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It is unbelievable! There we were in genitourinary medicine looking forward to the day in the not too distant future when we could actually complete a clinic and say “where have all the warts gone?” The Department of Health’s decision to go for Cervarix, which only contains human papillomavirus (HPV) types 16 and 18 as opposed to Gardasil, which contains 6, 11, 16 and 18 has shocked and appalled all of us working in sexual health. Here at last was a wonderful opportunity to make a major and lasting impact on one of the most common sexually transmitted infections in the United Kingdom. How could they have reached such a decision? All the science, all the trials, all the evidence showed both vaccines to be very effective at dealing with HPV 16 and 18 disease, but Gardasil had the huge added advantage of also preventing genital warts and cervical smear abnormalities caused by HPV 6 and 11.1 It is likely that the decision made was based mainly on the proposed cost of the vaccine submitted by GlaxoSmithKline (GSK) and Sanofi Pasteur MSD. To have overcome the major benefits provided by Gardasil, Cervarix must have come in at an incredibly low price.

Why would GSK have done this? Well, worldwide Gardasil has been the vaccine of choice, and in the United States Cervarix is not even approved yet, as the US Food and Drug Administration (FDA) seem to have issues, possibly including the interim data, or the adjuvant, or the effectiveness against HPV 18. This was possibly GSK’s last real chance of winning an exclusive national contract, so the price would have had to have been at breakpoint to overcome the Gardasil benefits. This could have presented the decision-makers with a cost saving that was so great it was impossible to ignore.

The longer-term benefits of using Gardasil would, however, in our opinion, still have made it the number one choice for the United Kingdom. In many developing countries cervical cancer is rampant and a vaccine for HPV 16 and 18, like Cervarix, will have an enormous benefit. In these countries genital warts are not a major health issue and little money is spent treating them, but in the United Kingdom it is different. If all 13-year-old girls were vaccinated with Gardasil there would have been a very apparent reduction in new cases of genital warts within 3 or 4 years—ie, our clinics would not have been seeing new acquisitions of genital warts in the usual 15–17-year-old girls who normally attend the clinic. This would begin to have big financial payback, as the current estimate of treating the 100 000 plus new cases of genital warts in England every year is at least £23 million.2 However, the benefits of only using a cervical cancer vaccine will not be seen until these young women reach the age of 25 years, ie, in 12 years time, when they begin to have their first cervical cytology.

It is also embarrassing that we appear to be the only country in Europe exclusively advocating Cervarix as the national vaccine. Are all these countries wrong and the United Kingdom right? There are ongoing delays about approval in the United States, which may hinge around the FDA’s reluctance to approve the new adjuvant, ASO4. It is an agonist of the Toll-like receptor 4 pathway, which enhances immunogenicity. On the contrary, the FDA had no problem approving Gardasil, which contained the tried and trusted alum-based adjuvant.

So, can anything be done about this disappointment? Well, Gardasil is licensed for use in general practice just like any other drug, so parents may actually go to a GP and insist on having the vaccine of their choice. Many GPs have already prescribed some doses of vaccine and have universally chosen Gardasil (personal observation). As for me, the minute Gardasil was licensed, I got a private prescription, went to my local chemist and purchased the required doses for my two daughters. I wasn’t waiting for any national programme—just as well!

Competing interests: COM has received lecture fees from both GlaxoSmithKline and Sanofi Pasteur MSD. Accepted 26 June 2008

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