Veterinary medicinal products: availability

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PURPOSE : the present communication aims to find possible answers to the health-care and welfare needs of food-producing animals on a basis guaranteeing a high level of consumer protection, in a context which presents a satisfactory economic interest for the medical veterinary industry. CONTENT : The Commission proposes as part of the general process for revision of the marketing authorisation system, to take account of the special features of the veterinary sector and the question of the availability of veterinary medicinal products. The Commission intends to finalise its proposals along these lines in 2001. The process, however, will take several years to complete. The heart of the problem, and its urgency, reside in the absence of Community MRLs for a large number of "old" active substances used to treat certain species. Thought must also be given to measures aimed at a sustainable broadening of the range of new veterinary medicinal products on offer in the "minor" segments of the market. The Commission trusts that the prospects opened by the measures for the short term (MRL extrapolation) and the medium term (revision of existing legal instrument) will reverse the current trend and also facilitate the sustainable development of new therapies for the species and indications which are currently ignored by the veterinary pharmaceutical industry. The Commission is nevertheless continuing its reflections on the possibility of developing in parallel a policy analogous to the "orphan drugs for human use" scheme for veterinary medicinal products, by means of a specific legal instrument. The paths to be explored should seek in particular to define indirect incentives to promote the development of the new veterinary medicinal products specific to these abandoned market segments (reduced registration fees, technical assistance from the Agency, longer exclusive market rights, and others). Direct incentives could be considered (financial contributions to R&D, reimbursement of certain investments on granting of marketing authorisation, voluntary co-financing by associations of breeders of the species concerned). But the Commission considers that if such a proposal should see the light of day, the scope and the ways and means of its application will need to be precisely identified.