


EU market access for Non-EU based company based on full service support

Challenge:	Solution:	How we excelled:
 <ul style="list-style-type: none">➤ Non-EU based Client requested support with submission of a product line encompassing 4 different pharmaceutical forms (i.e. tablets, IV, Oral Suspensions and Sachets) to obtain approval in 25 European Member States➤ This Non-EU based Client also asked ERA to manage post-authorisation activities after MAs were approved	<ul style="list-style-type: none">➤ ERA assisted the client with PIP application, Regulatory Strategy and recommended obtaining MAs via Decentralised Procedures➤ ERA sourced a Reference Member State (RMS) for each of the Pharmaceutical Forms by engaging with several National Competent Authorities (NCA) and booking DCP slots➤ ERA reviewed the documents received from the Client and conducted gap analyses to determine what further documentation was needed and these were requested from Client➤ ERA successfully assisted the client with Referral and Arbitration procedures for one of the pharmaceutical forms (when it was required)➤ ERA worked closely with the Client and the applicable RMSs to ensure that an End of Procedure was successfully obtained➤ ERA worked closely with the various National Competent Authorities (NCAs), where applicable, to obtain grant of the corresponding National MAs (providing translation service when required)➤ ERA worked closely with Client and applied various CMDh guidelines to ensure post-authorisation procedures (e.g. variations/renewals/MAT) were approved in timely manner	<ul style="list-style-type: none">➤ ERA team are adaptable and were able to manage this complex long-term project as each member of the team has over 18 years' experience, each, in the pharmaceutical industry➤ This level of knowledge and expertise facilitated the efficient application of CMDh and EMA Guidance documents when preparing applications➤ ERA have a wealth of knowledge & experience as a result of working with the various EU NCAs and could provide the client with a full dossier lifecycle management service which resulted in their successful entry into European markets

Outcome: Approval of 25 MAA Applications in Member States concerned in a timely manner