REGISTRATION OF HERBAL PREPARATIONS: PREPARING THE GLOBAL MARKET

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Abstract

The subject of this paper is related to the economical global changes seen in the last years, which have lead to worldwide-accepted registration rules. This regulation has to consider preferentially the human welfare and takes into account the regional cultural and technological differences. A minimal quality requirement must be established and universally adopted for international market purposes.

1. Introduction

The world we knew is no more the same. This pretty place hides under this peaceful blue appearance some tragedies. Plants and animal are and will still be extinguished; social differences are deeper and stronger. Although political borders still exist, day after day, trade barriers are falling down. As examples the European Union, the Mercosur, NAFTA and other supraregional treatises can be pointed out. The dream or nightmare of an unified economic world comes through.

We can already talk about the "trade pangea", in which all continents are linked economically together, with no limitation for the exchange of goods, including naturally phytopharmaceutical drugs. Of course we have to consider, this New World will be not "could turn deeper.

The falling of the trade barriers will conduct necessarily to an orderly market. This the land of milk and honey". Regional differences will still continue to exist and they means to rules, which must be globally accepted.

In this paper some questions about the implementation of the future phytomedicine market, which have to be answered or harmonized, will be pointed out.

Herbal remedies or phytotherapics, as any drug from other origins, could be seen as a source of hope or as a menace. This can be observed in a picture taken from a German magazine "Der Spiegel" published at the end of the eighties. The postponed question was, if herbal remedies are drug or poison, and the article talked about adverse reactions and poisoning through medicinal plants and the efforts of the German Health Authorities to transform such products as valid drugs. This picture shows the inherent duality present in all things around us. At once the allegoric "caduceus" means the healing effect of medicinal plants and of the products derived thereof. On the other side the dangerous snake represents the emergent hazard plants can cause.

To protect and cure or to threat, this is the question we are trying to answer.

Another question is related to the kind of medicine care level we have to regulate. Folk medicine must be protected in order to preserve the knowledge produced by generations. The mission of the knowledge owners is to protect, to preserve and to distribute their own information, with benefits to themselves and to other populations.

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Institutional medicine knowledge, on other side, can reach several populations at the same time. It should be government duty to regulate this in order to protect the health of their own population or of a supranational regulation, which must be provided in order to fulfill these purposes. Here we can consider a worldwide acceptable **Minimal Required Quality** Statement.

During WOCMAP II we have listened a lot of words related to the designation of plant products used with therapeutical aims. Phytomedicine, herbal preparations, phytoremedies, drugs, and so on. We have to find some day the most appropriate denomination. More important, however, and with common sense, such products must really show efficacy, safety and a constant and determined quality. These products have to be seen as a drug for every one, and not for "poor people" so it has to be accepted as any drug and not as a "second class" one.

Possible points of regulation could be:

- The origin of the plant raw material, that means it cultivation,
- Harvesting techniques and care, including post-harvesting actions and transformations,
- The supply of raw materials for industrial purposes,
- The industrial production of phytopharmaceutical products,
- The consumer's behavior and relationship to such products.

In the case of cultivation, familiar or community agriculture answer better to education than to legislation. Industrial cultivation on other side must comply several rules at least to avoid ecological risks, mainly those related to the preservation of biodiversity. This could be a good point for global legislation and also for local normatization, considering the regional necessities and peculiarities.

While for extrativism (wild harvesting) the better solution is education, except for those endangered plants, industrial harvesting is easier to control. The same consideration is valid for the international plant market.

The adequate distribution of plant material through suppliers must result from a direct agreement between industry and supplier. The industry has to specify the required quality for their own raw material, this could be also achieved by the establishment of appropriate Good Herb Supplier Practices. Governments can only control and regulate exported and imported plants.

For the industrial production of phytopharmaceutical products, as final and or intermediate products, the compliance of GMP rules existing since long time ago must be considered. The question to be answered is related to a possible adaptation of this Norms to the peculiarities of the phytopharmaceutical industry.

Of course the same legislation has to be applied for both governmental and private industries, because they produce the same product (Or may be not?).

Legislation means frequent control. What is easier to control? Products or industrial facilities? The answer can be found in another question: How many products do we have in the market in Argentina, Brazil or anywhere?

Thus a GMP-conform Laboratory will produce, with high probability, good products.

Finally, the consumer protection is a result of the control of the products, which are in the market and of the advertisement media.

For the registration of phytopharmaceutical products the WHO suggested and encouraged the assessment of traditional use, when sufficient and proved information exists. A question still remains: What means traditional use? Can a plant popularly called "penicillin" be accepted under such title "traditional used"? Are traditional informations enough for confirming efficacy and or safety?

Another question to be answered: The absence of adverse reactions reports is satisfactory to prove the product is safe?

The constant quality compliance of phytopharmaceutical products is also a weak point

in the legislation. What quality is necessary and what quality is feasible or possible?

Many countries and institutions have developed registration monographs in order to facilitate the registration. Here the question to solve is related to the adequacy of medicinal plant monographs to ensure quality, efficacy and safety of phytopharmaceutical drugs, or are specific product monographs more adequate.

To achieve the requirements of efficacy, safety and quality of phytopharmaceutical products, a great number of unsolved problems still exist, such those related to:

- Inexistence of multidisciplinary centres in adequate quantity and quality,
- Lack of knowledge for several plants, mainly for the non European ones,
- High costs linked to the testing (chemical, biological, agricultural, etc.) of such products,
- Time consuming of some research results,
- The insufficient analytical and development knowledge,
- A lot of people think such products are "magic products" or belong to a "second class medicine" and therefore the requirements have to correspond to such classification (soft products = soft requirements).
- Many governmental actions are still ineffective and few efforts are done in order to promote quality as an inherent and normal requirement of pharmaceutical drugs.

So, as it is seen, more questions than answers exist. Our mission, up to now, is to find solutions which may consider

- A worldwide acceptance of a minimal quality requirement. Quality is fitness for use and not only conformity to chemical and physicochemical characteristics.
- Phytopharmaceutical products are drugs and not any kind of product or a second class remedy.

Our efforts have to be directed now to find the harmonized Minimal Quality Requirements, which have as principal directive the beneficial use of phytotherapeutical drugs by Mankind.

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