CLINICAL FLASHCARDS

Why Cheaper Humira Alternatives Face Resistance

The Life Science Feed

QUESTION

What is the primary difference between a biosimilar and a small molecule generic drug?

ANSWER

Biosimilars are highly similar biological proteins produced by living cells, whereas generics are exact chemical copies.

QUESTION

How do living cells influence the final product of a biological medicine?

ANSWER

The specific manufacturing process within the living cells shapes the final structure of the complex molecule.

QUESTION

Which regulatory standard is required to demonstrate the clinical equivalence of a biosimilar?

ANSWER

A comprehensive comparability exercise involving analytical characterisation, pharmacokinetic equivalence, and clinical data.

QUESTION

What was the estimated peak annual revenue for the reference biologic Humira (adalimumab)?

ANSWER

It exceeded 20 billion dollars.

QUESTION

In the context of pharmaceutical law, what does the term 'patent thicket' describe?

ANSWER

A dense web of numerous patents filed on a single drug to delay competition from biosimilars or generics.

QUESTION

How many patents did Abbvie file on Humira to delay biosimilar entry in the United States?

ANSWER

Over 100 patents were filed.

QUESTION

When did the first adalimumab biosimilars enter the market in the United States?

ANSWER

They entered the market in July 2023.

QUESTION

What level of price reduction was observed in some NHS tenders for adalimumab biosimilars?

ANSWER

Prices fell by 80 ext{--}90 per cent from the reference biologic list price.

CARD 9 OF 50

QUESTION

The landmark Norwegian study published in 2017 regarding biosimilar switching is known as the _____ trial.

ANSWER

NOR-SWITCH

QUESTION

What was the primary clinical finding of the NOR-SWITCH trial after 52 weeks?

ANSWER

There was no significant difference in disease worsening between patients who switched to a biosimilar and those who remained on the reference drug.

QUESTION

Which reference biologic was specifically evaluated in the NOR-SWITCH trial?

ANSWER

Infliximab

QUESTION

What is the clinical significance of the DANBIO registry data in rheumatology?

ANSWER

It provided consistent evidence that switching to biosimilars is non-inferior and maintains disease remission.

QUESTION

Define the clinical 'nocebo effect' in the context of biosimilar transitions.

ANSWER

It is the worsening of symptoms or perceived efficacy loss caused by a patient's negative expectations of a switch.

QUESTION

What factor most directly contributes to higher rates of drug discontinuation during a biosimilar switch?

ANSWER

Poor patient counselling or negative messaging from healthcare providers regarding the switch.

QUESTION

What clinical skill is recommended to mitigate the nocebo effect during a transition to a biosimilar?

ANSWER

Transparent communication that emphasises regulatory equivalence and the robust evidence base.

QUESTION

What is the consensus from EULAR and ACR regarding multiple switches between different biosimilars?

ANSWER

Multiple switches appear generally safe based on available evidence, provided patient-level monitoring is maintained.

QUESTION

What does the 'biosimilar dividend' represent in healthcare policy?

ANSWER

The cost savings generated by biosimilar competition that are reinvested into expanding patient access and funding new therapies.

QUESTION

By 2022, how did biosimilar competition affect the NHS spend on adalimumab in England?

ANSWER

The annual spend fell by over 50 per cent while the number of treated patients increased.

QUESTION

Which classes of newer on-patent drugs were funded by the biosimilar dividend in the NHS?

ANSWER

The savings funded access to new IL ext{-}17 inhibitors, IL ext{-}23 inhibitors, and newer JAK inhibitors.

QUESTION

How do Pharmacy Benefit Managers (PBMs) in the US sometimes hinder the biosimilar dividend?

ANSWER

They may have incentives to favour higher-priced reference biologics that offer better rebates over lower-priced biosimilars.

QUESTION

In the United States, what does the FDA 'interchangeable' designation allow a pharmacist to do?

ANSWER

It allows the pharmacist to substitute a biosimilar for a reference biologic without the intervention of the prescribing doctor.

QUESTION

How does the European Medicines Agency (EMA) approach biosimilar interchangeability?

ANSWER

The EMA does not grant an interchangeable designation; instead, substitution policies are managed at the national level by individual health systems.

QUESTION

What is the main limitation of the biosimilar dividend regarding the total drug budget?

ANSWER

The savings are finite and apply only to older biologics, while new, more expensive on-patent therapies continue to enter the pipeline.

QUESTION

Why is 'analytical characterisation' a cornerstone of biosimilar approval?

