



PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

**PGEU Response
to the Consultation on Regulation
1924/2006 on nutrition and health
claims made on food**

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

The Pharmaceutical Group of the European Union (PGEU) welcomes the evaluation of Regulation 1924/2006 and in particular the discussion on health claims on plants used in food and the opportunity to respond to this consultation. We recognise the need to clarify the pending authorisation of health claims for food containing plants and make a clear distinction between these types of foods, traditional herbal medicines and more recently medical devices.

Traditional herbal medicines have a longstanding tradition in Europe, their effect is well understood and have been proven to cure and/or relieve symptoms in a variety of therapeutic areas. Traditional herbal medicines are often supplied via community pharmacies and pharmacists are duly qualified and knowledgeable to advise patients about the use and effect of traditional herbal medicines, possible side effects, contraindications and dosage. During the centuries of traditional use and vast investments in last decades from traditional herbal medicines' manufacturers, high quality manufacturing standards, efficacy and safety of herbal medicines are established.

Authorised herbal medicines follow an established and approved monograph that includes therapeutic dosing (posology), and are proven to be safe under established use. Herbal medicines' safety is systematically monitored within the EU's pharmacovigilance system, which is essential for developing reliable information on the safety of herbal medicines. Manufacturers producing these types of medicines have to comply with GMP standards and list possible side effects in the product labelling. The pharmacist relies on this information and the marketing authorisation when recommending traditional herbal medicines.

With regard to plants used in foods, even though in a number of cases they are the same plants or substances as the ones used in traditional herbal medicines, authorisation and labelling of such products is subject to food legislation. In addition, there are studies that have shown that these products in some cases contain higher or significantly lower amounts of active ingredient than traditional herbal medicines. Food producers do not follow the same level of manufacturing standards; neither are they obliged to list potential side effects or interactions of these products and, furthermore, those products are outside the pharmacovigilance system.

Pharmacists when dispensing or medical doctors when prescribing traditional herbal medicines have to be assured that the safety of such products is of the highest standard and have sufficient regulatory guarantees for efficacy of such product. The current legislative framework for foods containing botanicals

does not guarantee healthcare professionals that this is the case. In addition, healthcare professionals do not have a possibility to report adverse reactions or unwanted effects of those products when observed in practice.

We are concerned that should health claims for food containing botanicals be allowed under the regime laid down by Regulation no 1924/2006, traditional herbal medicines manufacturers will no longer be motivated to license their products under pharmaceutical legislation. In a longer term allowing health claims for foods containing plants without a robust scientific assessment at the highest possible standards will lower quality and safety standards of those products and endanger the traditional herbal medicines sector.

Finally, we wish to point out that medicines are intended to be used by patients to cure and/or relieve symptoms, where foods are intended to be eaten by healthy people with the greatest importance to their nutritional value and the nutritional effects of botanical ingredients is much less well understood.

PGEU believes that if health claims for foods containing botanicals are allowed without a robust scientific assessment at the highest possible standards this will imply serious, negative consequences for the traditional herbal medicines sector and will lower the quality of products containing botanicals, to the detriment of patients. **Therefore, we consider that Regulation 1924/2006 is 'fit for purpose' and should fully apply to all health claims, including health claims on plants and their preparations used in foods.**