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EU Discussion Paper on Veterinary Drugs and Maximum Residue Limits

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Report Highlights:

The European Union has published a "Discussion" Paper and seeks comment on a number of issues related to veterinary drugs, maximum residue limits, drug availability, trade issues, etc., no later than March 20, 2004. Their request for comments offers a rare opportunity for the USG and others to present ideas and viewpoints before EU legislation is drafted.

Includes PSD Changes: No
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EU Discussion Paper on Veterinary Drugs and Maximum Residue Limits

The European Commission is seeking comments on a discussion paper that will serve as the basis for the review of its legislation on residues of veterinary medicines. This review is needed to address deficiencies and problems that have arisen from the current rules and includes trade issues. Affected parties are encouraged to provide input at this early stage in the review and development process. Comments are due before March 20, 2004.

DG-SANCO and DG-Enterprise have developed a "reflection" or discussion paper presenting points that will be considered as part of a revision and modification of European Community legislation concerning residues of veterinary medicinal products¹.

The Commission's stated goal is to develop a better balance among the competing constituencies (consumer protection, animal health, welfare and trade requirements) concerning residues of veterinary drugs products used in food producing animals.

While the EU believes its existing legislation on veterinary medicinal products has greatly increased consumer protection, it has also significantly contributed to a decrease in the number and kinds of drugs available to treat sick animals.

Furthermore, the nature of the existing legislation has led to problems in implementing and enforcing the control of residues in foods of animal origin. These problems have also led to difficulties in the functioning of the Single Market and in international trade.

This paper analyses the reasons for these difficulties and seeks comment from the public on alternatives that will achieve a high level of consumer protection and permit continued availability and development of veterinary medicinal products for the European market.

The document notes that there are overlaps in the current legislation on residues of feed additives and of plant protection products (pesticides). Although this aspect is not covered in the discussion paper, coordination in control or supervision of residues in foodstuffs should be a future legislative goal for those substances that have multiple purposes.

The Commission expects to use the comments provided by the public in response to this document in the development of a proposal for new legislation on the evaluation of residues of pharmacologically active substances and for their control. In doing so, it expects to bring the relevant legislation into conformance with the principles of Regulation 178/2002 ('Food Law'), and would modify a number of regulations and directives, including Regulation (EEC) No 2377/90, and Directive 96/23/EC.

One goal is to develop a more consistent approach for risk analysis and control of residues of pharmacologically active substances that may appear in food produced in or imported into the European Union.

Ten questions have been posed on which comments and proposals are solicited:

1. Structures for the appropriate differentiation of risk assessment and risk management for the evaluation and control of residues in food of animal origin
2. Procedures for extrapolation of maximum residue limits
3. Procedures for provision of reference points for control purposes
4. Procedures for precautionary measures for substances in imported foodstuffs

¹ http://pharmacos.eudra.org/F2/mrl/RefIPaper/Reflection%20Paper%20on%20Residues_final_20031111.pdf

5. Procedures for short-term risk assessments in crisis situations
6. Procedures for the evaluation of Third Countries residue control measures
7. Procedures for the nomination of Community reference laboratories
8. Procedures for the establishment of plans for monitoring and targeted controls
9. Financing of measures of interest to the Community related to food safety
10. Residue control specific enforcement measures

Legislative Background:

The Community legislative framework on residues of pharmaceutically active substances or veterinary medicinal products in food, consisting mainly of the following pieces of legislation, follows:

Directive 2001/82/EC² provides that veterinary medicinal products can only be authorized or used in food producing animals if the pharmacologically active substances contained therein have been assessed as safe according to Regulation (EEC) No 2377/90. Moreover it contains rules concerning on the documentation of use, redesignation ('off label use'), prescription and distribution of veterinary medicinal products intended for use in food producing animals.

Regulation (EEC) No 2377/90³ ('MRL Regulation') introduced Community procedures to evaluate the safety of residues of pharmacologically active substances according to human food safety requirements. A pharmacologically active substance may be used in food producing animals only if it receives a favorable evaluation. If it is considered necessary for the protection of human health, maximum residue limits (MRLs) are established. Points of reference for the establishment of withdrawal periods in marketing authorizations as well as for the control of residues in the Member States and at Border Inspection Posts are established.

