NHS
South West
Clinical Senate

## Notes from Senate Council Meeting

Held on Thursday 6th December 2017
In Taunton Rugby Club

# Meeting Notes

| | | Action |
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| 1 | **Welcome and Senate business items** | |
| | • Attendance and apologies listed below.<br>• Final versions of the Principles for Reconfiguration and Tobacco Prevention will be circulated this week.<br>• The next Senate Council meeting (1st February 2018) will focus on workforce.<br>• The Senate Assembly is on 22nd March. The theme will be 'Clinicians as Change Agents'. Registration is open. Further details to follow.<br>• Today's topic is biosimilar medicines which was brought to the Senate by Stephen Brown the NHS England South Regional Pharmacist. Biosimilars are biologically produced biologic medicines.They are close but not identical to the source molecule. | |
| ***To what extent and how should the transition to use of biosimilar medicines be prioritised to enable the provision of best value care in the NHS?***<br><br>***Does the Clinical Senate support the uptake of biosimilar medicines at pace and how can their best practice use be maximised?*** | | |
| 2 | **Setting the Scene: Medicines Value Programme and Biosimilar Medicines Commissioning Framework** | |
| | This was presented by Stephen Brown, Regional Pharmacist, NHS England South.<br>The NHS spends £17.4 billion a year on medicines (£1 in every £7). The Five Year Forward View outlines that funding and efficiency is a gap which the NHS needs to close. One of the four key themes outlined by The Medicines Value Programme is medicines optimisation, which is of significance for biosimilars.<br>The Commissioning Framework for biological medicines was published in September 2017. This paper suggests that as the biosimilar market develops there is the potential to deliver significant savings of up to £300 million per year by 2020/21.<br>The table on page 4 outlines responsibilities for patients, prescribers, providers and commissioners. These responsibilities will be considered further in the group work during the afternoon session.<br>Some work has been undertaken to understand the drive to uptake use of biosimilars. For example it is known that a patient who is in a last resort treatment phase is unlikely to be encouraged to switch to biosimilars. The approach taken by Trusts and clinical views on biosimilars also impacts | |



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| | uptake.<br>Considerations:<br>• The NHS England South approach to the best value biologicals<br>• Communication across regions to share decision making<br>• Greater volume of evidence welcomed on switching<br>• Flexible conversation about switching to biosimilars v imposed switch<br>• How should incentivisation be used? | |
| **3** | **The MHRA Regulatory and Licensing Process** | |
| | This was presented by Anne Cook, Biologicals Quality Assessor, Licensing Division, MHRA (Medicines and Healthcare Products Regulatory Agency).<br>AC explained the process for developing biological medicines and the process for licensing biosimilar medicines.<br>The Regulatory and Licensing Process for biosimilars involves testing the quality of manufacturing. The same process is followed as for the reference medicine but with the additional 'comparability exercise' test.<br>.<br>Biosimilars are subject to a robust regulatory process and batches are not released to market unless they fall within the agreed range of standards. It is recommended that biosimilar are prescribed by brand for traceability purposes. | |
| **4** | **Pharmaceutical Perspective** | |
| | This was presented by Keiron Hughes, Head of Strategic Pricing, MSD Pharmaceuticals.<br>• Primary importance is to make medications accessible for patients.<br>• Awareness that as well as manufacturing the drug companies can provide Homecare Programmes for patients.<br>• Procurement model has changed with the drive for best value which could impact the security of supply of the product.<br>• NHS planning can affect security of supply where business cases for newly marketed drugs aren't agreed until sometime after its release.<br>• In the biologicals market, the originator is the first medication in the market and the biosimilar is the second The first biosimilar to enter the market has a first-mover advantage as there may be reluctance to move to subsequent entrants<br>• Variability in incentive agreements. The distribution of financial savings needs to be clearly outlined.<br>• Although there is freedom in medications pricing, the pricing must be justifiable to NICE. Therefore the freedom to price an originator is restricted to some-degree<br>• For all Procurement processes availability of supply needs to be considered. Tenders for 'generic' pharmaceuticals include a mechanism to ensure the NHS does not lose-out when alternative product is sourced at a higher price. For branded pharmaceuticals this is not the case. | |

