Article 89

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use set up by Article 121 of Directive 2001/83/EC and by the Standing Committee on Veterinary Medicinal Products set up by Article 89 of Directive 2001/82/EC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

3. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

4. Where reference is made to this paragraph, the management procedure laid down in Article 4 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

The period provided for in Article 4(3) of Decision 1999/468/EC shall be one month.

Article 90

Regulation (EEC) No *2309/93* is hereby repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 91

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at …, on …

For the European Parliament
The President

For the Council
The President

ANNEX I

1. Medicinal products developed by means of one of the following biotechnological processes:

   — recombinant DNA technology;

   — controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;

   — hybridoma and monoclonal antibody methods.

2. Veterinary medicinal products, including those not derived from biotechnology, intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals.

3. Medicinal products intended for administration to human beings, containing a new active substance which was not included in the composition of any medicinal product for human use authorised in the Community prior to the date of entry into force of this Regulation.

4. Medicinal products intended for veterinary use, containing a new active substance which was not included in the composition of any medicinal product for veterinary use authorised in the Community prior to the date of entry into force of this Regulation.

ANNEX II

Correlation table

Present Regulation	Regulation (EEC) No 2309/93
Article 1	Article 1
Article 2	***New***
Article 3	Article 2
Article 4	Article 3
Article 5	Article 4
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article 9	Article 8
Article 10	Article 9
Article 11	Article 10
Article 12	***New***
Article 13	Article 11
Article 14	Article 12
Article 15	Article 13
Article 16	***New***
Article 17	Article 14
Article 18	Article 15
Article 19	***New***
Article 20	Article 16
Article 21	Article 17
Article 22	Article 18
Article 23	Article 19
Article 24	Article 20
Article 25	Article 21
Article 26	***New***
Article 27	Article 22
Article 28	Article 23