The European Agency for the Evaluation of Medicinal Products
Product Information Management Project

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PRODUCT INFORMATION MANAGEMENT PROJECT

("PIM")

In 1999, the EMEA and the EFPIA started to develop a system for the electronic exchange of product information (SPC, Labelling and Package Leaflet) in support of new product applications or variations post-approval in the EU. The objective is to define a transport format to handle product information more effectively by reducing the effort required to produce and maintain the identical data included in the various documents and by facilitating the exchange of data between applicant and regulatory authority. In this way, the updating and reviewing of the data throughout the product lifecycle should be made considerably easier.

In February 2000, the first submission using the PIM was made as planned. The PIM is now in phase I pilot and several more submissions of product information using the PIM and linked to applications through the Centralised Procedure have been made. Analysis of these submissions has indicated substantial time and resource gains for both the applicant companies and the EMEA.

The EMEA is willing to accept the electronic submission of product information in parallel with the traditional forms of submission on a trial basis until further notice.

Companies wishing to trial electronic submission of product information using the Centralised Procedure should contact the EMEA in the first instance.

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