Public–private collaboration in vaccine research

Public sector scientists, for example those based in universities or in public health institutes, often collaborate with commercial organisations—including vaccine manufacturers—while taking on various advisory roles, mainly to regulatory agencies and policy makers. To what extent do these many roles constitute unacceptable bias or compromise? At one extreme, scientific independence of an individual or organisation might be inevitably compromised by commercial collaboration, whereas a contrary perspective argues that to systematically uncouple public health organisations from links to industry would deny or compromise the provision of crucial advocacy.

Research and expertise in relation to immunisation policy decisions deserve special attention, because they affect the future health of large numbers of individuals. We believe that the public–private interface in vaccine research should be preserved.

The research, development, and implementation of a vaccine are complex and costly processes. Provision of vaccines is a necessarily public–private partnership because, with few exceptions, only commercial vaccine companies have found it feasible to follow through on the difficult and expensive responsibility of development of a high-quality, safe, and effective product. However, the public sector is the only sensible and practical source of much of the epidemiological, microbiological, and immunological data that are essential to the development and implementation of a vaccine. Furthermore, outsourcing of clinical trials to established and approved research organisations, in accordance with strict regulatory guidelines, is an essential step in the registration of any new vaccine.

Two articles in The Lancet’s Vaccine Series describe some of these scientific challenges from the perspective of the vaccine industry. Private companies are in a position to provide essential information for judicious immunisation policies, but the primary responsibility for protection of the interests of the public lies in the public sector. In the past, fruitful collaboration has resulted in the development of vaccines with significant public health benefit.

The US National Institutes of Health and its Vaccine Treatment and Evaluation Units played a crucial part in early development of several important vaccines, for example, *Haemophilus influenzae* type b conjugates, hepatitis A, rotavirus, and human papillomavirus vaccines. In Canada, many vaccine-related organisations and universities were essential for the development of an acellular pertussis vaccine, research and development of vaccine adjuvants, and assessment of vaccines for immunisation programmes. The UK Health Protection Agency lists vaccine development and evaluation as one of the science themes essential for the evidence-based protection of the health of the population. The UK’s Department of Health and Health Protection Agency contributed substantially to the evaluation, licensure, and rapid implementation of meningococcal conjugate vaccines in the UK during meningococcal epidemics in the country. Our own institute, the National Institute for Health and Welfare in Finland, has contributed to the advanced phases of clinical development and to postlicensure research of *H influenzae* type b and pneumococcal conjugate vaccines. Thus the interdependence of public and private sectors is an indisputable and crucial component in the provision of safe and effective vaccines, and will probably remain so indefinitely.

Management, rather than disruption, of the public–private partnerships that underpin the provision of immunisation programmes is crucial. Measures that could be used to minimise the potentially harmful effects of conflicts of interest are: comprehensive and structured disclosure of potential conflicts of interest (including non-financial conflicts, such as expert testimony, membership of a governmental panel).

### Panel: Suggested criteria for vaccine research projects when public health institutes consider partnership with private industry

- Public health impact of vaccine could be substantial
- Expertise inside institute is appropriate to the task (and, preferably, institute is better placed to take the project than other alternatives)
- Project competes well in internal prioritisation of use of resources inside institute
- Intellectual property issues and ownership of data can be agreed on
- All scientific results can be published without censorship
- Funds for infrastructure and basic functions of institute do not depend on research contracts with industry
or other advisory board, relation with lobbying or advocacy organisations, charities, or funding bodies; interposition of an intermediary between donor and recipient in any financial relation; surveillance for fraud; transparency of the expert recommendation process; and provision of training to raise awareness of different forms of bias, accompanied by practical measures to limit exposure to marketing activities. In addition to management of interests, public health institutes need solid criteria for projects that can be undertaken in conjunction with industry (panel).

Postlicensure safety surveillance of new vaccines that are widely used in immunisation programmes is crucial to both regulatory and public health authorities, and to vaccine manufacturers. This activity should be paid for, but preferably not supervised and conducted by, the marketing authorisation holder. The marketing authorisation holder should be obligated to pay a specific surveillance fee to an independent body (eg, the European Medicines Agency, the European Centre for Disease Prevention and Control, or a non-governmental foundation) at the time of licensure. This body would then allocate funds to public research organisations that would actually undertake safety and effectiveness surveillance of the vaccines.

Vaccine companies need partnerships with the public sector to develop new vaccines that benefit public health. The involvement of the public sector in vaccine research not only directs development towards public health goals, but also ensures that research seeks to answer questions relevant to public health decision makers. Vaccine research and development benefits from maximum transparency, clear rules, and exchange of critical views on the research itself, rather than from discussion about the qualities and relations of the researchers. Thereby the public good is fostered, not jeopardised.

*Juhani Eskola, Terhi Kilpi
National Institute for Health and Welfare, Helsinki FI-00271, Finland
juhani.eskola@thl.fi

JE is a consultant in pneumococcal vaccine development, and a member of the Safety Monitoring Committee of meningococcal and typhoid vaccine development projects for Novartis. TK is principal investigator of a nationwide effectiveness study of the ten-valent pneumococcal conjugate vaccine; this collaborative clinical study is mainly funded by GlaxoSmithKline, and her unit received funding for a clinical trial on the safety and immunogenicity of a prototype pandemic influenza vaccine from Solvay Pharmaceuticals.