The European Agency for the Evaluation of Medicinal Products
Technical Co-ordination Unit

London, 13 April 1999
CPMP/QWP/8567/99

OPERATION OF TWO-YEAR TRANSITION PERIOD FOR APPLICATION OF NOTE FOR GUIDANCE ON RESIDUAL SOLVENTS TO MARKETED PRODUCTS

The Note for Guidance on Residual Solvents (CPMP/ICH/283/95) was adopted by the CPMP in September 1997 and came into operation in March 1998. This guideline applies to new active substances and new medicinal products and does not apply to existing marketed medicinal products.

Further to a proposal from the Joint CPMP/CVMP Quality Working Party in October 1998, the CPMP agreed that the Note for Guidance on Residual Solvents should be applied to existing marketed products with a two-year's transition period until July 2000. This was reported in the October CPMP Press Release.

Products should therefore comply with the ICH guideline under the following timeframe:

Product	**Should comply with guideline from:**
New Marketing Authorisation for **new** product (containing **new** active substance)	March 1998 (no transition period)
New Marketing Authorisation for product containing an **established** active substance	July 2000
Marketed products*	July 2000

* **Note:** Batches of medicinal product produced before this date need not be withdrawn.

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