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| **5** | **Case Study: Infliximab** | |
| | This was presented by Dr Nick Kennedy, Consultant Gastroenterologist, Royal Devon and Exeter Trust.<br>NK presented the switch to use of Infliximab biosimilars in Exeter. The key points are about identifying, consulting with and educating stakeholders; building a switch team; identifying potential cost-savings and agreeing and securing the gain-share with CCG and Trust; seeking approval at local Department and Trust; give information to patients; and collect pre and post treatment clinical and lab data and enter into the registry.<br>The benefits of switching are: using savings towards team expansion and service development e.g. virtual clinics for biologics, process for early detection of anti-TNF failure, tighter monitoring of adalimumab usage and support for Blueteq case management process.<br>NK has found no local resistance from clinicians about the use of Infliximab. There is some fear from clinicians of switching patients who have been hard to get into remission. The Nor-Switch study has proved useful in reassuring some clinicians.<br>NK felt that it was reasonable to push towards a cheaper pathway for patients by switching to the use of biosimilars in appropriate circumstances. | |
| **5.1** | **Patient experience of Switching** | |
| | A patient with a chronic condition who has experienced switching to Infliximab gave an insight into this experience. He reported that he experienced no adverse effects from his change to a biosimilar medicine. At the point of switching he had a face to face conversation about this with his specialist nurse who explained that the use of biosimilars was related to cost efficiencies. He found the nurse introduced the concept to him in a positive way and after the meeting he came away understanding that the biosimilar medicine was the same as the original and therefore he was not anxious about switching.<br>When asked about some Trusts who are imposing the switch to biosimilars via a letter to patients, he felt that the face to face approach was better. | |
| **6** | **Patient Experience and Survey Findings: What is important to patients when changing medication?** | |
| | This was presented by Kevin Dixon, Chair, Citizens' Assembly.<br>A survey asking patients about what would be important to them in the process of switching to biosimilar medicines was circulated via each Healthwatch in the South West. KD presented these findings. 95% of respondents agreed that they had no objections or concerns about switching to a biosimilar medicine if it was proven to be as effective and would help save the NHS money. The survey highlighted that of most importance to patients is to know why the medicine is being changed, how effective the new medication would be and about the side effects of the new medicine.<br>From focus groups KD ran in the Torbay area with Age UK and a visually impaired group – he found that there was no reporting of unhappiness/uneasiness about changing medication. Patients are concerned with having relevant quality information. | |

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| | KD expressed mild concern about the focus being on biosimilars being the cheaper option. A more rounded reasoning for the use of biosimilars would perhaps be received more positively by patients. Particularly as there is some residual notion that the more expensive a medicine is the better it is.<br>In general it was found that patients trust their clinicians. Therefore if the clinical team is divided on opinions about using biosimilar medicines, this could provide an unclear message for patients. | |
| **7** | **Group Work** | |
| | The Senate Council attendees split into three groups to consider:<br>1. The patient generally has a chronic debilitating disease so if a current treatment is proving to be effective should any change be considered purely on the ground of efficiency? How do we best address the importance of transition to the best value biological on the ground of cost-effectiveness for the population?<br>2. One prescriber role is as advocate for the patient; so how is this balanced against the responsibility to be a good custodian of NHS resource and maximise the cost effectiveness of the service, therefore enabling the NHS as a whole to provide a greater level of care to the population?<br>3. How should change be driven or influenced in order to remove barriers and provide the most cost-effective service to the local population? | |
| **8** | **Feedback and Recommendations** | |
| | Each group fed back and the Senate Council agreed that the move towards update of biosimilars should be prioritised.<br>Group 1: Communications plan is key; education about biosimilars for clinicians; consideration of the effect on patients which multiple switching would have.<br>Group 2: Evidence is required – to ensure confidence of clinical staff; link to royal colleges for clinical engagement; prescribers need freedom to prescribe (not just to prescribe the cheapest option); greater likelihood of nocebo effect.<br>Group 3: Importance of clinical trust and consistency; infrastructure in place and systematic approach to support the switch; gain share agreement with CCG.<br>The Senate Council also agreed that is was appropriate to recommend the switch to biosimilars at pace. It was suggested that as a starting point, Trust's could be encouraged to switch 80% of patients to biosimilars within the first three months of biosimilars being endorsed in their Trust. | |

