TRAVELLING SEMINAR ON QUALITY CONTROL OF PHARMACEUTICAL PREPARATIONS

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# CERTIFICATION OF IMPORTED PHARMACEUTICAL PREPARATIONS

by

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Dr. Wallen in his two page paper has capably given brief background information on the evolution and development of the present recommended certification scheme for imported pharmaceutical preparations.

2. Originally on the subject of improving the quality of drugs in international commerce the 20th W.H.A. requested the Director General to report to the 21st W.H.A. on the principles which should be included as regulations under Article 21 of the Constitution, supplemented if necessary by recommendations under Article 23. The 21st W.H.A. also after studying the Director General report and his suggested certification scheme to be included as a regulation and his Requirement for Good Manufacturing practice as recommendation, also passed a resolution requesting the Director General to report to the 22nd W.H.A. on the inclusion of a certification scheme on the quality of pharmaceutical products in international commerce and the requirement for good manufacturing practice in regulations and recommendations respectively.

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Now going over the resolution of the 22nd W.H.A. on the subject I couldn't recognise any mention on the previously suggested inclusion of the certification scheme as a regulation under Article 21 of the W.H.O. Consitution.

3. The regulation of the certification system is, in my opinion, the only way to make most of the drug exporting countries implement the scheme and consequently make all good drug manufacturers and national control authorities implement the recommendation of good practice in manufacture and quality control of drugs.

The suggested certification scheme (Annex 12 - 2)

1. The suggested certification scheme as it appears in Annex 12 - 2 was developed after study and thought, and if implemented as a regulation would definitely maintain a higher standard of quality of drugs in international commerce and would eventually eliminate bad manufacturing firms who are now specialised in exporting sub-standard drugs to developing countries.

2. However the suggested system for certification of individual batches although both vital and practical yet it cannot be applicable and available to importing country unless the batch has already been contracted for. In, my opinion, it is necessary to be able to get an official separate certificate from the public health authority of the exporting country certifying simply that they have authorised a certain drug to be placed on the market for use within the exporting country,

or otherwise give reasons why the drug is not so authorised. Such a certificate could be made available before any order is made or a contract signed by the importing country and it could be presented by the manufacturer with his offer. Such a certificate could be made a requirement for registration of drugs.

3. Success of the certification scheme in serving its intended purpose would depend on the following:-

a- enforcement of the international regulations and recommendation by all exporting countries in an equal manner, specially in their national legislation and enforcement by a well equipped and qualified national drug control authority.

b- The publication of up to date international specifications for pharmaceutical chemicals and finished pharmaceutical preparations covering all the range of drugs and their active constituents, presently used in the world.

c- The publication of up to date international specifications for the quality control of these drugs and their active pharmaceutical chemicals.

d- The availability of International Reference standards authenticated by W.H.O.

e- The drafting of certain specific regulations that should be included in the national legislation of each member country.

f- Development of national quality control laboratories in importing countries.

4. From our experience we have found the certification system, where available, is really useful. As a requirement for registration of any brand of drug a certificate from the national health authority is required. Some countries issue certificates in line with the suggested scheme and in these cases we have mostly found the products and manufacturers certificate are reliable. Attention should be drawn, however, that these countries are some of those who enforce very comprehensive legislation and have adequate means for effective control. As previously mentioned the certification system may not be all that effective and reliable if the exporting country does not enforce effective control on locally manufactured drugs. That why laboratory control facilities in the importing country is indispensible.

5. In conclusion, I think the suggested certification system could fullfil its objectives if it was passed as a regulation under Article 21 of the Constitution and if W.H.O. enhanced its efforts at central, regional and national levels to implement, develops provide and avail the facilities outlined in para 3 (a to f) above, which I believe are the factors that could make a success of the scheme.

COMMENTS.

Certification of Pharmaceutical Preparations

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In this presentation I would only like to comment on some points which really need some clarification from a more informed expert.

The aim of both the suggested certification scheme and the recommended good practice in the manufacture and quality control of drugs is to achieve good quality drugs in international commerce i.e. the supply of good quality drugs to importing countries.

As I pointed out in my brief paper, in both the 20th and 21st W.H.A. , the certification scheme was suggested as a regulation under article 21 of WHO constitution, while the good practice in manufacture and quality control of drugs was suggested as a recommendation under article 23 of the constitution.

It seems to me now that the 22nd W.H.A. has only recommended that member States adopt and apply the requirement for Good Practice and the certification scheme. I really do not know the reason for the change of attitude .

It seems to me that only through the regulation of the certification scheme that we could get, first its adoption and application by many exporting countries, and secondly to get implementation of recommended

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Good Practice in manufacture and quality control of drugs both by manufacturers and by the responsible public health authorities in these exporting countries.

As far as I know from my limited and not very reliable information the regulation of the certification system met with some opposition in the Executive Board, firstly because it could embarass honest countries and secondly because it might be rejected by a majority of drug exporting countries, I which case it might not serve its purpose.

Anyway it seems that the suggested certification scheme was tightened up a bit in comparison with the system previously suggested as a regulation, possibly to make up for its change into a recommendation coming to the certification scheme itself, it requires that -

1- The responsible public health authority of the exporting country to establish a list of manufacturers satisfying the requirements of Good Practices in the manufacture and quality control of durgs, to be exchanged between interested Governments. I do not know whether"interested Governments" means "any Government" on request or not

Yet here, and in the absence of a regulation, one wonders whether such a list will be freely given to any Government on request;

2- The responsible P.H. authority of the exporting country should certify on request that a certain manufacturer is satisfying the requirements of G.P.M.Q.C.D.

Also here one wonders, in the absence of a regulation, whether

the responsible P.H. authority of an exporting country could be willing nd able to certify that a certain manufacturer is not satisfying the requirement of G.P.M.Q.C.D.

3- Thirdly, the certification of individual batches as being produced in accordance with the requirements of G.P.M.Q.C.D. Does this mean that a manufacturer could get a certification with respect to a certain individual batch while he may not be respecting the requirements of G.P. with respect to his other products.

4- In the suggested batch certificate, one finds that it - includes a certification that the drug in question is authorised for use in the exporting country - and if not, to state the fact and give reasons therefore.

This is one certification which I think is important not just for a certain batch, but for any drug generally, and inspite of its limitations it could serve a good purpose in case a drug is not authorised for sale in the home market.

Lastly, as I mentioned in my paper, the certification scheme could serve its intended purpose if it was supplemented by efforts by WHO to :-

1. ensure that adoption and application is implemented in all drug exporting countries in a near equal manner through harmonisation of legislation and provision of adequate enforcement facilities and efforts;

2. publication of up to date international specifications for pharmaceutical chemicals finished products;

3. publication of up to date quality control specifications;

4. making available as many reference standards as possible ;

5. and lastly, but important under the circumstances, to provide effective assistance in the establishment and development of quality control laboratories in importing countries.