demonstrated within the restricted indication and therefore considered that the benefit/risk balance of Sebivo remains favourable.

However specific issues related to pharmacovigilance remain, notably the resistance of this drug of low genetic barrier as well as the growing evidence of muscular toxicity during the first 5 years period justify keeping the Marketing Authorisation of this medicinal product under close scrutiny.

Based upon the above defined pharmacovigilance issues of Sebivo, the CHMP decided that the MAH should continue to submit 6 monthly PSURs and that the MAH should submit one additional renewal application in 5 years time.

Amendments to the marketing authorisation

In view of new data submitted as part of the renewal application, the CHMP recommends amendments to the Annexes I, II, IIIA and IIIB. The CHMP requested the above mentioned changes on safety grounds and in order to maintain the positive risk-benefit balance of the product.