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Title:
Making the proper choices on education for the pharmaceutical industry

ABSTRACT
In this interview, Professor Peter Stonier shares his personal perspectives[1] and experience with Carl Naraynassamy over various aspects of professionalism in the pharmaceutical industry, and particularly on the place of education, competence, and professional bodies. Prof Stonier explains his support for the revalidation programme for pharmaceutical physicians in the UK, and argues the merits of inter-disciplinary learning, and the e-portfolio for a record of training and life-long learning. He also calls for more proactive risk management and less crisis management, a stronger leadership base, and for the influence of accountants and commercial people in the pharmaceutical industry to be tempered. Senior decision makers in the pharmaceutical industry, educators as well as all medicine development scientists should find this discussion of interest.

KEY POINTS
I urge those who feel that they are capable, and can commit to a project with a purpose to volunteer their time. In return they get to help maintain standards, work in multi-disciplinary teams and develop professionalism.

I do not understand the fixation with teaching only Good Clinical Practice (GCP). GCP is indeed important, but clinical research is so much more than GCP!

The consideration given to the values and priorities of accountants and commercial people weighs too much in industry decisions.

[1] These are the personal views of Professor Stonier that in no way should be deemed to represent the views of any organisation with which he is currently associated.

Pharmaceutical medicine as a specialty is now well established in the UK. How has education contributed to establishing the specialty?

To its credit the pharmaceutical industry responded positively to the various calls to open up to greater learning. You need to realise that not long ago now, neither the undergraduate medical education nor the post-graduate pharmaceutical medicine education available adequately prepared one for industry-based research and development. Pharmaceutical medicine as a specialist subject was then a foreign concept which many confused with clinical pharmacology. The British Association of Pharmaceutical Physicians (BrAPP) led the way with the first ever taught and examined diploma in Pharmaceutical Medicine. Later the International Federation of Associations of Pharmaceutical Physicians (IFAPP) built on the BrAPP syllabus, and now PharmaTrain has itself built on the IFAPP syllabus.

The education syllabus has indeed provided the credible common currency that has supported the steady growth of the specialty in the UK, and beyond.

Talking of professional associations, what role in education can they play today?

Again if we take industry physicians as an example, in the not so distant past, their role was less circumscribed. Over time many of their responsibilities have been absorbed by new specialist occupations like clinical research associates (CRAs). Associations are instrumental in giving structure to job functions and creating career paths, forging professional identity, and providing useful training especially when standard practices like good clinical practice (GCP) are introduced.

I have noted that today, and for many reasons, the industry favours more internal training, and subsidises membership fees less. This has impacted on the income received by associations. In turn, the research i.e. the knowledge-expanding initiatives performed by the scientific societies and associations are impacted. The whole industry then loses out.

Having said all this, much success has been registered by pan-industry initiatives like those on adaptive design methodologies, and risk-based approaches. Arguably the leadership there came from company appointed senior executives, and not from volunteer associations. If this reflects an evolution in the roles and responsibilities of collective organisations, then professional organisations may need to respond with stronger leadership.

Does the attrition in corporate support call for greater volunteerism?

There is immense benefit for an employer whose staff is involved with the industry associations. However, it is difficult today for a company to be involved in areas where it cannot justify a direct interest.

I would encourage individuals to volunteer for small projects. With experience, this can expand into more significant roles, like being on a specialist committee that guides the development of examinations. All this is very enriching.

Pharmaceutical medicine would never have developed as a specialty without so many volunteers. Most of the educational supervisors of the pharmaceutical physicians training in the workplace are volunteers. The trainees themselves who engage with curriculum revision groups do so pro-bono. As we speak there are those

who are giving their time free, for example to write textbooks, draft codes of conduct and revalidation guidelines. Of course, ultimately this benefits patients and future generations of research and development staff.

So, I urge those who feel that they are capable, and can commit to a project with a purpose to volunteer their time. In return they get to help maintain standards, work in multi-disciplinary teams and develop professionalism.

Does Europe have now the right approach on the skills needed to support its drug development objectives? Can projects like PharmaTrain make a difference?

Absolutely, Europe has the right approach. PharmaTrain[2] which is a joint project with the Innovative Medicines Initiative[3] is delivering the education platform for drug development science and pharmaceutical medicine jobs. The common training standards deemed essential to speed up drug development are now available. No doubt, more money is needed for the projects.

What we certainly need are patients; confidence in the industry; and trained investigators!

