



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES

## To interested organisations

Date: 17 August 2005

Dear Sir/ Madam

### **CONSULTATION ON A DRAFT REPORT BY THE VETERINARY PRODUCTS COMMITTEE ON THE RISKS ASSOCIATED WITH THE USE OF HORMONAL SUBSTANCES IN FOOD-PRODUCING ANIMALS**

1. I am writing to consult you on a draft report by the Veterinary Products Committee (VPC) on the above topic. The VPC is an independent scientific advisory body which advises Ministers on the safety, quality and efficacy in relation to the veterinary use of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the Medicines Act 1968 is applicable.

2. If you are aware of any organisations or individuals that might also be interested in seeing this letter and the draft report, please let me know; I will then arrange for copies to be sent to them. Owing to the size of the full report (61 pages) I have enclosed here the Contents page, Executive Summary, Overview, the Conclusions and Recommendations of the report and the membership of the Working Group that drafted the Report. The full report is available in electronic format on the VPC's website; [www.vpc.gov.uk](http://www.vpc.gov.uk) or from Isabel Sharma at the VMD (telephone 01932 338330 or email [i.sharma@vmd.defra.gsi.gov.uk](mailto:i.sharma@vmd.defra.gsi.gov.uk))

#### **Background to the Report**

3. In 1999, the then Minister of Agriculture, Fisheries and Food asked the VPC to assess the evidence in an Opinion produced by the European Commission's Scientific Committee on Veterinary measures relating to Public Health (SCVPH). The SCVPH assessment covered the risk to human health from the use of six hormonally-active substances, particularly from residues from bovine animals where such substances were administered for growth promotion.

The SCVPH concluded that the risks from hormone-treated meat were higher than previously thought and indicated that there was a significant body of evidence

suggesting that 17 $\beta$  oestradiol should be considered a complete carcinogen. It also concluded, with different levels of evidence, that there were risks to consumers from the other five hormones examined (testosterone, zeranol, progesterone, trenbolone acetate and melengestrol acetate).

4. The VPC set up a subgroup to assess the SCVPH Opinion. The subgroup was unable to support the SCVPH's Opinion, and had sufficient concerns about the scientific reasoning in a number of key areas to throw serious doubt on the conclusions of the SCVPH. However, the Group identified a number of areas where additional expert evidence should be sought.

5. Two other Committees also examined the SCVPH Opinion. These were the Safety Working Group of the Committee for Veterinary Medicinal Products (CVMP), which advises the European Commission on the setting of Maximum Residue Limits and the safety of veterinary medicines; and the FAO/WHO Joint Expert Committee on Contaminants and Feed Additives (JECFA). Their conclusions were very similar to those of the VPC subgroup.

6. The SCVPH reconsidered its Opinion in 2000 in the light of these other reports but did not revise it. The SCVPH acknowledged that there were gaps in the knowledge available at that time and noted that the commissioning of 17 research studies by the European Commission would provide further evidence. In April 2002, the SCVPH produced a further Opinion confirming the validity of its previous Opinions in 1999 and 2000 after revising it in the light of the most recent scientific data.

7. Defra Ministers asked the VPC to consider the issue again and advise on the SCVPH conclusions, including the research studies on which they are based. The VPC was also asked to advise on whether the SCVPH Opinion in April 2002 addressed the conclusions reached in the report by the VPC subgroup in 1999.

8. A second Working Group was established to consider this latest SCVPH opinion and to prepare a draft Report for consideration by the Committee.

### **The latest VPC Report**

9. The Working Group's draft report was considered by the full VPC in March this year, which suggested some minor clarifications. The VPC considered the amended draft in May before the Committee accepted the draft Report and recommended that it should be passed to Ministers prior to consultation.

10. As the Overview explains, following a critical evaluation of the scientific reasoning and methods of argument adopted in the key papers and studies cited in the SCVPH 2002 Report, the Working Group was unable to support the conclusion reached by the SCVPH that risks associated with the consumption of meat from hormone-treated cattle may be greater than previously thought. The weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable physiological effect.

In reaching this conclusion, the Working Group acknowledges there are important gaps in the evidence base that preclude producing definitive risk assessments for 17β oestradiol or the other five hormonally active substances.

### **Regulatory Impact Assessment (RIA)**

11. There is no need for an RIA in this instance.

### **Comments and Timing**

12. If you have any comments or questions on this letter or the draft Report, please send them to David Webb at the VMD (Direct line 01932 338327); e-mail [d.webb@vmd.defra.gsi.gov.uk](mailto:d.webb@vmd.defra.gsi.gov.uk). The closing date for comments is **Wednesday 9 November 2005**.

13. In line with Defra's policy of openness, we intend at the end of the consultation period to make this paper and copies of the responses we receive, publicly available through the Main Defra Library at Nobel House, 17 Smith Square, London SW1P 3JR.

14. If you want all, or part of your response excluded from this arrangement, please indicate this. The library will supply copies on request to personal callers or telephone enquirers: (Tel: 0207 238 6575). An administrative charge, to cover the cost of photocopying and postage, may be applied.

Yours faithfully

**Eric Crutcher**  
**Head of Residues Surveillance Unit**

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