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Physician Views: As FDA Becomes More Constructive on Regulation What is the Physician Perception Towards Abuse Deterrent Opioids?

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Abstracts

In the US, the misuse and abuse of opioid medications has triggered significant industry investment in new versions of pain relief drugs that employ abuse deterrent formulation (ADF). The FDA approved three new painkillers with abuse deterrent properties in 2014 (bringing the total number of approvals to four) and reports that 30 others are currently under development.

To support development efforts the FDA issued final guidance on the evaluation and labelling of abuse deterrent opioids in April. The guidance clarifies design of in-vitro manipulation and extraction studies, trials to assess clinical abuse potential, methods for evaluating post-approval use and pharmacokinetic assessment.

By the end of the year, the FDA is also expected to publish guidance on how generic versions of abuse deterrent opioids will be tested and marketed; providing a clearer view on how generic versions will be assessed both in terms of efficacy and deterrence, and whether generics will be required to use the same formulation technology as the originator product in question.

Branded ADF opioids raise not only an issue of increased cost – versus generic non-ADF products – but there is also the suggestion that these products are not always as effective as opioids that do not utilise ADF technologies.

With these products poised to remain an important drug category on the broader pharmaceutical landscape – as exemplified by the high number of drugs in development – FirstWord Pharma is this week asking US-based primary care physicians the following questions…

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How confident are you in your ability to effectively prescribe opioids for the treatment of chronic pain?

What role has the availability of ADF opioids played in improving your ability to effectively prescribe opioids for the treatment of chronic pain?

Do you have concerns that ADF opioids are less effective at reducing pain?

Since the availability of ADF opioids have you become more reluctant to prescribe generic opioids which do not have an ADF?

When generic versions of ADF opioids become available do you think they should be required by the FDA to demonstrate…

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