
2. Article 95(4) stipulates that if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

3. The Commission shall, within six months of the notification approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction to trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

4. The national legislation notified obliges the pharmaceutical entrepreneur to inform the competent federal authority in Germany within 15 days of all suspected serious adverse reactions irrespective of whether or not the reactions are expected and whether it occurs within or outside of the Community. In contrast to that, the amended provisions of Directive 75/319/EEC oblige the marketing authorisation holder to report suspected serious adverse reactions only to the competent authority of that Member State in whose territory the incident occurred. If the suspected serious adverse reactions occur in the territory of a third country, a reporting obligation is established only for unexpected reactions.

5. The German authorities justify their request by referring to the highest possible level of protecting public health in the use of medicinal products which could not be ensured after implementation of Directive 2000/38/EC. They further claim that the national provisions do not involve arbitrary discrimination, or a disguised barrier to trade between Member States, nor do they obstruct the operation of the internal market.

6. Further information regarding the request from the Federal Republic of Germany can be obtained from:

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(1) OJ L 139, 10.6.2000, p. 28.