**Present:**

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| David | Halpin | Consultant Physician and Honorary Associate Professor | Royal Devon and Exeter Hospital |
| Margaret | Abban | Public Contributor | Healthwatch Cornwall |
| Marion | Andrews-Evans | Executive Nurse | Gloucestershire CCG |
| Mary | Backhouse | Chief Clinical Officer | North Somerset CCG |
| Stephen | Brown | Regional Pharmacist | NHS England |
| Dr Anne | Cook | | |
| Katie | Cross | Consultant General Surgeon | Northern Devon healthcare trust |
| Malcolm | Dalrymple-Hay | Consultant Surgeon. Service Line Director | Plymouth Hospitals NHS Trust |
| Ellie | Devine | Senate Manager | SW Clinical Senate |
| Kevin | Dixon | CA Chair | Healthwatch Torbay |
| Caroline | Gamlin | Area Team Medical Director | NHS England South Region, South West |
| Keiran | Hughes | Head of Strategic Pricing | MSD MERCK |
| Joanna | Kasznia-Brown | Consultant Radiologist | Taunton and Somerset NHS Foundation Trust |
| Nicholas (Nick) | Kennedy | Consultant Anaesthetist and Intensivist | Taunton and Somerset NHS Trust |
| Nick | Kennedy | Consultant Gastroenterologist | RD&E |
| Bettina | Kluettgens | Director of Patient Safety | SWAHSN |
| Vaughan | Lewis | Clinical Director | Specialised Commissioning NHS South |
| Jane | Mitchell | Professional Lead for Physiotherapy | Cornwall Partnership NHS Foundation Trust (CFT) |
| Nick | Pennell | Citizens' Assembly Member | Healthwatch Plymouth |
| Maggie | Rae | Consultant in Health Care | Public Health England |
| Sarah | Redka | Senate Administrator | SW Clinical Senate |
| Emma-Jane | Waller | Pharmacist | Asda |
| Tariq | White | Assistant Director of Transformation and Outcomes | NHS England South Region, South West |

**Apologies:**

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| Diane | Crawford | Lead Scientist and Director of Medical Physics and Bioengineering | University Bristol NHS Foundation Trust |
| Sara | Evans | Consultant Geriatrician | Royal United Hospital Bath |
| Paul | Eyers | Vascular Surgeon | Taunton and Somerset NHS Foundation Trust |
| Melanie | Feldman | Consultant colorectal surgeon | Royal Cornwall Hospital Trust |
| Aileen | Fraser | Clinical Director | Bristol Community Health |
| Ceri | Hughes | Consultant Head and Neck Surgeon | University Hospitals Bristol NHS Trust |
| Benedict (Ben) | Lankester | Consultant Trauma and Orthopaedic Surgeon and Clinical Director | Yeovil District Hospital |

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| Bruce | Laurence | Director of Public Health | Bath and North East Somerset Council |
| Andria | Merrison | Consultant Neurologist | North Bristol NHS Trust |
| Dave | Partlow | Clinical Development Manager | South Western Ambulance Service NHS FT |
| Sally | Pearson | Senate Chair | Gloucestershire Hospitals NHS Foundation Trust |
| Ann | Remmers | Maternity and Children's Clinical Director | SCN |
| Philip | Rolland | Consultant Gynaecological Oncologist | Gloucestershire Hospitals NHS Foundation Trust |
| Peter | Rowe | Consultant Nephrologist | Plymouth Hospitals Trust |
| Mark | Stone | Pharmacist Consultant/Devon LPC Project Lead | Devon Local Pharmaceutical Committee and Tamar Valley Health Practices |
| Andrew | Tometzki | Consultant Paediatric Cardiologist | University Hospital Bristol NHS Trust |
| Miles | Wagstaff | Consultant Paediatrician, Neonatologist | Gloucestershire Hospitals NHS Foundation Trust |