

Fresenius Kabi meeting discusses ways to use biosimilars in hospital setting

Dr Andrew Watts from Bath University addresses the meeting sponsored by Fresenius Kabi



The Conrad Hotel on Dublin's southside was the venue for a fascinating evening of talks in October on subjects ranging from biosimilars to monoclonal antibodies.

Sponsored by pharmaceutical company Fresenius Kabi, the presentations on the night drew a large attendance, a healthy mix of hospital pharmacists and chemistry/biology experts.

Following the welcome and introduction by Tadgh Redden, Senior Oncology Pharmacist at St Vincent's Private Hospital, Dr. Andrew Watts took to the microphone after flying into Dublin from the UK for the event.

Dr Watts works as Senior Lecturer of the Department of Pharmacy and Pharmacology at Bath University, where his research interests lie at the interface of chemistry and biology, utilising synthetic organic chemistry to investigate biological systems. He is involved in the design, synthesis and use of derivatives as tools to study enzymes of biological and medical importance.

Dr Watts told *Hospital Professional News* that he was delighted to make the trip over to give his presentation on the 'Manufacture, Expiry and Stability of Monoclonal Antibodies'.

"I was asked by the sponsors to come over following a similar talk I did in front of NHS aseptic managers in the UK. They thought the content in the talk was something Irish hospital pharmacists would be eager to hear. I'm an academic, so I really enjoy going around speaking like this, learning about new things, about how things are carried out."

Dr Watts presentation covered a range of technical topics which were well received by the attendees.

He argued that when it comes to the manufacture of monoclonal antibodies, you cannot say that one manufacturing method is better than another.

Gary O'Brien, UCC talks to delegates at the meeting



Gary O'Brien and Dr Andrew Watts, clinical pharmacists with Tadgh Redden, senior oncology pharmacist at St Vincent's Private Hospital



Fionnuala Kennedy, Head of Pharmacy at Mater Private with Tadgh Redden, senior oncology pharmacist at St Vincent's Private Hospital



Tadgh Redden, senior oncology pharmacist at St Vincent's Private Hospital, Fionnuala Kennedy, President of HPAI, Natasha Doyle from Fresenius Kabi, Gary O'Brien, UCC, Gavin Butler, Fresenius Kabi and Dr Andrew Watts, Bath University



"Ireland is a small country but we are progressive," he said. "We have come a long way in relation to biosimilars, and we are doing a lot better compared to some countries, it's important to recognise that, but we can always do better."

"Most of biosimilar changes that has happened in hospitals here have come from the hospital pharmacies departments and their pharmacists. They really do a great job in convincing health professional staff to try improve usage. If you had to reassure patients that biosimilars are safe, one way to perhaps persuade them would be put into a registry for adverse reactions."

O'Brien added that as we move forward, it is not going to be one approach fits all, that it will probably be taken on a case by case approach.

"As a community pharmacist myself, I feel we have a lot to give in promoting biosimilars to the public. If you think about the switching back to generics capping in 2013, we were at the coalface of dealing with patients who were very upset about the changing from the propriety brands to generics. Community pharmacists, although not prescribing, can be used as place to talk to patients and help them get over any concerns they have with biosimilars."

Fionnuala Kennedy, Head of Pharmacy at Mater Private, said: "The existence of the different special interest groups (SIGs) in the HPAI facilitates a vital exchange of ideas, experience and learning among members."

"The Aseptics SIG is a particularly good example of how beneficial this can be. Their aims are to create a communication network for pharmacists working in Aseptic Services and to promote the educational requirements and role of the specialist pharmacist working in Aseptic Services, both internally and externally to the profession"

"The HPAI actively supports these SIGs and notes the important role they play in furthering the development of hospital pharmacy practices, assisting in the provision of continuing pharmaceutical education and representing the views of members working in their specialist areas."

"It really does come down to the bag and the particular drug [in question]," he said. "The drugs are different and the way they react can often change."

It must be pointed out, he added, that these were all accelerated studies, that they were not yet in use, so he wasn't going to draw conclusions about how an actual drug would work in storage.

"But it does show different drugs act different in different bags."

Dr Watts explained that the summary of product characteristic (SPCs) can only assign a relatively short shelf life for certain drugs, and due to logistics and the cost of these drugs, "it would really be much more beneficial if we had much longer shelf lives, not just for our ability to produce them in-house in our own aseptic units, but it would make it easier for external compounders to prepare and transport them also."

"There are a lot of valid reasons

why we'd want to extend shelf lives of these drugs," he said.

He explained that current short shelf lives are really only applied principally to minimise the risk of contamination.

"The shelf lives are not applied because the drugs go off, it is mainly to eliminate the chance of contamination."

According to Dr. Watts, there is no single way to assess biological drugs, because of their complexity and because of the nature of what they are, that you are going to need an entire range of techniques to assess them.

"So just to break down some of the key quality attributes that we need to assess," he said, "we need to look at abundance, aggregation, and biological activity, in particular, biological activity should be the cellular response. Shape is key when it comes to the monoclonal antibodies."

Biologics and Biosimilars

The other presentation on the night came from Gary O'Brien from University College Cork's School of Pharmacy, who also works at Broderick's Chemist in Cork.

O'Brien was in Dublin to discuss 'Biologics and Biosimilars - Enough of the Small Talk', where he explained to *Hospital Professional News* he would hope that attendees would take away that instead of constantly just talking about biosimilars, it is high time to sit down and come up with real ways of implementing them in the hospital and community setting.

"There's been enough wishy-washy talk about it, we need to start to use more of them," he said.

His talk focused primarily on the obstacles we face in introducing biosimilars in Ireland and how we can improve this moving forward.