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Dalli petitioned to solve 13-year inhaler issue

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Traditional asthma inhalers are L-shaped.

A German inventor who claims to have created an asthma inhaler that improves the lives of millions of patients and saves billions of euros is petitioning European Commissioner John Dalli to resolve a 13-year-long “injustice” which prevented him from selling it.

Christoph Klein’s inhaler, the Effecto, is different from traditional inhalers because it is a straight tube instead of L-shaped so it can easily be used while lying down, which is when most asthma attacks happen.

He says the inhaler has all the necessary certifications (including a CE mark) to be sold as a medical device without medication. Since the medication goes straight through the patient’s throat instead of making two right-angled turns, more medication gets to the lungs, making it more effective at dealing with an emergency attack. The inhaler can also be used to treat other illnesses.

But in 1997, the Bavarian government claimed the product could be unsafe and convinced another German state to issue a sales injunction against the company which began selling the inhalers. It also notified the European Commission about the injunction.

However, instead of analysing whether the product was dangerous and proceeding with a safeguard procedure, the European Commission “did nothing”, meaning Mr Klein was never given a chance to appeal against any decision.

In 2005, the inhaler was sold under a new name and another sales injunction was issued. The company says that so far 30,000 inhalers were sold legally before the sales injunctions and although being used more than 199 million times, no negative reports were received.

Mr Klein claims the Bavarian authorities tried to protect their pharmaceutical industry by issuing the “unwarranted” injunction. He also questions the motivations of the European Commission.

Although Mr Klein blames Mr Dalli’s predecessors, matters were made worse because the Maltese commissioner did not present himself to respond to allegations during a recent petitions committee meeting.

The meeting was held following a legal opinion by the Committee on Legal Affairs, which confirmed Mr Klein’s rights were denied and that he had a right for damages.

“It cannot be that the Commission is above the law,” the chairman said, while calling for a “full, honest and clear explanation” of the Commission’s conduct since 1997 and an explanation of what action it intends to take.

If the answers are not sufficient then the Petitions Committee can call for a Temporary Commission of Inquiry.

The company says the inhaler could save between 25 and 35 per cent of the costs for asthmatics. With around 34 million asthmatics in the EU, the insurance companies and the National Health Service could have saved €50 billion had the inhaler been used since 1997 for asthmatics alone.

When contacted, a spokesman said Mr Dalli was not available for comment because he was on holiday.

The spokesman added that during the Petitions Committee meeting in July, the Commission was represented by the director responsible for Consumer Affairs as well as technical experts.


There they reiterated that the potential benefits of any medical device had to be carefully weighed against possible impacts on health and patient safety.

The spokesman said that Mr Klein’s rights had not been denied because market surveillance was up to member states and he had used all existing legal remedies at a national level. She added that the German authorities still required more documentation to certify the product’s safety, a claim the company denies.


The company argues that the European Commission must take a stand through safeguard proceedings rather than follow the views of member state with no proof of its own.

“If they do not develop their own opinion then the potential for corruption is higher. Maybe the member state has its own reason for keeping the product off the market,” a company spokesman said.


Comments

w. planz (1 hour, 7 minutes ago) 

Mr. Dalli seems to be the one to correct the injustice. Why wouldn't he? The way I see it, he has a choice to either be part of the problem or part of the solution!

l fenech (8 hours, 7 minutes ago) 

Sur Dalli, hu nifs kbir il-gewwa u ahsibha fit. (Mr. Dalli should take a deep breath and think about it.)

T Camilleri(9 hours, 36 minutes ago) 

Does anyone not believe that there is a cartel between the pharmacist companies oligopoly and that they have good contacts in every sector of the State and EU institutions?

<http://www.timesofmalta.com/articles/view/20100822/local/dalli-petitioned-to-solve-13-year-inhaler-issue>