We cannot afford to lose the standards established by PharmaTrain especially when globally universities are increasingly offering the PharmaTrain syllabus. We now need to appoint a maintenance body that will help to ensure that established standards are maintained. And the industry needs to send their staff to these training courses! I believe that developing a regime of bottom-up payment by users offers more security long term for the programme than planning to rely on government subsidy.

We need to recognise that in Europe as elsewhere, funding for drug development is generally affected by the loss of patents and the rapid attrition of brand loyalty after the loss of patents. Moreover, other countries are adopting the model pioneered by the National Institute for Health and Care Excellence in the United Kingdom to assess the value of new medications. Having said that, according to the US Food and Drug Administration2012 and 2014 have been bumper years, especially for anti-diabetics, vaccines and orphan drugs. If this indicates that the tide is turning, maybe there will be more money for training now that we are also coming out of the patent cliff?

How do you read the industry's attitude to training in general?

Much has changed in the makeup of the industry. Many decision makers are now based in the USA, where pharmaceutical medicine is neither officially recognised as a medical specialty nor is there much support for it from industry physicians. This is an illustration of the industry not speaking a common language. And in my experience, this makes it harder for European physicians to gain support for training in pharmaceutical medicine.

I may give you another graphic illustration. Not long ago, in recognition that the availability of clinical pharmacologists was crucial to drug development, the Association of the British Pharmaceutical Industry (ABPI) began to offer training bursaries in clinical pharmacology. But now that hardly any pharmaceutical company

[2] http://www.pharmatrain.eu/
[3] http://www.imi.europa.eu/

runs a clinical pharmacology unit, and some 40% of drug development is outsourced to Contract Research Organisations (CROs), this support became less relevant and the bursaries stopped. In a sense, this is now the responsibility of CROs. We see a situation where the industry cannot afford to train its staff, and neither can it afford not to train it. On the other hand, the CROs do not have a mandate to charge the industry the costs of training staff. This uncertainty over the responsibility for training between CROs and Pharma is unhealthy.

Having said this, we have still industry supported programmes like GSK's Academy of Pharmaceutical Medicine which caters for both physicians and scientists.

I find that companies are too focused on the short-term. Also, I do not understand the fixation with teaching only Good Clinical Practice (GCP). GCP is indeed important, but clinical research is so much more than GCP!

In order to enable the integral process of drug development to be appreciated, companies should aim for cohesion in training. Training should not occur in silos as it is now! While project teams are multi-disciplinary, especially for the increasingly common virtual teams, training does not take place enough in a multi-disciplinary environment. It is essential for the teams to learn together, so that they can better appreciate other sectors' needs. It is equally essential that learners can access those platforms where they can learn directly from their peers from different companies.

…..what about confidentiality?

Companies often use the cover of confidentiality as a reason for not allowing their staff to attend external courses. This argument does not stand! The industry also contracts a large number of independent pharmaceutical physicians and consultants who work here today and there tomorrow. The vast circulation of knowledge associated with this level of staff mobility cannot be a lesser threat.

How do we ensure that the right training and of the right quality is delivered?

In the UK the General Medical Council (GMC) which is the regulatory body for UK physicians applies a high level of control on the training of physicians. This is unseen in Europe. The training curriculum for physicians specialising in pharmaceutical medicine by law must be approved by the GMC. The GMC will also audit training events, and if warranted, can withdraw the accreditation granted to course providers, as it did recently.

A critical weakness in the European set-up is the absence of a standard setting body equivalent to the GMC. This variability in the control of physician education across Europe needs to be addressed. Currently several institutions offer Master degrees but there is no credible standard setting body to which they answer. Hopefully PharmaTrain will receive funding to step into this role.

I talked earlier of the mandatory process of revalidation for doctors in the UK. Revalidation is directly linked to the fitness to practise and must be seen as a key communication to the public, reassuring it on the competence of doctors. Whilst it is an administrative process, it is not a mindless exercise. Physicians are actively learning when they focus their minds on gathering the evidence of their training. It is an opportunity to put their work into context, to set out clearly the value of the task, and especially to integrate the task within the continuum of tasks. As learning for revalidation is self-driven, it allows physicians to focus on their needs rather than on

other people's agenda. It allows the dog to wag its tail, rather than the reverse. Revalidation does justice to the work of physicians.

In the UK, the General Medical Council i.e. the regulator for doctors ensures that doctors in practice have protected time for training. Technically doctors in the pharmaceutical industry come fully within their ambit, and are equally expected to have protected time to train. But then there is the usual tension between delivering services, and making time for one's education. Then there is the significant cohort of industry physicians who are not registered with the General Medical Council, and whose education is therefore not regulated by the GMC. The increasing recognition that better trained doctors lead to better patient outcomes and more patient centric medicine is undeniable support for encouraging training.

