Corrigendum

Corrigendum to: ‘Guidelines for the diagnosis and treatment of pulmonary hypertension’ [European Heart Journal (2009) 30, 2493–2537]. The Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS), endorsed by the International Society of Heart and Lung Transplantation (ISHLT). Authors/Task Force Members: Nazzareno Galie (Chairperson) (Italy); Marius M. Hoeper (Germany); Marc Humbert (France); Adam Torbicki (Poland); Jean-Luc Vachiery (France); Joan Albert Barbera (Spain); Maurice Beghetti (Switzerland); Paul Corris (UK); Sean Gaine (Ireland); J. Simon Gibbs (UK); Miguel Angel Gomez-Sanchez (Spain); Guillaume Jondeau (France); Walter Klepetko (Austria) Christian Opitz (Germany); Andrew Peacock (UK); Lewis Rubin (USA); Michael Zellweger (Switzerland); Gerald Simonneau (France).

Withdrawal of sitaxentan in the treatment of pulmonary arterial hypertension

The 2009 ESC Practice Clinical Guidelines for the diagnosis and treatment of pulmonary hypertension included the endothelin receptor antagonist sitaxentan in an algorithm of evidence-based treatment for pulmonary arterial hypertension. Sitaxentan was recommended with a Class I/Level A grade of evidence in WHO functional class III patients and Class IIa/Level C grade of evidence in WHO functional classes II and IV.

Sitaxentan was initially authorized by the European regulatory agency as Thelin in 2006 but in December 2010, after the manufacturer withdrew Thelin from the worldwide market following new information on two cases of fatal liver injury, marketing authorization was also withdrawn by the EMA.

In the light of the withdrawal and the EMA’s advice to patients taking Thelin (not to stop medication but review treatment at the next scheduled appointment), the Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the ESC and the European Respiratory Society (ERS) has issued its own recommendations for treating physicians. This has been published in the European Heart Journal in February as a CardioPulse article (Eur Heart J 2011:32:386–387).

The Task Force recommends:

1. For the time being, no PAH patient should start de novo therapy with Thelin
2. For patients already on treatment with Thelin, transition to another endothelin receptor antagonist such as bosentan (Tracleer) or ambrisentan (Volibris) should be considered.
3. In cases where a PAH patient was treated with Thelin because of previous adverse reactions with Tracleer and Volibris, the transition to another class of PAH-approved drugs should be considered (prostanooids or PDE-5 inhibitors)

The Task Force is monitoring the status of sitaxentan, along with all other clinical developments relevant to pulmonary hypertension. This information will be incorporated in the next update of the ESC Practice Clinical Guidelines.

The online version of the Guidelines has been updated with a note added to the title page bringing attention to the fact that the drug has been withdrawn. The occurrences of ‘sitaxentan’ have also been highlighted where they occur throughout the text.

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