

January 2011

## Glucose-lowering therapy with rosiglitazone

The 2007 ESC Practice Clinical Guidelines on Diabetes, Pre-Diabetes and Cardiovascular Disease<sup>(1)</sup> 'suggested' the use of glitazone drugs as glucose-lowering therapy in type 2 diabetes characterised by insulin resistance. No specific agents within this class were recommended. However, since publication of the guidelines the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has stated that the benefits with rosiglitazone do not seem to outweigh the risks associated with this drug as regards a possible risk for cardiovascular complications.

Rosiglitazone was initially authorised by the European regulatory agency as Avandia in July 2000 as second-line treatment in type-2 diabetes to be used when other treatments have either failed or are unsuitable for the patient. It was subsequently approved in combination with metformin as Avandamet and with glimepiride as Avaglim. Already by that time the risk for fluid accumulation and heart failure was mentioned and the use of the drug in patients with cardiac disease was discouraged.

In September 2010 the EMA<sup>(2)</sup> recommended the suspension of the marketing authorisations for these three rosiglitazone-containing medicines, noting that they would 'stop being available in Europe within the next few months'. The CHMP's recommendation was forwarded to the European Commission for the adoption of a legally binding decision.

The Task Force on Diabetes and Cardiovascular Disease of the ESC is monitoring the status of rosiglitazone, along with all other clinical developments relevant to diabetes. This information will be incorporated in the next update of the ESC Practice Clinical Guidelines.

1. 2007 ESC Practice Clinical Guidelines on Diabetes, Pre-Diabetes and Cardiovascular Disease. European Heart Journal 2007; 28:88-136.

<http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/diabetes.aspx>

2. Questions and answers on the suspension of rosiglitazone-containing medicines (Avandia, Avandamet and Avaglim)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Medicine\\_QA/2010/09/WC500097003.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2010/09/WC500097003.pdf)

Jeroen Bax (Chairperson)  
Committee for Practice Guidelines

Lars Ryden (Chairperson)  
Diabetes, Pre-diabetes & CVD Task Force

*To reduce the burden of cardiovascular disease in Europe*