ANSWER

It provides the detailed structural and functional evidence that the biosimilar is highly similar to the reference molecule.

QUESTION

Concept: Non-medical switching

ANSWER

Definition: Changing a patient's medication for reasons other than clinical failure, typically for cost-saving or administrative purposes.

QUESTION

What was the approximate annual NHS spend on adalimumab in 2018 before biosimilars became available?

ANSWER

It exceeded \pounds 400 million per year.

QUESTION

What risk exists for biosimilar savings in healthcare systems without structured Health Technology Assessment (HTA)?

ANSWER

The dividend may be absorbed into general budget savings rather than being explicitly reinvested in patient access.

QUESTION

Which inflammatory condition, alongside RA and Crohn's, is commonly treated with adalimumab?

ANSWER

Psoriasis

QUESTION

The FDA 'interchangeable' status is designed to remove _____ from the switching process.

ANSWER

prescriber friction

QUESTION

True or False: A biosimilar approved by a stringent regulatory authority is considered a 'lesser' drug than the reference biologic.

ANSWER

False, as it has been held to a very high bar through rigorous comparability exercises.

QUESTION

What was the specific biosimilar used in the NOR-SWITCH trial as a comparison to reference infliximab?

ANSWER

CT ext{-}P13

QUESTION

How does NICE in the UK use biosimilar cost savings during drug appraisals?

ANSWER

It references the generated savings as 'budget headroom' to enable the approval of newer high-cost biologics.

QUESTION

Which regulatory body granted the first adalimumab biosimilar approvals in 2018?

ANSWER

The European Medicines Agency (EMA).

QUESTION

What is the primary objective of 'pharmacokinetic equivalence' in biosimilar testing?

ANSWER

To demonstrate that the biosimilar behaves in the body in a way that is essentially identical to the reference biologic.

QUESTION

Why is matching the right drug to the right patient becoming more complex in rheumatology by 2026?

ANSWER

There is a significant increase in therapeutic options, including JAK, IL ext{-}17, and IL ext{-}23 inhibitors.

QUESTION

In the NHS model, what is the 'ideal' use for the biosimilar dividend?

ANSWER

Funding access to new biologics and treating a larger number of patients within the same budget.

QUESTION

What condition did the PLANETAS trial focus on in the context of biosimilar research?

ANSWER

Spondyloarthritis (SpA)

QUESTION

According to Sarah Mitchell, what is the 'tension' at the centre of biosimilar policy?

ANSWER

The fact that biosimilar savings are finite while the pipeline of new, expensive, targeted biologics is continuous.

QUESTION

What was the total number of patients randomised in the landmark NOR-SWITCH study?

ANSWER

481 patients.

QUESTION

Why are biologics described as 'large complex proteins'?

ANSWER

They are composed of intricate chains of amino acids produced by cellular machinery, unlike the simple structures of small molecule drugs.

QUESTION

What is the clinical responsibility when transitioning a stable patient to a biosimilar?

ANSWER

To provide proper patient counselling that reduces the likelihood of the nocebo effect.

QUESTION

The _____ trial was the 2017 Norwegian randomised controlled trial that established the safety of infliximab switching.

ANSWER

NOR-SWITCH

QUESTION

What systemic US issue has 'muted' the cost savings from biosimilars compared to Europe?

ANSWER

The complex rebate system managed by Pharmacy Benefit Managers.

QUESTION

Which organisation updated its RA recommendations in 2023 to reflect biosimilar evidence?

ANSWER

EULAR (European Alliance of Associations for Rheumatology).

QUESTION

What is the effect of 'pharmacist-level substitution' on healthcare access?

ANSWER

It streamlines the transition to lower-cost therapies by removing the need for a new prescription from the doctor.

QUESTION

How did the volume of patients treated with adalimumab in the NHS change after 2018?

ANSWER

The number of patients treated actually increased despite the reduction in total spend.

QUESTION

What is required for a biosimilar to be designated as 'interchangeable' by the FDA?

ANSWER

The manufacturer must meet a higher regulatory standard than that required for standard biosimilarity.

QUESTION

Which study served as the 52-week extension to the original landmark Norwegian switching trial?

ANSWER

NOR-SWITCH-2

QUESTION

Term: Biologic medicine

ANSWER

Definition: A medicine whose active substance is made by or derived from a biological source, such as living cells.

QUESTION

Why is 'no two manufacturing processes produce exactly the same molecule' relevant to biosimilars?

ANSWER

It explains why biologics can only be 'highly similar' rather than identical chemical copies.