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## Does the admission procedure lack the fourth hurdle (socio-economic criteria) ?

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**Summary** — Besides the 3 aspects of drug safety, *ie* stability, efficacy and harmlessness, a fourth hurdle for veterinary drug licensing is discussed: socio-economic criteria. These criteria have not yet been established and the scientific aspects are difficult to define. After discussion of the advantages and disadvantages of the fourth hurdle, the conclusion is that there is no need to introduce a fourth criterion into the admission procedure for veterinary drugs, feed additives or any other chemicals which increase animal health or promote their growth.

**admission procedure / veterinary drug / safety criteria / socio-economic aspect**

**Résumé** — **Faut-il faire intervenir un 4<sup>e</sup> critère (critère socio-économique) dans la procédure d'enregistrement ?** À côté des 3 aspects de la sécurité d'emploi des drogues (stabilité, efficacité et innocuité), un 4<sup>e</sup> critère (socio-économique) pour l'autorisation des drogues vétérinaires est discuté. Ce critère n'est pas encore établi et est difficile à définir sous un angle scientifique. Après discussion de l'avantage et de l'inconvénient de ce 4<sup>e</sup> critère, on peut conclure qu'il n'est pas nécessaire de l'introduire dans la procédure d'admission des médicaments vétérinaires, des additifs alimentaires ou autres produits chimiques qui améliorent la santé des animaux ou favorisent leur croissance.

**procédure d'enregistrement / médicament vétérinaire / critère de sécurité / aspect socio-économique**

I have been invited to this meeting to present some ideas regarding the requirements for the official admission of veterinary drugs or feed additives which are used to increase animal health and food production. The title of this presentation is a question, which may be answered very briefly by: "no!" This answer must be explained as follows.

There have been no investigations at all on this subject. So it is totally open for discussion by experts, non-experts or self-made experts.

Three hurdles have to be overcome for the admission of drugs: i), pharmaceutical properties such as durability and stability of the pharmaceutical formulation; ii), efficacy of the drug; iii), harmlessness of the chemical substance for animals treated with it and for consumers of the meat from treated animals.

All drugs which fulfill the 3 requirements totally are licensed without consideration the need in practical treatment or feeding management. The free drug market will decide if a drug is useful, or

better than already existing drugs. Free competition exists in our free market political system. Nowadays there are some compounds used in animal production in some countries for increasing meat, milk, fish and egg production, in general to increase feed production and that in an age of overproduction of food in some countries, at least in the member states of the EEC.

The same situation may occur in the field of food production from plants using fertilizers and pesticides. The effort to increase the economic income from plant and animal food production is legal and as such should be protected by the government.

So at present and to an increasing degree in the future we have to ask if this development of artificial food increase from animals by using pharmacological methods is really necessary. I shall try to provide some answers, but before that I have to define the questions. I am sure that there will be more than one question and answer depending on the political situation and on the stage of knowledge.

Three hurdles which I have just mentioned above have to be overcome and must be surmounted during the admission procedure by the authorities. The hurdles are established observing international standards and agreements following some developmental stages of drugs: i), pharmaceutical science: analysis for purity even after long storage and for durability even after being submitted to unusual conditions; ii), pharmacology describes the pharmacological responses of laboratory animals, or the antimicrobial effects, or the effects against parasites *in vivo* as well as *in vitro*. Sufficient doses and duration of effect, drug elimination as well as some other conditions which may influence pharmacological and toxic effects can be analysed. After statistical analysis of the

results we are able to predict the clinical effects upon health of animals. Furthermore, we can analyse those effects which have not been discovered during the pre-clinical assays and investigations and which may occur only in target animals treated after the license. So clinical pharmacology is responsible for the safety of use of veterinary drugs in veterinary treatment, or for other purposes such as growth promotion; iii), clinical investigations under standard conditions verify the efficacy and usefulness of the drug in sick animals.

After all the investigations we are in a position to describe the advantages and disadvantages of the new chemical which is going to be used in veterinary treatment. We are able to predict the risk, because well established control methods have been introduced into drug science. Following these procedures the scientific assessment of all veterinary drugs is therefore possible.

It is another question whether all veterinary drugs are investigated in this way. Many old or very old drugs are really still used in veterinary practice though our knowledge regarding their efficacy and harmlessness is inadequate today.

The Drug Act of Germany (and I am very sure of other member States) is the basis for re-controlling these chemicals and many of them will disappear from the drug market in the very near future, if no further investigations are carried out to increase the knowledge regarding those drugs.

At the present time, there is wider public discussion (mostly by those without any special knowledge about the real problems in these fields) regarding the requirement of an additional aspect of investigation. The question is whether the new drug is of economic importance for the society in a general sense from the point of view of overproduction of food of animal origin.

People say that those drugs which increase meat or milk or egg or fish production are not wanted in our countries. These chemicals will destroy the traditional situation of farm animal management and in so doing destroy the social relations of animal producers and food consumers in the economic society.

The socio-economic criteria (SEC) mean observation and consideration of the socio-economic structure of society as a whole. We should consider the following aspects of this new requirement: what are the criteria in detail? How can we determine and measure the criteria and quantify them? Is it necessary to observe the SEC and consider the results?

I only have my personal idea, which may be described as follows:

My first opinion is that it is not possible to predict the amount of change in socio-economic situation after use of a certain chemical in farm animals. It may be small or it may be large. Who will be able to estimate the advantage of bovine somatotropin (BST) in dairy cows in Europe or in the USA or in the developing countries in the next 10 or 20 years?

My second opinion is that the producer of the chemical and the company which will sell it are responsible for the success or failure. The free market for drugs will decide whether or not the development is in the correct direction. If the new drug is needed, maybe only in a certain type of farm animal production system or in some developing countries or under special con-

ditions, the substance should be used if the other 3 hurdles are overcome.

The results of pharmaceutical, pharmacological, toxicological and clinical investigations are obtained after following and observing international guidelines and standards. They are in general identical in every part of the world.

The interpretation of the results may be different, depending on the different benefit-risk assessments in some countries.

On the other hand, the consideration of socio-economic aspects requires different procedures and quite distinct methods. They are, if any, only related to the actual economic and political situation in a comparatively small part of the world. The member states of the European Community are not the world! Aspects change from country to country and from time to time. So after an international agreement it would be impossible to establish guidelines for these aspects in a scientific way. The decision will be made by the public or by politicians. As political decisions do not need a scientific base, they are open for public discussions between those who are involved in drug license procedures: i), drug producers; ii), drug users; and iii), in particular, public opinion. Public opinion can never be the basis for a drug admission procedure!

I have the feeling, but I am unable to prove it, that the SEC should not be introduced into the admission procedure for new veterinary drugs or feed additives!