

## From bugs to new drugs

A new model of product development based on collaboration between the public and private sectors is emerging



Handle with care: a technician at HPA Porton  
Andrew Jack SEPTEMBER 5, 2012

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In a cluster of buildings in the remote English countryside, secured by high fences and guards, technicians in white coats are preparing chunky glass flasks to be filled with deadly anthrax. Sitting alongside the British defence ministry's secretive weapons research unit at Porton Down, the technicians are working at the world's biggest factory for making anthrax vaccine. In nearby facilities, where their colleagues developed Dysport for treating cerebral palsy, they still make Erwinase, used to treat childhood leukaemia.

The workers are employees of the [Health Protection Agency](#), a UK government body, but the drug development work they are carrying out at the site in Wiltshire last year contributed £157m, roughly half the HPA's overall income. It is a sum that would be the envy of many biotechnology companies and the HPA is among a handful of public agencies – from the Pasteur Institute in France to the Walter Reed Army institute in the US – that is challenging the private sector's predominance in developing and making drugs, vaccines and diagnostics.

While HPA Porton is still unusual, the role of the public sector in drug development is increasingly a topic for debate among pharmaceuticals executives and policy makers. Sluggish innovation by drugs companies and their neglect of rare but serious diseases are sparking fresh interest in the role of the public sector, and how interaction with the private sector could boost productivity. In early 2011, the US National Institutes of Health announced a “translational science” unit to diversify from its traditional focus on funding early-stage science towards later-stage drug development, traditionally where the private sector gets involved.

Jean-Luc Bélingard, chairman of BioMérieux, a French diagnostics company, and former head of Ipsen, which first licensed both Dysport and Erwinase for manufacture and bringing to market, says: “I’m intrigued [by] novel ways of development. It should not be about ‘us’ in the private and ‘them’ in the public sector.”

The question today for any country eyeing a public sector model is how it would fit with how drugs are developed, manufactured and made available, given the constraints on capital, tensions over pricing and regulation, and concerns over efficiency and competition relative to commercial producers.

### **Dilemma over how the rewards are divided**

Thanks to research and development undertaken by the Health Protection Agency, the leukaemia drug Erwinase is helping thousands of children around the world who have an allergic reaction to the standard treatment. But it has also created a dilemma for the HPA.

The price for partnering with a commercial company to fund additional clinical tests and win regulatory approval has been a sharp rise in the cost to users. It is now sold in the US and elsewhere typically at \$75,000 per treatment, or about five times the UK figure.

Some observers feel the HPA should take a bigger royalty on sales in order to boost public sector funds and help provide fresh income to fund further drug development. Others argue that such a life-saving product – with much of the cost originally

For much of the 20th century, national governments operated their own vaccine facilities until – for reasons of cost and ideology – many were closed or sold to drug companies. But following concerns over potential global pandemics or biological terrorist attacks, there is renewed interest in building strategic national stockpiles of drugs and vaccines. “I’m really keen to grow our activities and use surpluses to invest in new facilities,” says Roger Hinton, deputy head of the HPA’s microbiology services unit. “We really see ourselves as helping UK companies get their products to the market place. A lot of companies want us to do work.”

Activities at its Porton Down facilities include testing potential new products and new ways to make complex drugs involving dangerous substances whose use is tightly controlled. One reason Mr Hinton’s unit exists is the heavy sunk investment and specialist expertise of past military research at Porton Down. His office has specially thick walls, a legacy of its construction after the second world war, when the site was designed to be able to withstand rocket attacks, possibly with radiochemical and biological warheads. By the late 1980s, the UK government was mulling its closure. But renewed concern over chemical and biological weapons potentially being developed by hostile regimes, the terror attacks of September 11 2001 and the ensuing anthrax scare, triggered fresh government funding of public

underwritten by taxpayers –  
should be available more  
cheaply.

more

bodies as well as biotech companies to develop  
new anthrax vaccines.

The agency was unusual in having either the  
experience or facilities needed to conduct such  
work safely. It had for decades produced small  
quantities of anthrax vaccine for tanners and

sheep shearers. In fact, that is just one example of the civilian applications fostered by the  
facilities' military origins and expertise. Its past research into "weaponised" aerosol particles  
contributed to a wider understanding of how infections spread, which has won the HPA a name  
for testing experimental vaccines for tuberculosis and flu, including for the H5N1 bird flu strain  
in Asia.

The high level of biosafety in its laboratories – including sophisticated measures to avoid leaks  
into the environment – has helped win it licences to test potent products on animals. Shielded  
from animal rights activists, researchers have easy access to non-human primates such as  
macaques.

"Industry won't invest in these facilities," says Miles Carroll, site director head of research for  
the agency at Porton Down.

The site can also use its infrastructure to manufacture drugs from dangerous and highly  
regulated organisms such as botulism toxin, in a process that is too costly for the private sector,  
thanks to rules on handling dangerous substances. Botulism is the basis for Dysport, which last  
year generated royalties of £20m. The work on botulism led to Syntaxin, spun out as a company  
to achieve greater commercial freedom to research pain treatments, and in which the agency has  
kept an equity stake. Usually, it takes a royalty or ongoing consultancy fees.

Partnerships such as the one to license Dysport illustrate the niche the agency has developed in  
helping develop, test and make products, while finding commercial backers for regulatory filings  
and large-scale sales.

Erwinase, a leukaemia drug for the estimated 30 per cent of children with allergies to standard  
treatments, was developed in work led by a staff scientist. Long available in the UK, it took five  
years with the agency's partner Eusa Pharma, now part of Jazz Pharmaceuticals, to win approval  
from the US Food and Drug Administration last November.

However, while partnership with a private company provided the funding and expertise needed  
for regulatory approval, the high price now charged for the drug has sparked controversy.

Another concern is whether the HPA might be held to different regulatory standards because of  
its public sector status. "If anything, we get a harder ride. It would be embarrassing if we failed,"  
says Mr Hinton. "It is of course in the interests of industry to be ramping up the standards to  
take out the competition."

He sees capital constraints as the biggest challenge, and notes these will only become tougher as government budgets tighten. Also, his unit is moving to a new site nearer London, and is being brought under the direct control of the government's health department, which is likely to make it subject to general bans on consultants and limits on suppliers.

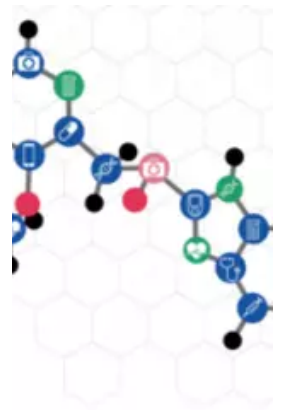
Such are the particular pressures faced by a publicly backed unit. "I would hope to be able to have greater commercial freedom to grow the business," says Mr Hinton. "We are forever being approached by biotech companies and governments to help with manufacturing but some of the public sector constraints on spending – for good and valid reasons – don't apply to our activities."

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