

Published 13 July 2010, doi:10.1136/bmj.c3747

Cite this as: *BMJ* 2010;341:c3747

## News

### Italy's drug regulator is cleared of any wrongdoing

Fabio Turone

<sup>1</sup> Milan

Nello Martini, former head of the Italian drug regulatory agency, Agenzia Italiana del Farmaco, has been cleared of the charge of "causing unintentional disaster," which in 2008 provoked his removal from his post. At the end of a hearing last week that took more than two years the Criminal Court in Rome stated that there was no legal basis to go to trial.

Senator Ignazio Marino, an MP for the opposition Democratic party and head of the parliamentary investigative committee on the healthcare system, told the *BMJ* that he will launch an investigation into Dr Martini's sacking.

"It is worrying that Dr Martini was fired on the basis of such weak allegations before he even had the possibility to defend himself, despite the fact that he had been doing an excellent job for many years, proving to be a loyal, competent, and rigorous professional. I think he should be given his position back," he said.

Dr Martini was accused of "causing unintentional disaster" by failing to update the safety warnings on many drugs.

But despite protests from experts that the allegations were groundless, because the delay in updating of warnings involved only minor rewording and did not pose a risk to public health, Dr Martini was sacked in mid-July. A few days later it was announced, to protestations from a number of senior researchers and clinicians, that the agency's responsibilities would be curtailed, with several functions, including drug pricing, reassigned to the health and welfare ministry (*BMJ* 2008;337:a1276, doi:10.1136/bmj.a1276).

"I have always been convinced that the agency shouldn't only have a regulatory role," Dr Martini explained to the *BMJ*. "My idea was that rules had to come within a context of promoting independent research and information, active pharmacovigilance, and continuing education of doctors. Furthermore, the responsibility for pricing allowed the agency to take into account the therapeutic value and the degree of innovation associated with each drug, so that we could assure access to innovative drugs while keeping spending within the limits imposed by government and also through the promotion of the use of generics."

After Dr Martini left, the agency's innovative programme to provide independent information to doctors, pharmacists, and nurses through bulletins and distance e-learning (*PLoS Medicine* 2007;4(5):e113, doi:10.1371/journal.pmed.0040113) almost came to halt. There are also concerns that funding that has allowed the agency to invest in research in public health since 2006 will be pulled.

Guido Rasi, the agency's new head, recently praised a risk sharing scheme introduced by Dr Martini in 2005. Francesco Perrone, director of the clinical trial unit at the National Cancer Institute, Naples, and an adviser to the agency on cancer treatments, said, "Among the many positive policies introduced by Dr Martini, this scheme of payment by results makes it possible to prescribe expensive cancer drugs through a registry: when the patient has no significant benefit, the therapy is discontinued, and the company reimburses the cost."

Cite this as: *BMJ* 2010;341:c3747

 CiteULike  Complere  Connotea  Del.icio.us  Digg  Facebook  Reddit  StumbleUpon  Technorati  Twitter [What's this?](#)

## Relevant Article

Doctors and researchers in Italy protest against dismissal of drug regulator

Fabio Turone

BMJ 2008 337: a1276. [Extract] [Full Text]

---

[Contact us](#) - [Privacy policy](#) - [Web site terms & conditions](#) - [Revenue sources](#) - [Site map](#)  
[HighWire Press](#) - [Feedback](#) - [Help](#) - © 2010 BMJ Publishing Group Ltd.