How does the future for homeopathic medicinal products in Spain looks like?

Order SSI/425/2018 on the communication to be made by companies marketing homeopathic medicinal products in Spain under the sixth transitional provision of Royal Decree 1345/2007

On 28 of April, an order of the Spanish Ministry of Health (MOH) was published in the Official Journal (BOE 103). According to this order, companies that are currently marketing homeopathic medicinal products in Spain in a "transitory situation" must, if they want to continue such marketing, communicate to the Spanish Agency of Medicinal Products and Medical Devices (AEMPS) their intention to apply for a marketing authorization for such products in accordance with the provisions of Royal Decree 1345/2007, governing the procedure of evaluation, authorization and registration of medicinal products for human use industrially manufactured.

The former Royal Decree 2208/1994, which was repeated, introduced a transitory provision, according to which companies marketing homeopathic medicinal products in Spain could continue marketing such products as long as they had submitted an application to obtain a marketing authorization within 6 months following the entry into force of such Royal Decree. Later on, such provision was regulated by the sixth transitory provision of Royal Decree 1345/2007, which provided that companies marketing these medicinal products must submit a communication to the AEMPS indicating their intention to follow the registration procedure foreseen for these products in said Royal Decree 1345/2007. The period for sending such communication was 3 months from the entry into force of the order of the MOH, establishing the minimum requirements and the procedure to be followed in order to make such communication.

The order SSI/425/2018 has come to implement these provisions, providing that those companies which are marketing these medicinal products and which are interested in continuing doing so, must send a communication through the website enabled by the AEMPS within the corresponding period, providing the information required and, in particular, informing whether or not the product in question will claim certain therapeutic indications. If such period elapses without sending any such communication, the company will not be able to continue marketing these medicinal products, which must be withdrawn from the market.

Once the period for the submission of communications has ended, the AEMPS will have a maximum period of 3 months to set a timetable so that companies that communicated their intention to register their products may submit the corresponding marketing authorization applications.

According to the provisions of Royal Decree 1345/2007, the ordinary registration procedure must be followed, attending to the specific characteristics of this type of medicinal products. However, there is a simplified procedure available for products having an oral or external administration route, provided that no specific therapeutic indications are claimed and that the degree of dilution of such product ensures its safety. If the application is not submitted in accordance with the established timetable, companies must proceed to withdraw the product from the market.