ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

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The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Marketing Authorisation Holder (MAH) should inform all healthcare professionals who are expected to prescribe/use Tygacil about the new important identified and potential risks of the product by means of a Direct Healthcare Professional Communication (DHPC)

Within 1 month of the Commission Decision the MAH shall ensure that all healthcare professionals who are expected to prescribe/use Tygacil are invited to participate in a specific Educational Program (EP), aimed at communicating scientific information regarding the new changes in the SmPC (i.e. the new identified risk of superinfection, and the new potentials risks of lack of efficacy and off label use). The key elements of the EP should have been previously agreed with the CHMP. Final materials for the EP should be approved by National Competent Authorities according to national regulations.