At all events, it is always the responsibility of the national authorities to investigate such behaviour, if it emerges that there has been a violation of one or more Community directives laying down minimum requirements in the field of industrial relations, and to enforce the rights in question where necessary.

The strategy to promote Corporate Social Responsibility (CSR) in the Union, which was proposed by the Commission in its Green Paper and in the subsequent Communication (1), does not make provision for sanctions mechanisms, as it defines CSR as company behaviour which goes beyond legal requirements. However, the Commission has pointed out that the legal requirements laid down in legislation must be respected and enforced.


(2003/C 222 E/055) WRITTEN QUESTION E-3200/02
by Paul Lannoye (Verts/ALE) and Caroline Lucas (Verts/ALE) to the Commission
(8 November 2002)

Subject: Vigilance concerning vaccines

Although vaccines fall within the category of medical preparations and a growing number of studies show that they have many undesirable effects, there is no vigilance concerning vaccines equivalent to pharmacovigilance, which is compulsory in order to detect any side-effects of medicines.

However, Decision 2119/98/EC (1) of the European Parliament and of the Council, whose purpose ‘is to set up a network at Community level to promote cooperation and coordination between the Member States, with the assistance of the Commission, with a view to improving the prevention and control, in the Community, of categories of communicable diseases, including diseases preventable by vaccination’, already forms part of a policy of Community vigilance with regard to vaccines.

Moreover, the specific research, technological development and demonstration programme to be implemented through direct measures by the Joint Research Centre for the period 2002-2006 also provides for specific research activities focusing on vaccine safety.

Does the Commission not therefore feel that a system of vigilance concerning vaccines should be set up as soon as possible at European level, in line with the provisions of Decision 2119/98/EC?


Answer given by Mr Byrne on behalf of the Commission
(11 December 2002)

The Commission is working closely with the Member States, under Decision No 2119/98/EC (1), to strengthen the surveillance of communicable diseases including the major vaccine preventable diseases. All the major vaccine preventable diseases are included in the list of communicable diseases to be progressively covered by the Community network (Commission Decision 2000/96/EC (2)) and a standardised case definition for reporting is defined (Commission Decision 2002/253/EC (3)).

An early warning and rapid response system is in place and it will ensure an appropriate public health response in case of notification of new events caused by major vaccine preventable diseases (Commission Decision 2000/57/EC (4)), including: diphtheria, infections caused by Haemophilus influenzae type b, influenza, measles, mumps, pertussis, poliomyelitis, rubella, hepatitis A and B, meningococcal disease, and pneumococcal infections.
Medicinal products for human use, including vaccines, are closely monitored to allow timely evaluation of new information relevant to the risks and benefits of these products, so that appropriate action may be taken, when necessary, to protect public health. The conduct of pharmacovigilance rests on a number of parties, i.e. the Member States, the Commission, the European Agency for the Evaluation of Medicinal Products (EMEA) and the Marketing Authorisation Holders.

All relevant information about suspected adverse reactions caused by medicinal products for human use occurring within or outside the Union will be taken into account in accordance with Articles 19-26 of 'Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products' (5) and Articles 101-109 of Directive 2001/83/EC of the Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (6). The Commission submitted to Parliament and Council a proposal to modify the above-mentioned Regulation and Directive in order to strengthen the safety of medicinal products within the Community.

Nevertheless, there is still a lack of scientific knowledge in many respects. For that reason the Commission has funded, within the 5th Framework Program, more than 65 research projects related to vaccine development and vaccination strategies. In particular regarding surveillance and adverse effects, it is relevant to mention two projects: 'European research programme for improved vaccine safety surveillance', designed to provide a scientific basis for improved vaccine safety surveillance and 'European Sero-Epidemiology Network 2', aiming at co-ordinating and harmonising the serological surveillance of immunity to a variety of vaccine preventable infections (measles, mumps, rubella, diphtheria, pertussis, varicella zoster virus, hepatitis A and hepatitis B).


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(2003/C 222 E/056) WRITTEN QUESTION P-3218/02

by Marianne Eriksson (GUE/NGL) to the Council

(7 November 2002)

Subject: Visa enabling Russian citizens to enter the EU

In September this year I invited three women who work at a women’s crisis centre in Murmansk to participate in a European Parliament conference on prostitution and trafficking in women, on 9/10 October 2002. When I spoke to Belgian diplomatic staff in Moscow and St Petersburg about the possibility of obtaining visas for them, everyone I spoke to gave different answers, but it seemed clear that the women would have to go to Moscow with my original invitation, and that even then they would not be certain of obtaining a visa. I also spoke to the Swedish visa authorities about the possibility of their flying via Sweden, but was told that a visa for Sweden would not be sufficient for them to travel on to Belgium (Schengen agreement), and that they would require a visa for each separate EU country. I think it