

## FORM FOR TABLING PARLIAMENTARY QUESTIONS

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To the: COUNCIL   
COMMISSION 

ORAL QUESTIONS	WRITTEN QUESTIONS
Oral Question with debate (Rule 108) <input type="checkbox"/> Question Time (Rule 109) <input type="checkbox"/>	Written Question (Rule 110) <input type="checkbox"/> Priority Written Question (Rule 110 (4)) <input type="checkbox"/>
AUTHOR(S): Caroline Lucas	
SUBJECT: Use of animal testing for pharmaceutical products (please specify)	
TEXT:  <p>The use of animals in experimentation is controversial for ethical and other reasons. It is most welcome that the Commission has taken many steps to reduce the number of animals used, and to foster development of new test methods that can entirely replace animal use.</p> <p>Whilst much attention has been paid to the chemicals and cosmetics sectors, efforts to reduce and replace animal testing for pharmaceutical products have lagged behind due in part to the case-by-case nature of drug evaluation. However, in the immediate term, it appears that greater communication, co-operation, and reciprocity of approval between the EU and third country regulators could help to reduce the number of animals used to test pharmaceuticals. Although work has been done to harmonise test methods and information requirements for drug licensing through groups such as the International Conference on Harmonisation, it appears that current practice regularly allows or even requires additional animal testing to take place for approval of the same product in different countries. Licensed drugs, especially those in human use, should not need to return to the animal testing stage.</p> <p>Would the Commission outline efforts taken to ensure that additional animal testing is not required by EU regulators when products developed and accepted in third countries are imported into EU, and also outline measures taken to ensure that EU approval of pharmaceutical products leads to acceptance of the products when exported to third countries, without the duplication of animal testing?</p> <p>Furthermore, would the Commission give an estimate of the total number as well as the percentage of pharmaceutical products developed and approved for use outside the EU, but subsequently imported into the EU, for which additional animal tests have been required by EU regulators over the last two years?</p>	
Signature(s):	Date: 3/2/06

As a horizontal initiative, the Commission agreed, in November 2005, with industry on a European partnership to promote alternative approaches to animal testing. The objective is to further refine, reduce and replace the use of animals in testing in different industrial sectors, including parts of the pharmaceutical sector. The Commission is currently in the process of identifying possible actions that could contribute to this objective. To this end, the partnership has set up a working group to tackle problems related to additional or double animal testing.

As regards European legislation on medicinal products<sup>(1)</sup>, the qualified person of the importer of a medicinal product coming from a third country has to ensure that each production batch has undergone, in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure that the quality of a medicinal product is in accordance with the requirements of the marketing authorisation. Depending on the type of medicinal product these requirements may include animal tests. This provision is irrespective of whether the product has been manufactured in the Community or in a third country.

Exceptions of this re-testing requirement are foreseen for those cases, where the product is imported from a country, with which an agreement on mutual recognition (MRA) of inspection systems of manufacturers exists for that particular type of product. The EC has signed such MRAs with Canada, Switzerland, New Zealand, Australia, and Japan. These agreements are operational for defined categories of medicinal products. In addition, an MRA with the United States was concluded, but has not become operational for the sector on medicinal products.

As conclusions under the respective good manufacturing practice compliance programmes of the parties should be mutually accepted, medicinal products exported from the European Union to MRA partner countries should not be subject to further re-testing.

Detailed figures on animal tests for products manufactured in the EU and subsequently re-imported in the EU are not available.

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<sup>(1)</sup>Article 51 of Directive 2001/83/EC of the Parliament and of the Council, of 6 November 2001, as amended, on the Community code relating to medicinal products for human use and Article 55 of Directive 2001/82/EC of the Parliament and of the Council, of 6 November 2001, as amended, on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001.