

LETTERS



SCREENING AND TREATMENT FOR HEPATITIS C

Reducing the price of new hepatitis C drugs in the Tuscany region of Italy

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In most European countries, regulatory agencies are engaged in approving reimbursement schemes for the new interferon-free direct antiviral agents (DAAs) for hepatitis C.^{1,2} The degree of reimbursement differs across countries and sometimes between regions of the same country.

Owing to budget constraints, most national approvals for reimbursement have been restricted to patients with more severe disease, according to ethical and clinical considerations.^{2,5}

In May 2015, the Tuscany region of Italy proposed a regional tendering scheme that extended reimbursement to about 20 000 patients with milder disease.⁶ This tender will probably close over the next month.

This project has been debated among institutions, politicians, patient associations, scientific societies, and experts in the field.³ Opponents (such as the Italian Medicines Agency⁴) argue that the proposal is not pharmaceutically sustainable; another criticism is that the effectiveness of newer DAAs relies on a surrogate endpoint with no information on long term effects; finally, trying to eradicate this disease locally has been questioned on theoretical grounds. Ethics has been advocated by all stakeholders, but ethics seems to support both prioritising patients with severe disease and ensuring that those with milder, but potentially progressive, disease are treated. The American Association of the Liver recently recommended treating all hepatitis C infected people except those with a life expectancy of less than 12 months due to unrelated conditions.⁷

Patients' associations initially argued that extended coverage in one region only would be an infringement of equity but now recognise that it might pave the way for other regions to follow.

It is unprecedented for an effective treatment not to be used in patients with mild disease for economic reasons. The cure rate is high in mild disease, so eradicating the disease in these cases would save healthcare costs and prevent onward transmission.

Reducing drug costs by increasing competition between manufacturers could be a solution. At its first run, the Tuscan tender set a maximum treatment cost per patient of about one tenth of the drug's full price, but at the second run no such limit will be applied.⁶ The results of the Tuscan tender are eagerly awaited by scientists, clinicians, and patients.

Competing interests: Although the authors have been formally involved in the Tuscan project, the opinions presented here do not necessarily reflect those of the Tuscany region; all the information reported herein is publicly available.

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