



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public Citizen's Health Research Group

03 March 2014
EMA/128533/2014
Inspections and Human Medicines Pharmacovigilance

Dear Sir,

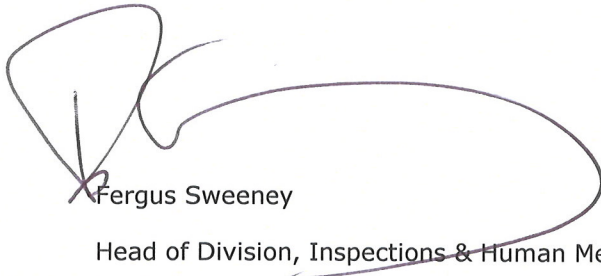
Subject: Petition for black box warning on testosterone drugs

Thank you for your letter to Professor Guido Rasi, received on 25 February 2014 regarding the safety profile of medicines containing testosterone. Your letter raises concerns about cardiovascular safety based on studies and calls for prominent warnings in product information.

I would like to inform you that the issue is under assessment and will be considered at the March plenary meeting of the EMA Pharmacovigilance Risk Assessment Committee (PRAC). PRAC minutes are published following their adoption and therefore the initial position of the committee will be available at the following web address:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000353.jsp&mid=WC0b01ac05805a21cf

Yours sincerely,



Fergus Sweeney
Head of Division, Inspections & Human Medicines Pharmacovigilance

Cc: Prof Guido Rasi

