



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

**POSITION PAPER ON DEFINITION OF A NEW BIOLOGICAL ACTIVE SUBSTANCE IN
TERMS OF ACTIVE, PASSIVE IMMUNITY AND IMMUNOMODULATORS WHICH THEN
CONSTITUTE A NEW ACTIVE INGREDIENT IN THE CONTEXT OF PART B OF THE
ANNEX TO COUNCIL REGULATION (EEC) NO. 2309/93**

ADOPTION BY CVMP	11 February 1998
DATE FOR COMING INTO OPERATION	1 March 1998

A biological active substance is considered new if:

- the antigen or antiserum is contained within a product indicated against a newly emerging species of pathogen, or
- a new antigen or antiserum is contained within a product indicated against a disease where existing products are proven and recognised not to alleviate suffering from the said disease in the particular target species;
- the product consists of a substance which through immunological mechanisms affects the physiological function of an animal (e.g. one which causes immunocastration), either if the substance has a new efficacy claim or if a new active substance has a different mode of action;
- the product consists of a substance, which modulates the function of the immune system either if the substance has a new efficacy claim or if a new active substance has a different mode of action.