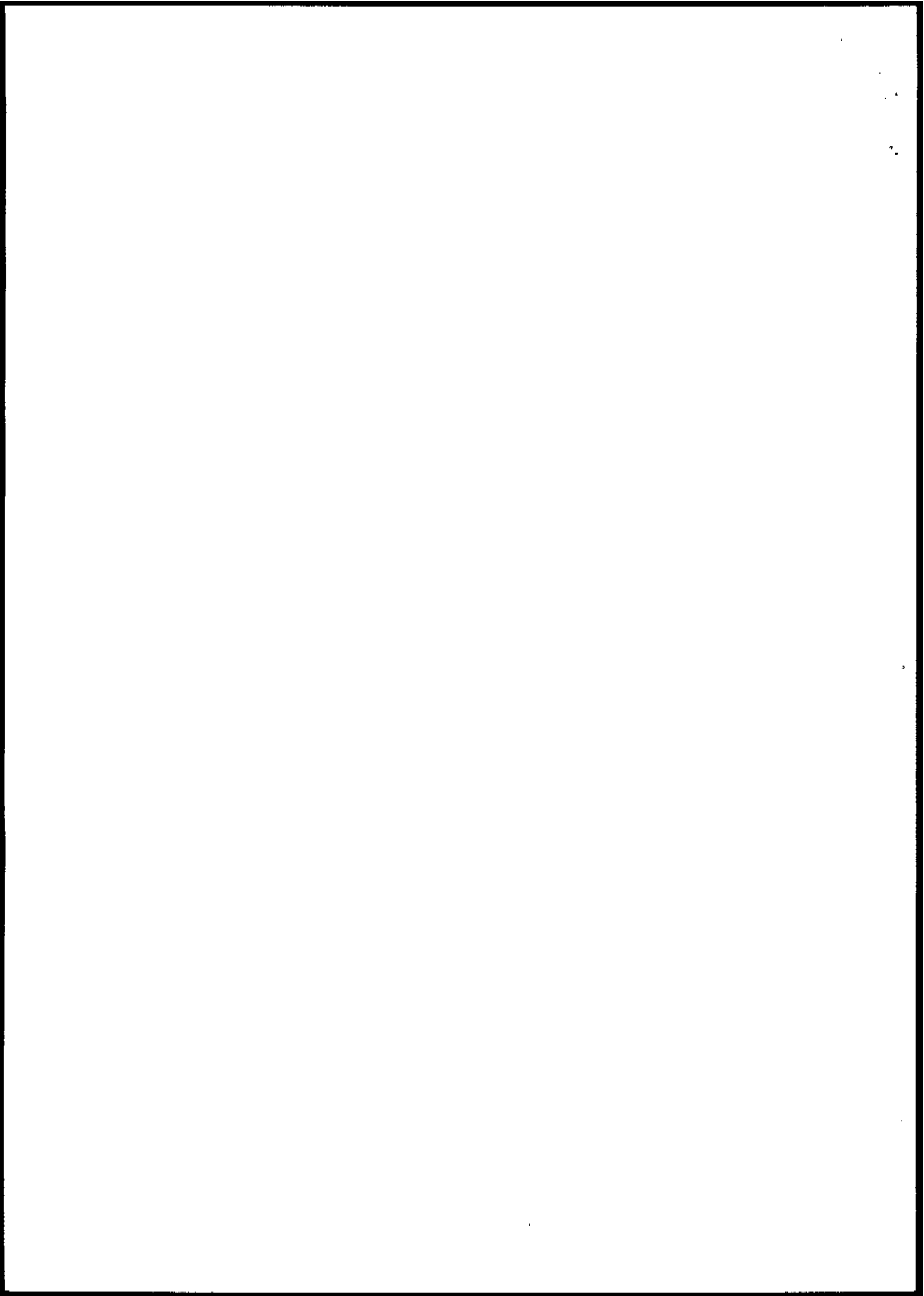
It was suggested that a representative from the Ministry of Welfare, Health and Social Affairs of the Netherlands should become a member of the Advisory Board to ensure harmonization in the classification.

A proposal for a new Advisory Board will be prepared by the Collaborating Centre and discussed with the WHO Drug Utilization Research Group which will meet in Verona in June 1991.

Annex 1

LIST OF PARTICIPANTS

- Mr B. Jöldal
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Grain de sel

"SOURIEZ"

Voici une bonne résolution à prendre dès maintenant pour 1991 !

La légende dit :

"Lorsque vous faites la grimace 37 muscles travaillent, et lorsque vous souriez, seulement 4 fonctionnent, alors.....

économisez de l'énergie....

SOURIEZ !"

