

'Biosimilars' for children with IBD need more research, ESPGHAN expert panel states

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Children with inflammatory bowel disease (IBD) who are doing well on specific biological medications should not be switched to recently approved "biosimilar" products, concludes an expert consensus statement of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). The statement appears in the *Journal of Pediatric Gastroenterology and Nutrition*, the official journal of the European Society of Paediatric Gastroenterology, Hepatology and Nutrition and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

While biosimilars could reduce costs and increase access to effective biological medications, long-term studies are needed to confirm their safety and effectiveness specifically in [children](#) with IBD, according to the statement by the ESPGHAN Pediatric IBD Porto Group. The statement also highlights the importance of post-marketing surveillance programs to confirm the efficacy, safety, and immunogenicity of new biosimilar products.

Biosimilars Show Promise for Pediatric IBD—but More Research Needed

The Pediatric IBD Porto Group was tasked with developing consensus recommendations for pediatric gastroenterologists treating children with IBD: Crohn's disease and ulcerative colitis. Biological medicines

directed against tumor necrosis factor (TNF) can induce and maintain remission in children and adults with IBD. Anti-TNF therapy has become increasingly important in patients with childhood-onset IBD, given the necessity to heal their intestine in a timely fashion so that normal growth can be restored.

Anti-TNF medicines are complex protein-based drugs derived from a biological source. Because of the structure of these biological molecules as well as the trade secrets of the companies producing the original products, the new versions are very similar but not exactly identical to the originator drug—and are therefore called biosimilars.

As the patents for anti-TNF medicines expire, biosimilar products are coming to the market. This will lead to decreased drug costs, and thus increased access to these very expensive agents. Based on studies for other diseases (such as rheumatoid arthritis), the European Medicines Agency has approved the use of biosimilars for the anti-TNF product infliximab for all conditions—including IBD. Biosimilar infliximab is not yet approved by the US Food and Drug Administration.

But the Porto Group experts point out that even minor alterations in the production process of biologics may lead to changes in cell behavior, causing differences in structure, stability or other quality aspects of the end product. Any of these differences may affect the treatment's safety, efficacy and—most importantly with biological medicines—immunogenicity.

Immunogenicity is the development of an allergic reaction to the drug because antibodies have been formed, thereby limiting future use. In children, the risk of developing antibodies to anti-TNF therapy is even more worrisome than in adults, since children have more severe IBD and may need anti-TNF treatment for a longer period.

Given the lack of data on the use of anti-TNF biosimilars, the ESPGHAN Pediatric IBD Porto Group raises concerns about the introduction of these agents—particularly in children with IBD. In the new statement, they advocate giving high priority to performing pediatric trials with long-term follow-up to support the approval of the new biosimilar products.

Until those results are available, the experts agree that children with a good response to a specific biologic agent should not be switched to a biosimilar. They also state that postmarketing surveillance programs—monitoring effectiveness and possible safety problems after approval—should be a "mandatory requirement" for the marketing of biologics and biosimilars with respective indications.

More information: "Use of Biosimilars in Paediatric Inflammatory Bowel Disease: A Position Statement of the ESPGHAN Paediatric IBD Porto Group" [DOI: 10.1097/MPG.0000000000000903](https://doi.org/10.1097/MPG.0000000000000903)

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