specimen obtained at enrolment in the two trials, and additionally at yearly visits in PATRICIA only. In the Costa Rica Vaccine Trial, the samples were tested with Hybrid Capture 2 (Digene, Gaithersburg, MD, USA) using *C trachomatis* DNA. In PATRICIA, samples were tested with Roche Amplicor (Roche Diagnostics Corporation, Basel, Switzerland). The results showed that balance within dose by group was maintained during the 4-year follow-up. Thus, HPV vaccine recipients who received fewer than three doses were similar to the recipients of the control vaccine in terms of sexual behaviour risk. These data for *C trachomatis* suggest that women receiving three HPV vaccine doses in PATRICIA might have been at lower risk (less opportunity for HPV exposures) than those receiving only one or two doses. Hence, our infection data for *C trachomatis* do not lend support to biases that could explain our findings.

In the absence of a formal randomised trial to directly assess single-dose efficacy of the HPV vaccines, our data are interesting and raise the question of the minimum number of doses needed to confer lasting protection. As stated in our initial publication, our data are insufficient for consideration of policy change at this time. Further investigation of single-dose protection by HPV vaccines is now warranted.

FS and M-PD are employees of the GSK group of companies, and own stock shares and stock options in the GSK group of companies. CMW received funding to conduct the clinical trial and reimbursement for travel from the GSK group of companies via University of New Mexico, and reagents and equipment for HPV genotyping studies were provided to the University of New Mexico by Roche Molecular Systems. AH and ARK declare no competing interests.

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Will the revised class waiver list make it?

The 2007 European Paediatric Medicine Regulation requires a paediatric investigation plan (PIP) for drugs being developed for adults before marketing authorisation is given, unless a waiver is granted by the Paediatric Committee (PDCO) at the European Medicine Agency (EMA). Waivers can be given because the medicine is likely to be ineffective, unsafe, not have a significant therapeutic benefit over existing treatments, or intended to treat an illness that only occurs in adults. PDCO published a list of class waivers in 2008 (revised in 2009 and 2010) that provide exemption from the obligation to submit a PIP or specific waiver request. 42 class waivers were for medicines for the treatment of illnesses (25 malignant) that do not occur in children.

We, as paediatric oncologists and parents, pointed out that medicines were unjustifiably waived according to this list.[1] For example, crizotinib is authorised for the treatment of ALK-positive lung cancer and was given a class waiver because lung cancer does not occur in children. However, ALK is a driver of paediatric malignancies (eg, anaplastic large cell lymphoma, neuroblastoma, and inflammatory myofibroblastic tumours) and crizotinib showed tumour responses in an academic paediatric phase 1 trial.[2] We called for the implementation of PIPs on the basis of the mechanism of action of drugs and revocation of the class waiver list.[3]

In July, 2015, the EMA published a revised class waiver list, to come into effect in 2018.[4,5] Eight class waivers were revoked because the diseases can occur in children, including two for cancer (liver or intrahepatic bile duct carcinoma and kidney or renal pelvis carcinoma) and 15 were revised.

PDCO should be congratulated for its extensive work, which provides detailed information about medicines that are likely to be ineffective in children with cancer. However, we wonder whether this revised class waiver list will increase the availability of potentially effective drugs. For example, the class waiver can be applied for any medicine developed in adults for lung carcinoma (panel). With the revised list, only taxoids, thymidylate synthase inhibitors, pyrimidine-containing medicines, and platinum compounds will be class waived. For other drugs, a pharmaceutical company will need to submit a PIP or a request for a waiver. PDCO will now have the opportunity to review more medicines for children. However, if the company decides to request a waiver because

***Panel*: Class waivers for medicines for the treatment of lung cancer**

- In the current class waiver list: treatment of lung carcinoma (small cell and non-small-cell carcinoma)
- In the revised class waiver list: the class of first-generation taxoid and thymidylate synthase inhibitor and pyrimidine-analogue-containing and pyrimidine-analogue-containing and first-generation and second-generation platinum-containing medicinal products for the treatment of lung malignancies

the illness does not exist in children even though the drug's mechanism of action is relevant for paediatric malignancies, PDCO cannot force the company to assess a drug in children. The revised class waiver list will not prevent a repetition of the crizotinib story and the development of many oncology drugs for children will still be dependent on the willingness of a pharmaceutical company to voluntarily provide a PIP, as has occurred with the BRAF inhibitor dabrafenib.

In conclusion, although this important initiative by PDCO is progress, we are concerned that it might not substantially reduce the number of relevant medicines unjustifiably class waived. As we have emphasised before, the real change will come from considering the mechanism of action of a medicine, and setting up an efficient prioritisation process involving all stakeholders, industry, regulatory, parents, and paediatric oncologists, and more efficient obligations and incentives.[6,7]

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