BEUC The European Consumer Organisation

The Consumer Voice in Europe

Mysimba

Letter sent to the Director Andrzej Rys – DG SANTE – European Commission on 26 January 2015 (Ref. BEUC-L-2015-004/MGO/IPA/cm)

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Re: Mysimba

Dear Mr. Rys,

I'm writing to you on behalf of BEUC, the European Consumer Organisation, in order to share our serious concerns with regard to the weight loss medicine Mysimba and to ask the European Commission not to grant a marketing authorization for this product.

On 19 December the European Medicines Agency (EMA) Committee for medicinal products for human use (CHMP) has recommended granting a marketing authorisation for Mysimba (naltrexone / bupropion) for weight management of overweight or obese adults[1].

We are particularly concerned about the potentially fatal consequences of Mysimba on the heart and about the fact that the long term ***safety*** of the product has not been established yet.
The CHMP admitted it had concerns about the increased risk of seizures. Moreover a study to continue monitoring longer-term cardiovascular safety with the medicine has been planned but has not been conducted yet. Taking into account that people who are obese or overweight are already at risk of heart problems and high blood pressure, the uncertainties with regard to cardiovascular outcomes in the long term, should be given more weight in evaluating the benefit/risk ration of the medicine.

Mysimba is a combination of two active substances (bupropion and naltrexone) already approved for use in other indications. Bupropion is an amphetamine and it is already used for tobacco withdrawal and depression. Adverse effects include seizures and exacerbations of hypertension. Naltrexone is used in the treatment of alcoholism and heroin addiction. Possible side effects include gastrointestinal disturbances, insomnia, restlessness, joints pain and headaches. The two substances act on the parts of the brain that control food intake and energy balance, as well as reducing the effect of the part of the brain that controls the pleasure associated with eating food. However the exact way that the substances work is not fully understood yet

[1] EMA Press Release, Mysimba recommended for approval in weight management in adults, 19 December 2014.
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/12/WC500179334.pdf

In recent years many weight loss medicines - including amphetamine type products like Mysimba - were withdrawn from the market due to serious adverse effects.

In particular, in 2000, the EMA withdrew the marketing authorisation of several appetite suppressants with a similar mechanism of action (clobenzorex, dexfenfluramine, fenfluramine, fenproporex, etc.), due to disproportionate and serious adverse drug reactions. In 2009, Subitral (sibutramine), an appetite suppressant structurally related to amphetamines, was also withdrawn by the Agency[2]. In 2010, the anti-diabetes drug Mediator (benfluorex) which was often prescribed off label as a weight loss medicine, was withdrawn from the market after having caused between 500 and 2000 deaths.
In addition, in 2013, the EMA gave a negative opinion[3] on the dangerous fixed-dose combination phentermine/topiramate and the application for the medicine Belviq (lorcaserin) was withdrawn[4] by the company itself following the provisional negative opinion of the CHMP[1].

The EMA recommends that patients who take Mysimba should be evaluated after 16 weeks, and if they have not lost at least 5% of body weight, the treatment should be stopped. However experience shows that in reality, patients and health care professionals do not necessarily follow these kind of recommendations and guidelines for the safe use of medicines are often not implemented in practice.

The results of the pivotal studies with Mysimba show that the ***effectiveness*** of the medicine in promoting weight loss is negligible and in any case it is clinically relevant only if those who take the medicine also change their life style by adhering to a reduced calorie diet and practicing physical activity.
While we are well aware of the fact that overweight and obesity represent a major risk factor for a number of chronic diseases, including diabetes and cardiovascular diseases, we think that an extremely modest degree of weight loss (if any) achieved through a drug therapy cannot justify exposing obese or simply overweight patients to a disproportionate risk of adverse drug reactions, especially since the weight loss is very often regained within months of discontinuing diet and treatment.

To sum up, we argue that the benefits of the medicine for patients and for public health do not outweigh the risks especially taking into account the potential long term safety risks, its modest effectiveness and added therapeutic value.

On this basis, we call on the European Commission and the Member States representatives in the EU human pharmaceutical committee to put consumers' health first and not to grant the marketing authorization for Mysimba.

We hope that these concerns will be taken into account in the interest of consumers and public health.

Yours sincerely,

Monique Goyens
BEUC Director General

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[2] Prescrire, Press release, 19 December 2014.
[3] http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002350/WC500139215.pdf
[4] http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2013/05/WC500143811.pdf