Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisations

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for cladribine (apart from products with multiple sclerosis indication), the scientific conclusions of the PRAC are as follows:

In view of available data on excretion of cladribine in human breastmilk from the literature, the PRAC considers that excretion of cladribine in human milk is at least a reasonable possibility. The PRAC concluded that the product information of products containing cladribine (apart from products with multiple sclerosis indication) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for cladribine (apart from products with multiple sclerosis indication) the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing cladribine (apart from products with multiple sclerosis indication) is unchanged subject to the proposed changes to the product information.
The CHMP recommends that the terms of the marketing authorisations should be varied.

Annex II

Amendments to the product information of the nationally authorised medicinal products

Amendments to be included in the relevant sections of the Summary of Product Characteristics
(new text **underlined and in bold**, deleted text ~~strike through~~)

- Section 4.6

The recommendations for use during breast-feeding should be amended as follows:

Breast-feeding
~~It is unknown whether cladribine is excreted in human milk.~~ **Limited data from case reports have shown that cladribine is excreted in human milk. The quantity is not yet well established**.
Because of the potential for serious adverse reactions in nursing infants, lactation is contraindicated during treatment with cladribine and for 6 months after the last cladribine dose.