FRIENDS OF THE SCOTSMAN

There's a lot more to pharmacy than just preparing our prescriptions

Specialist disciplines unite to trace the entire journey of a drug 'from bench to bedside', writes **Professor Donald Cairns**

One of the most striking things that I have observed during my career – I have worked in four different UK schools of pharmacy, otherwise known as Pharmacy and Life Sciences at RGU – is the breadth of expertise that colleagues bring to a school of pharmacy.

Unlike, say, departments of chemistry, biology or medicine, which are highly specific to a narrow subject field, pharmacy has breadth. It encapsulates many sub-disciplines and builds a bridge between the traditional sciences of chemistry, biology and physics with the clinical sciences.

A school of pharmacy allows us to examine the entire journey of a drug quite literally 'from bench to bedside' and beyond. In many ways, the expertise that exists within the school mimics the activities of a small innovator pharmaceutical company and takes that experience onto the clinic.

Drug discovery is a process of innovation and creation fuelled by the desire to address an unmet medical need. It begins with the generation of ideas, identifying those of value through modern approaches such as computer-aided drug design. These ideas are then materialised with the synthesis of a new chemical entity (NCE), in a chemistry laboratory. Once synthesised, the NCE needs to be identified and fully characterised, and this requires the use of sophisticated analytical and spectroscopic techniques such as infra-red (IR), nuclear magnetic resonance (NMR) spectroscopy, mass spectrometry (MS), or a combination of techniques.

Alternatively, the active substance may be a natural product produced by a plant, an animal or a micro-organism. In this case, the active compound must be isolated and extracted from a complex background of related chemicals (perhaps many thousand), identified and characterised. These techniques are all studied by students within the school's labs.

Once the NCE has been identified and the structure determined, the sample must be analysed to ascertain its purity and to determine whether there are any potentially hazardous impurities present. This is usually done in our analytical chemistry laboratory, using separation techniques of gas or liquid chromatography.

Any compound used therapeutically must comply with the purity requirements of the British or European pharmacopoeia. These publications provide legally binding standards on all pharmaceutical manufacturers. If a preparation complies with the requirements of the pharmacopoeia, it is labelled with the letters 'BP' or 'EP' after its name.

In addition to the chemical identification of the drug, a sample must undergo pharmacological testing to ascertain whether it possesses any efficacy (or, more prosaically, to see if it works at all). These analyses are undertaken in pharmacology laboratories using a mixture of in vitro assays (ie studies carried out within a laboratory), or in vivo studies requiring the use of whole animals.

Substances administered to a body seldom remain unchanged and are usually modified into more water-soluble derivatives, called 'metabolites,' by enzymes in the body. This must be studied to ensure these metabolites are not toxic or hazardous. Very often, the initial compound must be refined to produce a compound where any benefit outweighs the risk of undesirable side-effects.

At the end of this process, if everything has gone to plan, there will be a candidate compound against the chosen disease state. This now needs to be formulated into a medicine.

The terms 'drug' and 'medicine' are often used synonymously but they are quite different. A drug is the active chemical substance, whereas a medicine is the formulated product supplied to the patient. For example, aspirin is a drug, but aspirin tablets are a medicine. Hydrocortisone is a drug, but hydrocortisone ointment is a medicine and so on.

Great skill is required to produce a stable medicine with a sufficiently long shelf-life which is also palatable and easily taken – this is accomplished in pharmaceutics labs. Paracetamol has an awful taste, but syrup preparations manage to disguise the unpleasant taste and allow the product to be taken by children.

The discovery and manufacture of drugs and medicines is only one aspect of the work of a school of pharmacy and life sciences.

A huge amount of the work we do is concerned with 'patient-facing' aspects, or clinical pharmacy practice. These describe the clinical interactions a pharmacist has with the patient to ensure that he or she is receiving the correct medicine, at the correct dose, for the correct condition. Pharmacists are the experts in medicines and should be involved in all aspects of therapeutics.

In the UK, pharmacists may initiate drug therapy without recourse to a physician. This development of non-medical prescribing, recognises the pharmacist's unique knowledge of medicines and their uses, and has revolutionised pharmaceutical care in recent years.

