
WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

Switching around the world: Mexico

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I would like to thank the organisers of this Pre-Assembly Workshop for having invited AFAMELA to present the switching developments which have occurred in Mexico during the past years and to provide a perspective of the Rx to OTC process in the coming years. You may wonder how a developing country like Mexico has a considerable amount of OTC brands, close to 500, and is one of the countries with the highest number of active ingredients authorised as OTCs, even though:

-Mexican consumers do not have the same level of medical education as their counterparts in North America or Europe,

-self-prescription is still widely practised and

-a general reimbursement system for medicines does not exist in Mexico.

Before I explain how Mexico has reached its current circumstance, I will brief you about the main switches which have occurred in the past years. Once I have mentioned the key factors that have led to such switches, I will provide a perspective of the near future. I will end this presentation by making some conclusions which might be taken as lessons for other developing countries.

Main switches in Mexico between 1995 to 1998

From 1995 to 1998, Mexico experienced impressive growth in the number and diversity of products and active ingredients authorised as non- – prescription medicines. During this period, the Mexican Ministry of Health authorised the switching of at least 200 non-prescription products and those active ingredients known as “ second

generation “ or “ major switches “ such as vaginal miconazole, naproxen sodium, H2 antagonists, topical ketconazole, etc. The market also had remarkable growth in qualitative terms since some well-documented herbals were incorporated into the group of non-prescription products. Herbals such as Gingko Biloba, Valerian, Saw Palmetto, Hypericum Perforatum, just to name a few, brought not only new therapeutic alternatives but expanded the self-medication scope. Vitamins and minerals that do not exceed their safety limits or are presented as injectables also contributed to the expansion of the group of non-prescription medicines.

Due to these switches, the Mexican non-prescription market currently is comprised of 500 different non-prescription brands, classified in 41 different therapeutic categories. This diversity allows Mexican consumers to relieve or to prevent common ailments and symptoms and to treat recurrent conditions or fight against tobacco addiction.

Another good example of the remarkable switching development occurring in Mexico took place last year, when the Ministry of Health authorised the switching of 31 active ingredients. This was a notable event since it was the first time in which Mexican health authorities made a decision based upon ingredients rather than specific products. This authorisation brought newer or better non-prescription ingredients, mainly topical antifungals, analgesics, antibiotics and corticosteroids. It also opened new therapeutic categories such as systemic antispasmodics, cystitis remedies and gastric protection.

Last, but not least, this decision meant a giant leap forward in the position the Mexican market has in terms of the availability of non-prescription products in comparison with other countries. It now has 77 OTC ingredients out of the 194 included in the last WSMI Compilation of Selected Ingredients in 19 countries. With this amount of ingredients Mexico ranks sixth among coun-

tries with the highest number of OTC ingredients, not too far behind the leaders such as the United Kingdom, Germany, Canada and Australia, and ahead of the United States and Japan.

It is also important to note that, with the exception of two main categories such as mild asthma preparations and trichomonocides and a few ingredients like oral fluconazole, tretinoin, ibuprofen 400 mg and non-sedating antihistamines, the Mexican market has a similar variety of therapeutic options that exists in some developed countries.

Key factors having led to the switches authorised in Mexico

Among the leading factors that can be identified as the main causes for the impressive amount of switches authorised in Mexico from 1995 to 1998, I think that the positive attitude shown by the Ministry of Health towards responsible self-medication in this period deserves mention. This open disposition has not only reflected a full understanding of the inner characteristics and benefits of this practice, but has also represented a dramatic shift from the attitude the Ministry had towards self-medication and non-prescription products in the recent past. No more than ten years ago, the Ministry of Health had a cautious attitude towards non-prescription products based on the assumption that their availability might lead to improper use, delay of diagnosis and squandering of resources. Non-prescription products were merely considered commercial phenomenon aiming to expand a product's life cycle and to increase pharmaceutical companies' profits.

Different reasons may explain the dramatic change in the Ministry of Health's attitude. On a general level, I might say that from the beginning of this decade the Mexican government has tried to penetrate into the existing globalising trends or practices and, in this way, to become a modern society. NAFTA (the North-American Free Trade Association) has also played its part in this process in spite of the fact that the three parties did not negotiate registration or distribution of medicines within this agreement. Basically, NAFTA gave the Mexican Ministry of Health exposure to the experiences and points of view of their counterparts in Canada and the United States with regard to responsible self-medication and OTCs.

These two factors may explain the Mexican Ministry of Health's renewed open position towards responsible self-medication and the development of a practical / realistic approach for Mexico. Without losing its inner meaning and/or well-recognised benefits, the Mexican Ministry of Health has looked at responsible self-medication as an alternative to the widely practised self-prescription. This viewpoint has led to the development of switching guidelines, the organisation of a specific department to assess the registration or switching of non-prescription herbal products, and of course, to the significant number of switches that have taken place.

As you may imagine, AFAMELA played a key role in the development of the renewed attitude of the Ministry of Health towards responsible self-medication and OTC products. AFAMELA witnessed and supported such at-

titudes as it has continuously provided an updated flow of information on the benefits, evolution and latest trends in responsible self-medication. In addition, AFAMELA's proposals have always been backed up by the prestige WSMI had among Mexican health authorities, stressing the fact that AFAMELA follows WSMI guidelines or policies in such a way that it can be considered as its Mexican "arm". A good example of this position lies in the fact that the Mexican Ministry of Health looked at the WSMI Compilation of Ingredients as a reliable document for the switching of 31 active ingredients that took place last year.

With regard to what could be expected as the future of switching in Mexico, I would say that such future would mainly be based on the reclassification of brands containing any of the aforementioned number of active ingredients. This reclassification may lead to a dramatic expansion of the market, as it would bring a considerable number of OTC products into the market, introduce better ingredients and open new therapeutic categories. With regard to drugs for the treatment of chronic conditions such as hypercholesteremia, osteoporosis or diabetes, which represent the next step in the development of responsible self-medication, there is no doubt that Mexican consumers could make adequate use of them. Nevertheless, I may say that before these drugs are switched, Mexican consumers need to raise their consciousness of the need to seek medical consultation, an essential practice for the proper management of drugs in the aforementioned conditions.

Conclusions

As a representative of a national manufacturers association, I would like to make reference to some activities developed by AFAMELA which may be replicated by other associations in the developing world interested in helping their Ministries of Health understand the benefits of expanding responsible self medication through effective Rx-to-OTC switching.

- First, AFAMELA positioned consumer empowerment and pharmacists orientation in the proper use of non-prescription products as the key elements that lead and support a sound switching process. Consequently, AFAMELA had developed an educational campaign for consumers and supported the development of educational material, or the organisation of training courses for pharmacists.
- Second, AFAMELA promoted the dissemination and exchange of information on the latest trends and advancements in responsible self-medication between health authorities, academia and the industry as a means to have them properly informed in this area and to reach a common criteria among these groups.
- Third, AFAMELA has promoted the development of a transparent and predictable regulatory framework for the registration, switching and advertising of non-prescription products as long as a set of proper regulations in such areas are key elements for a sound responsible self-medication development.

Summarising, I may say that strong Rx-to-OTC switching can take place and have positive results not only in developed countries but also in those known as

developing ones. In particular, the experience in Mexico shows that switching provides benefits to public health, as long as the availability of non-prescription products reduces the risks that arise from the use of Rx products without medical intervention, since the OTC products come with all the information needed for proper use. In

the case of developing countries, this may be taken as a specific benefit to be added to the general purpose that Rx-to-OTC switching has of giving support to people's common need and universal demand of taking care of their health by themselves.

