Pharmacoeconomics 2012; 30 (5): 443-445
1170-7690/12/0005-0443/$49.95/0

Human Papillomavirus Vaccination Is Not Exclusively a Matter of Price

The article by Garattini et al.[1] is very interesting because it is tightly focused on the prices of vaccines utilized to immunize against some specific human papillomavirus (HPV) genotypes. This issue is very intriguing due to the relevance of the economic and social burden of HPV-related diseases.[2] Hence, their article provides an opportunity to address other remarkable concerns about HPV vaccination. Economic theory states that a price-based policy decision may contribute to enhance the competitiveness among producers; this is a common effect expected for any good. However, drugs and devices do not belong to an ordinary group of goods, and this is especially true for biotech products such as vaccines.

Firstly, in Italy, the implementation of an immunization programme is not only a matter of vaccine price. There are many managerial aspects to take into account. The vaccination may require additional personnel (or alternatively overtime costs, depending on its administration scheduling). A communication plan about HPV-related diseases and their prevention (vaccination alongside screening) plays a crucial role in establishing a successful public health intervention (vaccination may represent the first interaction between the healthcare service and potential vaccinees or their parents).[3] Furthermore, it is very useful to orchestrate some educational sessions for the main healthcare professionals involved in the management of HPV vaccination (such as paediatricians, gynaecologists and GPs) to accomplish an effective coordination of resource utilization. Beyond the price of vaccines, all the above-mentioned organizational issues are time- and cost-consuming factors that can also affect the decision-making process of health authorities.

Secondly, another additional unique factor that is worthy to note in the Italian context is given by the different modalities of implementation of tenders among regions. The tender process can be based on price or on both quality and price. In this regard, in 2008, the Italian Supervisory Authority for Public Contracts[4] provided its opinion concerning tender procedures: "Considering that the drug market is controlled, the price cannot be the only criterion to compare products, because it is set by the regulatory authority from the beginning." Therefore, "the assignment of a contract must be operated through the implementation of objective criteria that respect the principles of transparency, non-discrimination and equality, ensuring the evaluation of offers in a competitive context." The Authority recommended that the assessment of each offer should be established on both quality and price (i.e. cost effectiveness).[5] Since the actual procedures of implementation of the vaccination programme are delegated to individual regions, different tender modalities and several prices are achieved. Although under the constraint of a limited budget, in each Italian region, the objective of the health authority is to maximize the net benefits to public health in full compliance with the universal principles of equity of access to treatment and prevention.[6] Nevertheless, organizational health systems and the associated programmes of HPV immunization vary largely across regions, even in terms of the number of cohorts targeted. Beyond the basic target cohort of girls aged 12 years, for which an HPV vaccination must be granted free of charge and be actively promoted (according to a decree issued by the State-Regions Conference),[7] one, two or sometimes three additional cohorts characterized by different age can be immunized[8] with several patterns of access: free of charge, by a co-payment or by facilitated access. Moreover, an administration fee is commonly added. The communication about these healthcare services may or may not be passed on. All these factors can make the estimation of the actual cost of HPV vaccination in Italy very difficult.

Thirdly, and on the contrary to the expected results, a lower vaccine price is not necessarily associated with a higher vaccination coverage rate. To some extent, this sort of organizational effectiveness indicator seems to be a variable independent

from possible tender price. At present, the most current data available from the Italian National Health Institute indicate that in a region where one of the lowest prices was achieved, the coverage rate for the 1997 cohort corresponded to 45.6%.[9] On the other hand, in some regions where the tender prices could have a tendency to be higher, the coverage rates in the 1997 cohort were almost two-fold that previously reported (80.7% and 76.3% in a southern and a northern region, respectively).[9]

In conclusion, we should consider whether the price-based competition does or does not improve the quality of services provided by public health-care providers. The Italian practice could be helpful only in countries with a very similar public health system. Considering the specific macro-environmental conditions, it is improbable that other countries could learn a lesson from the Italian experience. However, all European countries could gain from best practices implemented by other nations; an interesting example is given by the UK, which very recently made the decision to change the tender criteria for the proper assessment of HPV vaccines (namely, criteria not exclusively based on price).[10]

Alessandro Capone and *Giampiero Favato*
Institute of Leadership and Management in Health (ILMH), Kingston University London, London, UK

Acknowledgements

Alessandro Capone was employed by Sanofi Pasteur MSD Italy as Health Economics and Market Access Director from October 2006 to September 2009. From October 2009 to December 2011, he was a consultant to Sanofi Pasteur MSD Italy. Sanofi Pasteur MSD markets the quadrivalent anti-HPV vaccine in the European Community. Alessandro Capone has also received consulting fees from Bristol-Myers Squibb, Pfizer, Merck Sharp & Dohme, AstraZeneca, Sanofi-Aventis, Serono, GlaxoSmithKlein, Lundbeck, and Boehringer Ingelheim

Giampiero Favato declares no conflicting interests.

