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What price controls? US FDA keeps focus on generic competition

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US President Donald Trump shows no indication of trying to spoil biopharma's beauty pageant, the JP Morgan healthcare conference, the way he did last year. The latest sign that the White House had backed away from hard price controls and moved towards intensified competition came in the form of a new set of guidelines for generic drug applicants.

Essentially telling makers of copycat pills to get their acts together, the documents yesterday sought to reduce the number of multiple-cycle reviews; unlike innovative drugs this is the rule rather than the exception in generics, with an average of four before approval. More generic entrants can help reduce the prices of older drugs, but it is expensive new therapies that are causing the pharmaceutical sector to take a growing share of the nation’s healthcare expenditures.

Documents released by the US FDA provide guidance to generic drug manufacturers on how to sharpen up their ANDA filings to increase chances of achieving a first-cycle approval, along with a separate set of instructions for reviewers to follow to speed registration.

The deficiencies in ANDA submissions that the FDA cited included timely notification of legal actions and settlements related to drug patents; drug packaging and labelling; product quality; and manufacturing site compliance.

Be clear

The companion handbook for drug reviewers spells out the ways they must communicate the flaws in ANDAs that they reject to help applicants succeed in the next cycle. This will include the use of standard templates to document the deficiencies.

In addition, the roles of reviewers are clarified to reduce duplication of effort and speed the assessment of ANDAs.

Accelerating the review time of generic drugs has been a focus of the FDA commissioner, Scott Gottlieb, who was seen as a pharma-friendly appointment to the drug regulator who would likely steer administration policy towards competition and away from price controls.

It was in the midst of last year’s JP Morgan conference that Mr Trump, even before he could be sworn into office, called a temporary halt to a biopharma rally with vague words about competitive bidding to rein in drug prices (*Fickle Trump showers disappointment on biopharma's golden day, January 12, 2017*).

Release of the new set of generics-focused documents should help reinforce confidence that the administration has no intention of enacting price controls. Combine the sputtering pricing effort with tax cuts that are widely seen as a prelude to a new round of mega-acquisitions, and the sector looks like it could be headed for another bullish year.

But with a round of price increases for elderly products having been announced and the first gene therapy to be approved in the US, Spark's Luxturna, having a list price closing in on the $1m mark, rising pharma costs remain a top-line risk.

Should polling reveal that Democrats have a chance of taking back one or both houses in mid-term elections later this year the allure of biopharma could evaporate as November approaches.

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