Pharmacists are also involved in pharmacovigilance, clinical trials and improving healthcare for the population, as a whole. Pharmaceutical public health allows the pharmacist to give advice on topics such as smoking cessation, alcohol reduction, emergency contraception, and much more.

The staff expertise and excellent facilities available within the School of Pharmacy and Life Sciences at RGU allow each step of the drug journey to be studied and demonstrated in a fully integrated manner from bench to bedside. If we do this well, we will inspire and educate the next generation of leaders in pharmacy.

Professor Donald Cairns, head of the School of Pharmacy and Life Sciences at Robert Gordon University

↑ Schools of pharmacy involve many sub-disciplines to build a bridge between the traditional sciences of chemistry, biology and physics and the clinical sciences

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ROBERT GORDON UNIVERSITY ABERDEEN

Holyrood's proposed organ opt-out bill seriously misleading the public

It's not a 'soft' system where family have final say, writes **Dr Calum MacKellar**

The number of persons waiting for life-saving organs is, unfortunately, continuing to increase right across the world, including in Scotland.

As a result, the Scottish Government is seeking to change the law with the Human Tissue (Authorisation) (Scotland) Bill in an attempt to increase the number of organs from deceased persons that can be removed for transplantation.

But although the intentions of the Government are commendable in attempting to save more lives, it is actually misinforming the Scottish public about what is really being suggested in the bill.

This is because it is distorting the truth when stating that the primary purpose of the bill "is to introduce a 'soft' opt-out system of organ and tissue donation for the purpose of transplantation".

In this regard, opt-out systems represent legal systems enabling persons to instruct that their organs not be removed for transplantation after death (for example, by carrying a refusal card, informing relatives or joining a register) while the organs from all those, who have not left such instructions, can be removed.

These include soft opt-out systems whereby nearest relatives have a final say as to the removal of organs and hard opt-out systems whereby relatives do not have a say.

When the propose Scottish bill is actually examined, however, it is clear that what is being suggested is a form of hard opt-out system for the most common organs such as heart, lungs, kidneys, liver, eyes, pancreas, and not a soft opt-out system where relatives have a final say.

Indeed, according to the proposed bill, when the deceased has left no indications about what should happen with his or her organs, then the deceased is 'deemed' to have authorised the removal and use of his or her organs for transplantation.

Moreover, in this case, if no clear evidence exists that the deceased was unwilling to donate his or her organs, nearest relatives would have absolutely no legal right to oppose the removal of these common types of organ.

This means that Scotland would become one of the very few countries in the world to enact a form of hard opt-out system for organ removal for transplantation which is generally considered as unduly traumatic for relatives in most other European countries.

The nearest relative would only be able to have a final say, in certain circumstances, for the removal and use of less common types of organs for transplantation, such as the face, reproductive organs and limbs. Only, in this case, would a form of soft opt-out system exist.

Moreover, the bill suggests that organs can still be removed from the deceased and used for research, education, training, audit and quality assurance even if he or she has left no indications for such a possibility.

This is because when relatives have no actual knowledge that the deceased person was unwilling for his or her organs to be used in such a manner and this person has not opted-out of transplantation or left any indications about such purposes, then these relatives may still authorise the use of organs in these ways.

Most people welcome the possibility of donating their organs after death in a spirit of altruism. But this bill will completely transform the context to one in which the state may be entitled to appropriate the organs of those who have left no wishes without their nearest relatives having any legal right to a final say.

This is unfortunate, since when the relatives of a deceased person have no final say about whether certain organs should be removed in an opt-out system, this could lead to an undermining of public confidence in the whole system and thereby eventually reduced the number of available organs.

An example of the dangers that may arise when healthcare professionals 'deem', 'assume' or 'presume' are the wishes of a person is what specifically led to the scandal at Alder Hey Children's Hospital in Liverpool in the 1990s.

At this hospital, body parts of children were retained after post-mortem examination when healthcare professionals 'presumed' that this would be acceptable to parents without consultation.

The Scottish Government should not, therefore, make the same mistake in preventing nearest relatives to have a legal right to a final say about what happens to their loved-one's organs.

Dr Calum MacKellar, director of research of the Scottish Council on Human Bioethics

Scottish Council on Human Bioethics

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