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Biosimilars and the management of double binds

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Pharmaceutical regulators have a dual responsibility. On the one hand, they need to protect and promote public health; while on the other hand, they have a role in stimulating pharmaceutical innovation through scientific advice, regulatory guidelines and other forms of regulatory dialogue. Although regulators are acclaimed for their scientific expertise and independence, they are also criticized for being a source of bureaucracy and thus stifling innovation. I will analyze the emergence of the EU biosimilar regulatory framework and the need for biosimilar ambassadors within hospitals. I demonstrate that in an uncertain environment, European regulators have created a regulatory framework for biosimilars that stimulates innovation while attempting to maintain high safety standards. But, alignment with doctors is essential in order to stimulate the cost-effective application of biosimilars in clinical practice. This case study provides valuable lessons on how to handle the biosimilar challenges in a highly volatile pharmaceutical sector and within a specific regulatory and healthcare framework.

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