References

1. Garattini L, van de Vooren K, Curto A. Pricing human papillomavirus vaccines: lessons from Italy. Pharmacoeconomics 2012; 30 (3): 213-7
2. Favato G, Baio G, Capone A, et al. Il burden of disease indotto da HPV in Italia [abstract no. 624]. In: XIIth National Conference of Public Health, Italian Society of Hygeine (SItI); 2011 Oct 12-15; Rome. Igiene e Sanità Pub 2011; Suppl. 3: 521
3. La Torre G, Chiaradia G, de Waure C, et al. Aspetti organizzativi ed etici del vaccino quadrivalente: report HTA del vaccino quadrivalente anti-HPV Gardasil. Ital J Pub Health 2009; 6 Suppl. 2: S50-64
4. Autorità per la vigilanza sui contratti pubblici di lavori, servizi e forniture [parere no. 78, PREC 55/08/F]. 2008 Mar 20 [online]. Available from URL: http://massimario.avcp.it/cgi-bin/showdoc.pl?id = 3380 [Accessed 2012 Jan 17]
5. Mennini FS, Costa S, Favato G, et al. Anti-HPV vaccination: a review of recent economic data for Italy. Vaccine 2009; 27: A54-61
6. Italian Ministry of Health. Principles and objectives of the Ministry of Health [in Italian; online]. Available from URL: http://www.ministerosalute.it/ministero/sezMinistero.jsp?label = principi [Accessed 2012 Jan 17]
7. Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome di Trento e di Bolzano. Strategia per l'offerta attiva del vaccino contro l'infezione da HPV in Italia [online]. Available from URL: http://www.statoregioni.it/Documenti/DOC_016696_264%20csr.pdf [Accessed 2012 Jan 17]
8. Giambi C. Ricognizione delle decisioni regionali in merito alla vaccinazione anti-HPV e primi dati di copertura vaccinale a fine anno 2009. Italian National Institute of Health, Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute. [online]. Available from URL: www.epicentro.iss.it/focus/hpv/pdf/HPV-2009.pdf [Accessed 2012 Jan 17]
9. Giambi C. Stato di avanzamento della campagna vaccinale per l'HPV: dati di copertura vaccinale al 30/06/2011. Italian National Institute of Health, Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute [online]. Available from URL: http://www.epicentro.iss.it/problemi/hpv/pdf/HPV-30-06-2011.pdf [Accessed 2012 Jan 17]
10. Department of Health. Contract for the supply of human papillomavirus vaccine in the UK, 2011 [online]. Available from URL: http://www.contractsfinder.businesslink.gov.uk/Common/View%20Notice.aspx?site=1000&lang=en&noticeid=184264&fs=true [Accessed 2012 Jan 17]

The Authors' Reply

In reply to Capone and Favato's letter referring to our article on pricing HPV vaccines in Italy,[1] we are answering their interesting comments point by point, for the sake of clarity.

- We agree that market competition is hard to apply to drugs and devices, but – like many other colleagues – we think that a major commitment of health economists should be to strive to find interesting examples, like that described in our article, where competition can help achieve sustainable prices.[2,3]
- We agree that implementing an immunization programme is not only a matter of vaccine

price, but includes the costs of campaigning and managing vaccinations. Although this analysis goes beyond the scope of our article, it is worth noting that labour costs are fixed and constitute the major share of the expenses borne by the Italian NHS for vaccinations, followed much further down by communication costs for campaigning. It might be expected that the more of their limited budget regional health authorities spend for purchasing vaccines, the less they have to invest in incentives for public health professionals and communication for the target population, although these investments do not necessarily lead to better performance in practice.

- We agree that HPV tenders could include other criteria in addition to price, as happens for any kind of tender. For instance, if this vaccination were extended to males, other goals should be included besides cervical cancer prevention, and the two vaccines could hardly be considered equivalent anymore (the quadrivalent one being more effective in this scenario). This could lead to the addition of a quality score in tender clauses, as we underlined very recently in another publication,[4] although it is simplistic to make this option coincide with cost effectiveness, as claimed in the letter.
- We agree that a lower vaccine price is not expected to be associated with wider vaccination coverage, the former stemming from administration and management, the latter from healthcare organization. We never claimed this in our article, but just evidenced the strong relationship between prices and timing of tenders.
- We agree that the very recent UK tender is an interesting example, although we regret, like others,[5,6] the lack of transparency on a crucial issue, i.e. the price awarded – an easy lesson to draw from Italy.

Livio Garattini, Katelijne van de Vooren and *Alessandro Curto*
Centre for Health Economics (CESAV), Department of Public Health, 'Mario Negri' Institute for Pharmacological Research, Ranica, Bergamo, Italy

Acknowledgements

CESAV received unrestricted grants for contract research and continuing medical education programmes from a few pharmaceutical companies, including the Italian subsidiary of Sanofi-Pasteur MSD.

References

1. Garattini L, van de Vooren K, Curto A. Pricing human papillomavirus vaccines: lessons from Italy. Pharmacoeconomics 2012; 30 (3): 213-7
2. Klemperer P. Auction theory: a guide to the literature. J Econ Surv 1999; 13 (3): 227-86 [online]. Available from URL: http://economics.ouls.ox.ac.uk/11924/1/Survey.pdf [Accessed 2012 Jan 25]
3. Laffont JJ, Tirole J. A theory of incentives in procurement and regulation. Cambridge (MA): MIT Press, 1993
4. Garattini L, van de Vooren K. Extending HPV vaccination to boys: an economic perspective. BMJ. Epub 2012 Jan 13 [online]. Available from URL: http://www.bmj.com/rapid-response/2012/01/13/re-should-hpv-vaccine-be-given-men [Accessed 2012 Jan 25]
5. Godlee F. Why don't we know how much vaccines cost? BMJ 2011; 343: d6239
6. Hecht R, Kaddar M, Schmitt S. Transparent pricing of vaccines would help poor as well as rich countries. BMJ 2011; 343: d7414