ACCEPT NO SUBSTITUTES

Following his company's withdrawal from the ABPI over the issue, Peter Martin of Norgine discusses generic substitution

In October, based on the results of a public consultation, the coalition Government abolished controversial proposals for the introduction of automatic generic substitution (GS). We hear from Peter Martin, chief operating officer of Norgine, a company whose high-profile withdrawal from ABPI membership was motivated by the ABPI's support for GS, an idea Norgine believes would have threatened patient safety.

Are you surprised by the decision to drop the proposals for GS?

I am certainly delighted by what I see as a common sense outcome from the public consultation that had raised serious concerns about this seemingly self-serving proposal from big pharma. I also consider it a significant coup for patient safety in the UK. I never lost hope that the right conclusions would ultimately be reached. Forcing pharmacists to replace prescriptions for branded medicines with any from a variety of generics is a bad idea for a host of reasons. In any case, there was no evidence whatsoever that GS would have provided any benefits to the NHS.

That is not to say the DH should abandon efforts to find efficiencies and save money within the NHS. But looking for a means other than promoting disruption to patients' established medication regimens seems more sensible and much safer. Additionally, safeguarding not just big pharma but those innovative companies researching and developing existing molecules – delivering new indications and new formulations for example – is also in the interest of the general public.

As a small-to-medium-sized manufacturer that conducts this kind of research as well as working on incremental innovations, your business must now be in a safer position too?

Well, Norgine has the capacity to undertake a reasonable amount of research and development into new products, but as a company we have never seen the benefit of introducing the umpteenth statin, quinolone antibiotic or ARB, for example. That is, the tired old Me2NCE (me-too new chemical entity) formula beloved by pharmaceutical dinosaurs.

While such products often have a substance patent, and are therefore protected from generic competition for years, they rarely constitute a genuine innovation in value to patients, or those who treat them. Our growth – and I'm pleased to say that we've experienced double digit sales growth [at constant exchange rates] for 23 years consecutively – is based purely on the fact that our products add value for patients and the healthcare systems within which we operate.

An innovation must, by definition, convey a new advantage; the benefits (for the payer, the

prescriber, the carer and of course for the patient) of any innovation should be recognised. Another new chemical entity in a crowded class is not inherently beneficial, and is not inherently innovative just because it is patented.

Can you give an example of where additional value has been recognised from an older, unpatented product?

Thalidomide is an interesting example. It's rightly notorious for its teratogenicity of course, for which reason it was withdrawn from all markets where it was available for the treatment of morning sickness in pregnancy. Further research since then, however, into other indications means that it is now licensed and used widely to treat multiple myeloma.

The thalidomide product of today is a highly valuable therapeutic option for myeloma sufferers, but if the original product had neither been withdrawn nor subsequently further developed, this new indication would never have been discovered. Once the product had gone generic, the originator company would have ceased both its development and promotion, essentially 'fossilising' it in terms of formulations and – much more importantly in this case – clinical research into new indications.

It's actually a matter of chance that this didn't happen, which prompts a good question: how many opportunities for patients have been lost because of the tyranny of the NCE (substance) patent over genuine innovation when it comes to medicines?

How can we know the answer to that?

My point is that in the UK research and development into medicines without substance patents is neither valued nor rewarded appropriately, despite the fact that new indications, better formulations and other key incremental innovations for established medicines can convey important and valuable benefits not only to patients but myriad other healthcare stakeholders.

As a patient, are you heartened by the coalition's official plans for NHS reform?

I think, theoretically, they make me feel better in the longer term. In the shorter term, I am intrigued to see how they turn out.

As a patient, I see stories in the news about significant job cuts and other disruptive actions that the proposals have caused quite a bit of anxiety within the healthcare system. There could be more turmoil as SHAs and PCTs [Strategic Health Authorities and Primary Care Trusts] are unwound, with the risk that some eyes in the DH are turned more towards what's happening within the NHS rather than focusing on patient services. But if the reforms lead to a renewed focus on patient outcomes, as their intent seems to be, that can only be a good thing for me as a patient.

How do you feel about the NHS reforms White Paper *Equity and excellence: Liberating the NHS*?

It's very ambitious and, while I applaud its intent – particularly the focus on outcomes and local accountability – whether or not it happens, and how it happens, will be intriguing.

We've now come almost full-circle. This White Paper and its proposals are reminiscent of the old fund-holding proposals, which were originally put in place by a Conservative Government, but were later rolled back to some extent.

There have been repeated moves in the past to try to move responsibility and accountability from what people consider to be bureaucracy through to practitioners, and particularly GPs; Tony Blair did something similar himself, and the latest White Paper is very much in that same mould.

My favourite quote ever about the NHS came from Ken Clarke, who was also a very good Health Secretary in most respects. He said: "Every time I mention the word 'reform', GPs reach nervously for their wallets." This was a perceptive, if somewhat barbed, comment because if you want to get change enacted within the NHS then there has to be some kind of reward, fiscal or otherwise, for the people who are subject to that change.

Do you think 'GP fund-holding' worked last time?

Fund holding worked in the respect that people were able to reinvest some of the savings they made for practice-specific services, with some GPs really buying into the spirit of things and delivering major improvements for their communities.

It will be fascinating to see the developments this time because, while some are already happy to take on responsibility for the types of activities proposed, there are other GPs who will never be willing, or able, to do this. I also think care must be taken to avoid perverse incentives that actually discourage good patient care and better outcomes, and which, while they may save money in the short term, will ultimately increase costs.

Do you feel positive about the still-new coalition's attitude and approach to pharma?

I welcome the signals that this Government won't be looking to re-negotiate the existing PPRS before 2014. If everything that follows is as positive, then the pharma industry in the UK can really buckle down to serving our customers – payers, prescribers and, above all, patients – in a secure environment that will bring out the best in us.

I am also interested in value-based pricing, around which there seems to be a lot of rhetoric at the moment. It's an elusive concept: nobody seems to know what it actually is. But because it seems clear that value-based pricing will take over from the PPRS when the current scheme expires, it's vital that companies operating in the UK gain a clear understanding of it as soon as possible.

So to answer your question, I'm moderately optimistic I guess.

> "This White Paper is reminiscent of the old fund-holding proposals"