# Resolution on Petition 0473/2008 by Christoph Klein (German), concerning the failure of the Commission to take action regarding a competition case and the harmful impact of this on the company concerned

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Following the debate which took place during the sitting of 18 January 2011, the European Parliament adopted a resolution tabled by the Committee on Petitions on Petition 0473/2008 by Christoph Klein (German), concerning the failure of the Commission to take action regarding a competition case and the harmful impact of this on the company concerned.

Parliament considers that the Commission's reply to the Committee on Petitions failed to respond sufficiently to the questions raised by the petitioner and the committee members or to the concerns raised in the opinion of the Committee on Legal Affairs. It calls on the Commission immediately to take the steps needed to end the still-pending procedure initiated in 1997 under the safeguard clause of Article 8 of Directive 93/42/EEC. Members call on the Commission urgently to respond to the legitimate concerns of the petitioner – who has been experiencing this intolerable situation for 13 years and has consequently suffered considerable loss of earnings – and to take the necessary steps to enable the petitioner to assert his rights.

The background to this case concerns Council Directive 93/42/EEC on medical devices, which provides that manufacturers of Class I medical devices can place such a device on the market without intervention by a notified body , and that is up to manufacturers to demonstrate that their devices meet the requirements of the directive. In order to ensure that these requirements are met, Member States must carry out market surveillance and to take the necessary measures, which include the safeguard clause procedure under Article 8 and measures under Article 18 in the case of an unduly affixed CE marking. The manufacturer concerned demonstrated to the responsible body in the Member State that its device fulfilled all legal requirements for the placing of a Class I medical device and product carrying the CE marking on the market. However, the German authorities had been expressing safety concerns about the device in question (an inhaler) since 1996 and had informed the Commission about the matter with a view to a safeguard procedure, but the Commission did not consult the manufacturer and never issued a ruling. As a result, a decision on the matter is still pending and the petitioner is left without any available means of legal redress.

The company in question legally sold products before the first sales injunction was issued in 1997, and, according to the authority responsible, satisfied all the provisions of Council Directive 93/42/EEC. However, the authorities of Saxony-Anhalt imposed a sales ban on the device in 1997, at the insistence of the Bavarian authorities. The manufacturer placed the device on the market under a new name in 2003, and in 2005 the Government of Upper Bavaria ordered it to be withdrawn from the market, under the German Medical Devices Act, without informing the Commission as it is obliged to do under the Directive. In 2006, the manufacturer informed the Commission of the second sales prohibition with a view to initiating infringement proceedings against Germany for breach of Article 8(1) of Directive 93/42/EEC.

Parliament notes that the Commission claims that there was insufficient proof that the inhaler satisfied the essential requirements, as stipulated in the Directive, and it concluded that there was no need for a new

product safety review because the case fell under Article 18 rather than Article 8 of the Directive. The manufacturer submitted a petition to the European Parliament in 2008 stating that the Commission, in its handling of the case, had breached its obligations under the directive and failed to fulfil its duty to act as the Guardian of the Treaties.