

To coincide with the launch of the British Biosimilars Association, NHS England's Chief Pharmaceutical Officer Keith Ridge answer five key questions on the uptake of biosimilar medicines.



Q) How big a role does the NHS see for biosimilars in widening access to biological medicines and easing pressure on budgets?

Keith Ridge: The development and use of biological medicines has led to important strides forward in the effective treatment of a number of diseases and the care of patients. In many ways it's not surprising therefore that biological medicines are commercially successful, with the majority of medicines in the top 10 expenditure wise being biological medicines. Across the globe, health systems are learning more about the potential of biosimilar medicines. The international experience is that biosimilar medicines tend to come to market at a lower cost than the equivalent already in use. As more biosimilars are becoming available for a wider number of health conditions, the NHS will carefully consider whether they present opportunities for considerable savings against other higher priced drugs. NHS England supports the appropriate use of biosimilars which will drive greater competition to release cost efficiencies to support priorities for patient care generally, as well as the treatment of an increasing number of patients and making headroom for the utilisation of new, clinical and cost effective innovative medicines.

Q) What is the NHS already doing to encourage increased uptake of biosimilars and what

more can it do in future?

Keith Ridge: It is important that patients and NHS staff have access to authoritative information about biosimilars. Therefore NHS England has published 'What is a biosimilar medicine?' a document which provides key clinical and non-clinical stakeholders with accessible information on how to support the appropriate use of all biological medicines, including biosimilar medicines for the benefit of NHS patients. Further information and the document is available via link - <u>http://www.england.nhs.uk/ourwork/pe/mo-dash/#biosimilars</u>.

It is the first collaborative publication on biosimilar medicines at a national level and has been developed by NHS England in partnership with the Medicines and Healthcare product Regulatory Agency (MHRA), National Institute of Health & Care Excellence (NICE), the Royal Pharmaceutical Society (RPS) and the pharmaceutical industry trade associations.

We have also run two workshops, one in the North of England and one in South. The events were well attended. We brought together patient representatives with healthcare professionals, NHS commissioners and policymakers, and pharmaceutical industry representatives to discuss how to make the most of the opportunity biosimilars offer.

Q) Is the NHS satisfied with progress so far in adoption of biosimilars? What are the main obstacles and how can they be overcome?

Keith Ridge: There is variation in uptake of biosimilar usage across the country. This is normal when new treatments of any form are introduced, as clinicians get familiar with new approaches to treating patients. It is critical that patients and NHS staff have confidence about biosimilars, hence our "What is a biosmilar" guide and the two regional events. It is very important that locally NHS organisations do not just simply switch to using biosimilar medicines without robustly consulting patients, including taking into account individual patient needs and wishes, including giving patient the choice of which medicine to use. Taking time to explain biosimilars properly to patients usually results in the majority of patients being comfortable with biosimilar medicines being used for their treatment.

Although biosimilar medicines are not considered generic equivalents to their originator biological medicine because the two products are similar but not identical, they have met regulatory requirements in terms of comparative quality, safety and efficacy. Where NICE has already recommended the originator biological medicine, the same guidance will usually apply to a biosimilar of the originator.

Q) Does the NHS believe that biosimilars should be interchangeable with originator products and should patients be switched between the two?

Keith Ridge: It is critical that patients and NHS staff have confidence about biosimilars, hence our "What is a biosmilar" guide and the two regional events. It is very important that locally NHS organisations do not just simply switch to using biosimilar medicines without robustly consulting patients, including taking into account individual patient needs and wishes, including giving patient the choice of which medicine to use. Taking time to explain biosimilars properly to patients usually results in the majority of patients being comfortable with biosimilar medicines being used for their treatment.

Ongoing assessment and diagnosis of a patients' clinical needs will need to be observed before a long term decision is made on how to make the most of these important medicines. In principle there should be no reason why biological medicines which are designed for specific diseases, and work on a like for like basis similar to originator biological medications, should not largely replace the originator in the longer term once that originator medicine patent has expired.

This also forms part of the wider medicines optimisation programme which is about ensuring that patients get the right choice of medicine, at the right time. By focusing on patients and their experiences, the goal is to help patients to improve their outcomes; take their medicines correctly, avoid taking unnecessary medicines; reduce wastage of medicines; and help encourage patients to take ownership of their treatment. This will also increase overall value to the taxpayer.

Q: How much resistance is there to biosimilars from doctors and patients?

Keith Ridge: It is crucial that doctors and patients as well as staff across the NHS, from senior managers to commissioners, through to front line health professionals fully understand biosimilars and how they work before making such choices. The medicines regulatory process that surround biosimilars are rigorous. For example, sophisticated techniques are used to clearly demonstrate that the biosimilar is very similar to the originator product. Whilst there is likely to be some curiosity, in essence biological medicines are manufactured and licensed to work at the same standard as the existing originator biological medicine and therefore there should be no difference in clinical outcomes or quality.