New Advanced Therapies regulation triggers commercial launch process of SkinMed

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A New Regulatory Framework has been published in Spain, denominated “Real Decreto 477/2014, de 13 de junio, por el que se regula la autorización de medicamentos de terapia avanzada de fabricación no industrial”.

The norm allows consolidated medicaments, as our autologous SkinMed bioactive skin with keratinocites, to start commercial distribution to hospitals under the new “Hospital Exception” regulation. This regulation requests any hospital willing to use the product to register as user under the local Medicines Agency.

Biodan Skinmed will supply to any willing hospital all documentation needed for registration as user, and once registered, BioDan Skinmed will supply the skin cell culture to the hospitals. The skin will be produced either internally either internally or via subcontractors, under full GMPs.