MUTUAL RECOGNITION PROCEDURE - DENMARK

The mutual recognition procedure (MRP) in which the marketing authorization for a medicine, which has already been authorized in accordance to the national procedure in one EU or EEA country (the Reference Member State), forms the basis for authorization in another EU or EEA country.

The Reference Member State is responsible for the procedure and the scientific evaluation of the application. The Reference Member State is also responsible for preparing the public assessment report which is available at the website of the Heads of Medicines Agencies (http://mri.cts-mrp.eu/Human/).

Under the mutual recognition procedure, the Danish Medicines Agency has 30 days to issue a marketing authorization from the date when the Agency receives an acceptable Danish summary of product characteristics (SmPC).

New mutual recognition procedure MRP	All types	MRP, RMS	Complete procedure, incl. update	3038	73.325 DKK
			Complete procedure, incl. administrative update	3039	30.212 DKK
			Day Zero-procedure	3040	16.354 DKK

[1] Complete update of the assessment report prior to the procedure itself
[2] Only minor administrative update of the assessment report prior to the procedure itself
[3] No update of the assessment report which is conducted as a Day Zero-procedure