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Italian expert questions need for expanded vaccination schedule

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A vaccine expert who criticised plans to expand Italy's national vaccination programme has been threatened with legal action by government medical officers.

Vittorio Demicheli, of the Cochrane Vaccines Field, has said that plans to introduce vaccines against human papillomavirus (HPV) for males, rotavirus for infants, and herpes zoster and pneumococcal polysaccharide for elderly people are too costly and sometimes ill advised, questioning the motives behind the new national programme.

Demicheli, who was previously director of public health for Italy's Piedmont region, concluded in a letter to the daily newspaper *Il Sole 24 Ore* on 27 October¹ that more scrutiny of the plans was needed "not only to avoid an unnecessary expense in the current period of scarce resources, but above all to effectively ensure people's welfare."

He said that assessments by the Istituto Superiore di Sanità (Higher Institute of Health) given to regional health chiefs in 2014 questioned the effectiveness of pneumococcal polysaccharide vaccine and also meningococcal B vaccines, which appear in the new schedule. He also queried the HPV vaccine for boys and universal rotavirus vaccine for babies, and he challenged the wisdom of introducing herpes zoster vaccination.

"I'm absolutely pro-vaccine," Demicheli told *The BMJ*. "And I'm glad to say that my region has one of the highest vaccination rates in the country. But I'm concerned about this new schedule on practical grounds—in terms of cost and whether adding so many new vaccinations will make some parents nervous."

He said that the proposed 2016-18 schedule would double the total yearly immunisation bill to over €600m (£423m; \$642m). Although the plan was passed by regional health authorities at a national conference on 5 November the deputy finance minister, Pier Paolo Baretta, said that the required additional funding was not yet secure.

However, Demicheli said that the drug industry may have unduly influenced the beefed up vaccination schedule—a suggestion that prompted the authorities to respond in a letter to the same newspaper.²

Demicheli added that the timetable set out in the national vaccination plan was "a faithful copy of the 2014 Calendar for Life," a vaccination guide sponsored by the drug industry. He told *The BMJ* that some of the 20 health officials responsible for the revised schedule had received grants or payments from the industry.

In their reply the health officials—who included the chief medical officer, Roberta Siliquini; the director general for the Italian Pharmaceutical Agency, Luca Pani; and the president of the Italian Society of Paediatrics, Giovanni Corsello—said that Demicheli's statement was, "besides being false, dangerous to public health."

They said it gave the impression that "the decision makers, scientists and doctors who helped draft the plan did so simply because they were sponsored, or worse, corrupted by vaccine manufacturers, rather than acting on scientific evidence for the benefit of citizens."

The officials concluded their letter with a threat of legal action, stating that they were ready to take "all necessary steps, including criminal and civil actions, to protect their reputations harmed by the statements" in Demicheli's original letter.

Demicheli stuck to his guns, however, saying, "They failed to address any of the points I made, and simply threatened me."

1 Demicheli V. Piano nazionale vaccini, cura di trasparenza contro la "teoria del complotto." *Il Sole 24 Ore* 2015 Oct 27. <http://bit.ly/1kZCoBT>. [In Italian.]

2 Siliquini R, Palamara A, Lenzi A, et al. Piano nazionale vaccini: "pronti a iniziative giudiziarie contro gravissime e false affermazioni." *Il Sole 24 Ore* 2015 Oct 30. <http://bit.ly/1MhOWWI>. [In Italian.]

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