Rules on food control in general can be found in a variety of Community legislative acts, some of which are under consideration at this time.⁴

Additionally **Directive 96/23/EC** ('Residue Control Directive')⁵ contains specific requirements, in particular for the control of pharmacologically active substances that may be used as veterinary medicinal products in food producing animals. This includes primarily sampling and investigation procedures, requirements on the documentation of use, indication

² Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 1 http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00010066.pdf

³ Council Regulation (EEC) No 2377/90 of 26 June 1990 establishing a Community procedure for maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 224, 18.8.1990, p. 1, last amended by Commission Regulation (EC) No 1873/2003, OJ L 275 149, 25.10.2003, p. 9 http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_275/l_27520031025en00090011.pdf

⁴ Proposal for a Regulation of the European Parliament and the Council on official feed and food controls (COM/2003/0052 final) http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0052en01.pdf

⁵ Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products. OJ L 125, 23.05.1996, p. 10 http://pharmacos.eudra.org/F2/mrl/RefIPaper/Directive%2096_23_EC.pdf

for sanctions in case of noncompliance, requirements for targeted investigations and for the establishment and reporting of monitoring programs.

Moreover **Directive 96/22/EC**⁶ prohibits the use of certain substances for specific purposes in food producing animals and **Decision 1999/879/EC** prohibits the use of bovine somatotropin⁷.

For completeness it has to be mentioned that none of the legislation mentioned above defines 'food producing animals'. However some indication on how this term is to be interpreted is provided in Directive 64/433/EEC ('Fresh Meat Directive')⁸, Directive 96/22/EC and Directive 2001/82/EC.

The current legislative framework also contributed to the decreased availability of medicines for food producing animals in the European Community, a problem that has already been discussed in the *Communication from the Commission to the Council and the European Parliament on the availability of veterinary medicinal products*⁹. Moreover its implementation has led to various problems related to the control and enforcement of legislation of residues in foods of animal origin including difficulties in intra-Community and international trade.

This framework was designed in the late 1980s and early 1990s. Since then the Community and international legislation on food safety has developed further. The creation of the World Trade Organization and the adoption of the SPS agreement¹⁰ have had a significant impact on Community legislation related to international trade.

For the Community the re-structuring of legislation initiated by the White Paper on Food Safety and the consequent adoption of Regulation (EC) N° 178/2002 ('Food Law')¹¹ represent

⁶ Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC. OJ No. L 125, 23.05.1996, p. 3, as amended by Directive 2003/74/EC OJ L 262, 14.10.2003, p. 17

http://pharmacos.eudra.org/F2/mrl/RefIPaper/Directive%2096_22_EC.pdf and http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_262/l_26220031014en00170021.pdf

⁷ Decision 1999/879/EC concerning the placing on the market and administration of bovine somatotropin (BST) and repealing Decision 90/218/EEC OJ L 331, 23.12.1999, p. 71

http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_331/l_33119991223en00710072.pdf

⁸ Directive 64/433/EEC on health conditions for the production and marketing of fresh meat as incorporated by 94/103(51)/EEC, OJ L 1, 3.1.1994, p. 220, last amended by Council Directive 95/23/EEC, OJ L 243, 11.10.1995, p. 7

http://pharmacos.eudra.org/F2/mrl/RefIPaper/Directive%2064_433_EEC.pdf and http://pharmacos.eudra.org/F2/mrl/RefIPaper/Directive%2095_23_EEC.pdf

⁹ Communication from the Commission to the Council and the European Parliament - Availability of veterinary medicinal products COM (2000) 806 final

http://europa.eu.int/eur-lex/en/com/pdf/2000/com2000_0806en01.pdf

¹⁰ Uruguay Round of Multilateral Trade Negotiations (1986-1994) - Annex 1 - Annex 1A - Agreement on the Application of Sanitary and Phytosanitary Measures, OJ L 336, 23.12.1994, p. 40

http://pharmacos.eudra.org/F2/mrl/RefIPaper/Agreement%20OJ%20L001%2003_01_1994.pdf

¹¹ Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in food safety OJ L 031, 1.02.2002 p.1 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

a significant re-orientation of relevant Community legislation to consumer and international trade requirements. Moreover the European Court of Justice has released several rulings relevant in particular to the interpretation of Regulation 2377/90¹².

As a consequence, the Commission believes it is appropriate to reconsider the adequacy of Community legislation on residues of veterinary medicinal products.

The paper presents analyses of problems that have arisen in the implementation of the legislative framework in force and the impact of changes in general policies and modifications of basic Community food safety legislation.

Comments on the paper and responses to the 10 questions should be sent to: comments-mrlpaper@cec.eu.int or in writing to Mr. Philippe Brunet, Head of Unit DG Enterprise F2 and Mrs. Patricia Brunko, Head of Unit D3, DG Health and Consumer Protection, European Commission, Rue de la Loi 200, B-1049, Brussels, Belgium no later than **20 March 2004**.

Visit our website: our website www.useu.be/agri/usda.html provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information.

¹² Access to materials for the following cases (C 32/00, C23/00, C-248/99, T-212/99, 125/96, T-152/96, C151/98, T-112/97, T-120/96, T-105/96) may be obtained through the European Court of Justice website: <http://curia.eu.int/en/content/aide/index.htm>