We also need to recognise that unlike doctors, there are other important functions, like CRAs that do not have a legal structure that guides their education.

It is essential that education and training is made an integral part of the working environment. This is especially needed since the industry is not keen for its staff to attend university post-graduate courses. This is where the concept of outcomes-based education has merit. Every job function should have its matching job profile defined. Then training can be targeted to match the profile, i.e. the needs of the job. The various competency profiles need to be generated as a pan-industry undertaking by an independent organisation like the IMI. It is so important that a practitioner understands the scope of their actions. In the case of a pharmaceutical physician, for example, this would be understanding the value and consequences of putting their signature on a document. The competency framework would also lend itself to discussions on promotion, like keeping somebody on probation and justifying pay increases.

Too many of the resources spent on training are wasted. Typically there is no follow up on training received. It is meaningless to append the agenda of a training course attended as an attestation of competencies that an individual claims to hold. Typically in this instance, we would need a reflective commentary of the sort Plan-Do-Review. In other words, we need to know how the learning has impacted your personal development, and what will you do next time that you have this task to do. Having said all that, it is now necessary to have validated experiments to test the theories enunciated on this topic.

The format for collecting evidence of staff training is another topic that appears in need of some harmonisation. I hope that the industry will see the benefit of adopting the electronic portfolio (e-portfolio) model that has been successfully used by UK pharmaceutical physicians and every doctor in the UK National Health Service. In a nutshell, the e-portfolio is simply an electronic compilation of one's work. Although there are some legitimate concerns over confidentiality, but no less than everywhere else, and for which there are safeguard protocols the e-portfolio has provided a convenient vehicle for submitting evidence of training. It is especially adapted to capture reflective practice, learning experiences and quality improvement activities which are a form of learning and continuous improvement that I would encourage the whole industry to adopt.

Are there enough trained educators in the industry?

No! Another critical weakness of education and training in the medicines industry must be the small number of educators who are formally qualified to educate. The industry should follow the lead of the universities which now accept that 'knowing' whilst essential, is not a sufficient entitlement to teach. Therefore it is important to encourage lecturers to learn how to educate others. There is certainly insufficient research generated evidence on which to make decisions on matters related to education.

We also need to recognise that learners and teachers fall within the same continuum. It is now well accepted that adult educators learn together with those they are engaged to educate. This makes them facilitators for the transfer of knowledge. Companies must give more value to learning together strategies, to inter-professional development, and to reduce training which involves heavy downloading of information from 'subject matter experts'.

What else would benefit the development of medicines?

The consideration given to the values and priorities of accountants and commercial people weigh too much in industry decisions. Traditionally, the company's medical department which housed the medical ethos counterweighed this tendency. In recent times, as multi-disciplinary teams have replaced functional groups, the concept of the medical department has gone. The counterweight could be restored if there were more scientists, and doctors, in positions of leadership in industry. We need to re-empower scientists, and doctors, in society generally, and industry specifically.

We also need to be more risk assessors instead of being crisis managers. Crisis management may be cheaper but it costs lives. Even the regulators now encourage us to practise a management premised on the degree of risk. How can we not be challenged in the way we think? We only need to look at the crack showing with the development of follow-on biosimilars. Unlike the development of generics, every biosimilar will require its own risk strategy. And many feel that the development of biosimilars would have been swifter if the skills for risk management especially the post-risk assessment judgment skills were there. We must actively offer more training to support the development of biosimilars. There is a long queue of learners out there!

It all comes back to leadership. Leadership should not be the province of a few. Everybody, in all functional groups has a role to play in leadership.

CONFLICT OF INTEREST

Both Peter Stonier and Carl Naraynassamy confirm that they have received no external funding in relation to this interview.

Peter Stonier is Board Director of the PharmaTrain Federation, a not-for-profit membership organisation fostering education and training in pharmaceutical medicine / medicines development science in the EEA. He is Programme Director of the UK postgraduate specialty training programme in Pharmaceutical Medicine with the Pharmaceutical Medicine Virtual Deanery. He is visiting Professor in Pharmaceutical Medicine at King's College London, Institute of Pharmaceutical Sciences, Faculty of Life Sciences and Medicine.

Carl Naraynassamy declares that there are no potential conflicts of interest in the generation of this document.