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Understanding the commercial value of Biosimilars: Learning from launches in EU and US

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It has been 17 years since the first approval of Epo Biosimilar in Europe. The US only saw its first approval in 2015. In Europe, biosimilars have gained significant market shares for most molecules with a significant uptake for IV hospital-administrated (bevacizumab, rituximab, trastuzumab, infliximab) or self- administered (Adalimumab) reaching a range of 70 to 80% uptake.

This rapid adoption can be attributed to favorable regulatory pathways, price competition, and large acceptance by physician and patient.

In comparison, the US market has seen a more conservative adoption of biosimilars. Patent litigations and aggressive market retention tactics by brand- name drug manufacturers have slowed the penetration of biosimilars. This is particularly true for Medicare part D biosimilar, adalimumab capturing less than 3% market share after a 12-month launch.

However, some IV oncology-infused, Medicare part B biosimilars trastuzumab, bevacizumab, and rituximab, have gained high uptake as seen in Europe (>80%). Key lessons from the EU's experience, such as pricing - like the 82% price drop of Humira biosimilars in Denmark – should inform future choice and launch strategies.

As we anticipate future trends, the recent introduction of the Inflation Reduction Act in the US could become a catalyst for biosimilar growth. The policy is expected to incentivize the uptake of biosimilars.

Companies which want to launch biosimilars should carefully choose which future biosimilars to launch in which country considering many factors such as the rank of launching, impact on pricing, physician acceptance, IV vs SC, and big regulations such as the Inflation Reduction Act. With informed strategies reflecting regional /local market insights, biosimilar manufacturers can capitalize on the impending opportunities, fostering a market conducive to growth, competition, and increasing patient access to vital and cost-effective therapies.