European Federation of Associations of Health Product Manufacturers
EHPM

EHPM Comments on Roadmap for the Review of Health Claims Regulation

Introduction

EHPM welcomes the roadmap for the review of specific elements of Regulation (EC) No 1924/2006 on nutrition and health claims. The first page of this paper will focus on the specific issue of botanicals. The second page will list some other elements of the health claims regulation which the 2016 consultations are not intended to address but which will need to be addressed at some point if the regulation is to function effectively.

Botanicals

EHPM considers that the questions in relation to botanicals listed in the roadmap are the correct ones to be focussing on. The roadmap provides an excellent summary of the situation as it stands and the issues that need to be addressed. Some preliminary observations from EHPM are:

- **Economic Study:** The roadmap makes reference to an external contractor that will be hired by the Commission to prepare a study on the botanicals issue. The economic importance of the sector, both in terms of level of sales but also jobs linked to the industry is extremely important. The majority of the companies operating in this sector are SMEs that simply cannot afford to invest in producing the clinical trial level data sought by EFSA for all other claims. Anything other than a more proportionate assessment process for botanical claims will inevitably lead to significant job loss. We consider that the Commission in framing an appropriate policy should have access to exact figures on the number of people dependent on the continued existence of the sector for employment. This study could focus on the key markets for botanicals in Europe, Italy, France and Germany for example). The study could also examine the significant legal costs for companies submitting health claims applications due to the lack of clarity on requirements. Access to key economic data when framing policy is a vital aspect of the 'better regulation' and the 'think small first' approach. EHPM strongly encourages the Commission to include a thorough economic study within the remit provided to the external contractor.
- **National Best Practice:** Many of the botanical health claims that would be rejected under the standard EFSA evaluation process are widely accepted as valid in the scientific community and were previously accepted by multiple national authorities. The fact that many EU Member States have established practice in the field of botanical regulation should not be overlooked during the review to be carried out by the Commission. Italy has the largest market in Europe for botanicals and a well-developed regulatory system. A proportionate system for assessing claims has to move away from the absolutist approach of EFSA. Foods are not drugs and should not be assessed as if they are. The Member States with the most to offer in terms of national expertise in this area are also the ones with the most to lose if harmonisation at EU level is not done properly. EHPM therefore urges the Commission to look closely at the systems in place for the use of claims in the Member States with the most developed regulatory systems for botanicals and the largest markets.
- **Borderline Issue/Mutual Recognition:** The Single Market strategy published by the Commission on 28 October 2015, highlighted market access issues posed by the lack of implementation of mutual recognition by Member States. Recent research by EHPM showed that at best 50% of Member States apply the principle for food supplements. Particularly in the case of botanicals, many products which are accepted and have a long history of use as a food supplement in one Member State are considered as a medicine in another. EHPM suggests that the Commission include the issue of mutual recognition in its consultation on botanicals in 2016.
- **Positive Lists Options:** EHPM welcomes the inclusion of the positive list option in the roadmap and consider that the BELFRIT list defined by Belgium, France and Italy could provide the basis for a harmonised solution to the management of safety at EU level. This would require further work on the list to take into account botanicals used in other Member States. An evolution of the list as described in the previous sentence could secure the backing of enough Member States for its adoption in EU legislation to be realistic. Any positive list system would also clearly require a mechanism to allow for the list to be adjusted to take into account innovations in the food supplement sector.

General Observations on Health Claims Regulation

Listed in this page are some questions in relation to the implementation on the health claims regulation that are relevant for all health claims not just the botanicals category. EHPM appreciates that these elements are not intended to be addressed in the 2016 consultations but the regulation will only function properly when these points are also tackled.

- **Are the objectives of the regulation being met?** There are serious grounds for arguing that the objectives of the health claims regulation in terms of consumer protection are not being met. Companies manufacturing in Europe, are extremely restricted in the information they can provide consumers. It is not good risk management practice to prohibit consumers from receiving at point of sale honest, accurate and meaningful information about the value of a product. At the same time, there has been a huge increase (10% in some Member States) of products sold over the internet from third countries many of which carry totally inappropriate claims and unsafe ingredients. Through examining rapid alerts for food supplements in 2014 for example, it is clear that the great majority for alerts (146) for food supplements derived from products imported from third countries. These included products with active substances not approved for use in food supplements and claims with no scientific basis. In comparison, the 49 alerts for food supplements originating in the EU were mostly related to different categorizing of the same product in different Member States. Lack of basic information previously available on labelling (often in the form of a qualified claims) results in consumers sourcing products from websites in third countries that claim health benefits that in many cases are not valid. Aside from misleading the consumer, in many cases these products are also unsafe.
- **Why are there still not pre-submission meetings for applicants?** Only 18 of 130 applications for article 13.5 health claims received since Regulation (EC) No 1924/2006 came into force have been successful. This extremely high rejection clearly shows that the current system is not working. Many companies have invested heavily in clinical trials and safety assessments only to find that these are not even considered by EFSA for reasons that could easily have been addressed had a pre-submission meeting been possible. Clinical trials can cost from €250,000 to €1 million but companies are denied the chance to discuss with EFSA to clearly define criteria before investing the money. The European Medicine's Agency (EMA) holds pre-submission meetings with applicants, which is an example of best practice. EFSA's assertion that such meetings could compromise the independent assessment subsequently carried out by its scientists does not stand up to scrutiny. If the Commission can make the resources available to EFSA to hold such meetings and instruct them to do so then investment in innovation will increase.
- **Is the standard applied to claims by EFSA appropriate?** Many of the health claims rejected by EFSA were approved by the national authorities in Member States when this area was regulated at national level. How can claims accepted as valid by multiple national authorities suddenly be considered invalid? How is it that many claims that are still widely used and accepted in other regions around the world continue to be rejected by EFSA? Much of the problems surrounding the implementation of the health claims regulation could be resolved through the NDA panel proposing conditional wordings for claims. Food may have a different positive physiological or nutritional effect with different subjects as is also the case with medicines. Even an approved medicine might work well for one subject but not for another. For substances such as glucosamine where there is clearly evidence to suggest a beneficial effect, the simple insertion of the "may" before "support joint flexibility" would provide a claim that is accurate, understandable to the average consumer and in no way misleading. For the EHPM and its members, the major short-coming with the current implementation of the nutrition & health claims regulation is that it is limited to scientifically accepted statements of fact about the relationship between isolated food ingredients and specific beneficial effects on health; it does not facilitate evaluation of the complex effects of complex food ingredients on health; and it prohibits honest, accurate and meaningful communication about the historical use of foods and about the insights of emerging science. A science-based solution is needed that addresses these issues in the context of the fundamental principles identified in the nutrition and a health Claims Regulation.

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