EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Gérard Bapt
Assemblée nationale
126 rue de l'Université
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13 July 2011
EMA/551776/2011
Directorate

Dear Mr Bapt

Subject: Your letter to Commissioner Dalli dated 28 June 2011

I am writing to you to clarify a few facts in relation to your letter addressed to Commissioner Dalli on 28 June 2011.

I would like to inform you that Dr Xavier Kurz started working for the Belgian Center of Pharmacovigilance on 1 July 1994 as a part-time external University-based scientific expert in the context of a service contract between the University and the Ministry. In this function he also participated as Belgian representative in the Pharmacovigilance Working party of the CHMP from 1995 to 30 August 2004. Dr Kurz has worked at the European Medicines Agency as a pharmacovigilance expert since 1 September 2005.

In his role as scientific expert Dr Kurz reviewed all available cases of aortic valve deficiencies in patients taking anorectic agents reported to the Belgian Center of Pharmacovigilance at that date and drafted an expert report on 17 December 1994. The report reflected also the view of an expert of the Belgian Evaluation Commission for medicines for human use and concluded that multiple drug exposure made it difficult to establish a causal association. The report was reviewed by the Belgian Evaluation Commission for medicines for human use on 13 January 1995 and brought to the attention of other European Members States. The Belgian Evaluation Commission for medicines for human use endorsed the conclusions of the report that based on data available at that point in time no further measures were necessary.

I would like to clarify that in no way did Dr Kurz minimise or contest a safety signal. Quite to the contrary, Dr Kurz was the coordinator in Belgium for the epidemiological study (IPPHS), conducted to assess the risk between the occurrence of pulmonary primary hypertension and anorectic agents. The IPPHS study included patients with primary pulmonary hypertension diagnosed from 1 September 1992, through 30 September 1994. The study showed an increased risk associated with fenfluramines and was a key element in the first European review of the benefit/ risk of anorectic agents. The

European Commission Decision of 9 December 1996 on this review can be linked directly to the issues raised in the study co-authored by Dr Kurz[1] demonstrating his important contribution to public health.

The safety of fenfluramines in the late 1990s has been the subject of two Community wide referral procedures which finally led in the year 2000 to a Commission Decision withdrawing the marketing authorisations of medicines for human use which contained dexfenfluramine and fenfluramine.

The first of these procedures was initiated in May 1995 by Germany shortly after the establishment of the Agency, due to concerns regarding primary pulmonary hypertension leading to a series of labeling restrictions to minimise the risks. Subsequently in 1997 further to reports of cardiac valve disorders all Member States suspended the Marketing Authorisations and triggered a follow up referral procedure, leading to a Commission decision to withdraw the Marketing Authorisations.

I would like to reiterate my absolute confidence in Dr Kurz's scientific and personal integrity. He has been a most valuable expert in pharmacovigilance and pharmacoepidemiology, both prior to starting working at the European Medicines Agency and since joining the Agency. His contribution to European Public Health is highly appreciated throughout the European regulatory network.

Sincerely,

(Signature on file)

Andreas Pott
Acting Executive Director

[1] Abenhaim L, Moride Y, Brenot F, Rich S, Benichou J, Kurz X, Higenbottam T, Oakley C, Wouters E, Aubier M, Simonneau G, Bégaud B. Appetite-suppressant drugs and the risk of primary pulmonary hypertension. International Primary Pulmonary Hypertension Study Group. N Engl J Med. 1996 Aug 29;335(9):609-16