Implementing Biosimilars – Learning

Themes from a meeting with a single Trust re barriers to uptake of biosimilars - 29th January 2018

February 2018 – final
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Background

Leads from the Commissioning Support Units (CSUs) met with pharmacy leads from an Acute Trust in the North Region for the purpose of;

- Optimising the Regional Trust biosimilars questionnaire.
- Improving our understanding to enable the delivery of the questionnaire.

This was a face to face meeting with Pharmacy leads from an acute Trust in Manchester. This Trust has a large use of biosimilars covering paediatrics, adults and across several clinical specialities.

The learning points will be captured in the NHS Trust questionnaire final report. The following is a summary of the key learning;

Key learning points

Purchasing and procurement

- There can be a lead in time for completion of procurement/tendering, which may go beyond the period of launch of a new biosimilar. Trusts will be required to follow the tendering timelines unless interim prices have been made available.

Product launch – indications

- Biosimilars are not always available in every indication (ie the licensed use for a clinical diagnosis). Where licensing is not available, then patients would not be switched. Clarity maybe required on this point to confirm accuracy.
- Biosimilars may not always be available in the right formulations, or strengths. For example, rituximab was not initially available in both strengths making it difficult to switch all patients at once.
- Each formulation requires assessment by the Trust to ensure they are safe, and suitable for all patients. For example, if a graduated syringe formulation is not available, then dosing for children may not be possible for children on part doses. Or if it is produced only as an auto-injector syringe that administers only a whole dose, then this may not be suitable for all patients who have smaller doses.

Product launch - formulations

- Where drugs are to be given as infusions (in bags), then these may need to be made up from vials into an infusion bag. This can take up nurse/clinical time in the clinical unit/ward, and has its own risk of error if this preparation is done on the ward during busy clinical time.
- If an infusion is standard and is to be administered to a large number of patients by a Trust, then ready-made infusion bags with the right amounts and strengths can be made up off site as a batch by a specialist manufacturing unit. These bags will be unlicensed (as they are not being made up for the individual patient), and so governance processes (Trust committee assurance) need to be completed to optimise patient safety.
- Infusion bags prepared by manufacturing units require stability data and quality control, and so there may be a lead in time before this is completed and the supply is readily available for a new biosimilar product. The ability of manufacturing units to respond to the demand, or keep the supply continuing may also be an issue.
Note: Adalimumab; there are a large number of different biosimilar preparations that maybe launched over the next year. Each could have different licensing, costs, and maybe different devices (eg types of subcutaneous injection for self-administration).

Product launch – introduction

- There is an increased workload to introduce a new biosimilar and minimise patient risk. These include; clinical training for using different product devices, implementing or changing clinical protocols, and checking and signing off. These maybe digital protocols, or on paper.

Storage & administration

- For every new product (eg biosimilar) there will be additional administration to carry out to manage the stock safely in pharmacy, and in the clinical area such as the ward or in outpatients.

- Some biosimilars require refrigeration. This requires space in the pharmacy fridges, ward fridges and fridges in patient’s homes where self-administered formulations are used. In the extreme, a new fridge may need to be hard wired in a pharmacy at some cost (eg £5k). So, the physical size of the packaged product is important, and can vary significantly. For a Trust, it could remove the option for certain biosimilars that are particularly bulky. This may be a significant issue for large trusts with several hundred patients when introducing a new biosimilar.

- For patients self-administering injections, there needs to be a check that patients have the fridge space for storage with the quantities prescribed.

For example, there were large differences in pack sizes for some low molecular weight heparins.

Clinical specialities

- There are differences between clinical specialities for adoption and roll out. Main clinical areas for biosimilars are cancer, rheumatology, dermatology and gastroenterology.

- Some of these such as rheumatology, maybe more familiar with drug regimens, and have established approaches to manage use and uptake.

- The different clinical specialities and their patients may have different levels of concern in relation to clinical risks from switching to biosimilars for existing patients. For example; a flare up for a rheumatology patient whilst significant, may be controlled with traditional drugs quickly and there may not be long term consequences. Whereas, a flare up of a gastrointestinal patient could result in major bowel surgery for a patient and affect their ability to work as a young adult. This may affect patient consent and clinician concerns.

- Royal colleges endorsement is also a factor for patients and clinicians.

- Social media can have a big influence on patients’ views about the switch. This provides the avenue for sharing patient experiences. Therefore, it is important to ensure a well-planned process, and that patients have access to the right support to build the reputation of the Trust and department for future biosimilars switches.
Resources - finance

- Concerns were expressed that CCG gain shares can take a long time to set up, eg 1-2 years. During this time financial benefits can be lost. There is complexity with the range of different stakeholders involved e.g. finance, pharmacy, contracts.

- The high cost drugs pharmacist model with NHSE works well for this trust.

- It was noted that whilst set up resources are required, there are ongoing costs to manage the use of biosimilars, and there are concerns where short term gain shares don’t cover the need longer term.

Shift to outpatients/day case

- Pharmacy are often involved with the process of change – gaining committee and consultant consensus, governance, product and clinical leadership for the change, and they may provide the patient level changes. However, where pharmacy doesn’t have a strong established presence in the clinical department, then this can be slower to achieve. Pharmacy is often active in rheumatology and haematology but may be less so in other clinical specialities. Where patients are managed via outpatients, these may not have pharmacy presence to work with the staff on the logistics and change.

Biosimilars patient national registry

- Best practice recommends that records of use of batches of biosimilars are kept on a national registry at patient level. The entries are done at patient level by the trust – requiring clinician or administration time. This is recommended to monitor the use of particular batches for any safety concerns.

- However, some biosimilars are not on a national registry, and a trust may exclude these brands from local use for this reason. This may cause issues if these are the most cost effective product being recommended by the commissioner.

Patient helplines

- If a large trust is doing a switch, best practice is to consent the change for each patient and provide a helpline or the ability for patients to contact the department with any concerns. This may need additional resourcing or planning to cover these calls to the right clinicians.