Evaluate Vantage

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# Biologics look set to lose US drug price negotiation loophole

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The 10 drugs that will be subject to US price negotiation later this year remain unknown, but on Wednesday the Centers for Medicare & Medicaid Services laid out how it might set about those discussions. And buried in that 91-page document was a “bombshell”, as SVB Securities analysts described it, that could remove some presumed protections for top-selling biologics. Drugs with the same active ingredient will be considered the same product, even if approved under different BLAs, and the earliest approval across all formulations used to determine eligibility for negotiation. Under IRA legislation, biologics become eligible 13 years after approval. This means that launching a subcutaneous formulation of, for example, Darzalex, will not restart the clock on eligibility. Halozyme, which has licensed its subcutaneous MAb technology to a wide range of developers, dropped 4% today. Evercore ISI analysts highlighted Novo Nordisk's Ozempic and Wegovy, which have the same active ingredient but were approved five years apart. Whether this clause survives remains to be seen – SVB foresees loopholes and litigation – but the negotiation process is likely to be highly complex. Pink Sheet reported that CMS is suggesting net prices and clinical benefit of therapeutic alternatives as critical starting points for the negotiations.

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