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FDA to take a great EAP forward

Elizabeth Cairns

As she left the FDA last month, then commissioner Margaret Hamburg reiterated the importance of swift evaluation of medical products by the agency. Now one of the efforts spearheaded during her tenure is to come to fruition: the expedited access programme (EAP) for medical devices opens for submissions next week.

EAP is a loose equivalent of the breakthrough therapy designation used in biopharma, and is designed to allow devices that address unmet needs to gain approval decisions more swiftly. And the FDA now says that EAP will cover de novo submissions as well as premarket approvals, meaning that a broader range of technologies – and companies – can take advantage of this route.

Surrogate endpoints

Starting on April 15, companies will be able to seek EAP designation, according to a blog post by Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health. To be eligible for this status, a device must treat or diagnose a condition that is potentially fatal or irreversibly debilitating.

In practice, though, the definition could cover quite a wide range of technologies, with the loosest criterion being simply that availability of the device is in the best interest of patients.

Examples of such a device could be molecular tests to identify a large number of potential pathogens, including common, rare, and/or emerging pathogens, simultaneously, the FDA says, or an insulin pump with a new mechanism to detect low blood glucose and automatically stop insulin delivery.

If a device is awarded EAP designation its developer will be able to collaborate with agency staff at an earlier stage than would otherwise be possible. The company will gain a better idea of what clinical data will be expected in its submission, and the FDA intends to be more willing to accept intermediate or surrogate endpoints.

Naturally much greater emphasis will be placed on postmarketing studies. If these do not provide sufficient evidence that the device is safe and effective, the FDA will be able to rescind its approval – as, of course, it can for any device.

De novo

Inclusion of de novo submissions as well as premarket approvals (PMAs) in those eligible for EAP designation appears to be a new plan; no mention was made of these products when the draft guidance was released last year (*Vantage Point – New FDA expedited review could halve the cost of device development, May 13, 2014*).

This chimes with the FDA's separate plans to streamline the de novo approval process (*The FDA's latest push to speed medtech approvals, August 28, 2014*). Under EAP, they will get faster still.

However, when it comes to postmarketing trials, companies seeking de novo approval of an EAP-designated device will not see the same benefit as EAP-designated PMA submissions. This is because once a de novo request is granted, the product can serve as a predicate for subsequent 510(k) clearances, which only call for the follow-on device to show substantial equivalence.

Thus, the FDA says, it would be "problematic" if a de novo-approved device was subsequently shown to be unsafe or ineffective in postmarket studies. A 510(k) application would not use a device approved via PMA as a predicate because the former is low-risk and the latter high; in other words, they would be too different.

If devices walking the de novo pathway will not benefit from this shifting of the clinical burden to the post-approval stage, EAP will be of much less use to their developers. It is as well the de novo process itself is being made slicker.

Knock-on effect

In a statement emailed to *EP Vantage*, the US medtech industry lobby group AdvaMed said it commended the agency for its efforts to speed innovative devices to market, but suggested that more could be done.

“AdvaMed has proposed a new breakthrough pathway which builds upon [the] FDA’s EAP and would provide for transitional Medicare and Medicaid coverage for products designated and approved by FDA as ‘breakthrough’,” said Janet Trunzo, senior executive vice-president of technology & regulatory affairs.

Perhaps that will come in future. But for now, the expedited pathway is a positive step and could have a knock-on effect on the industry as a whole. Following the megamergers of 2014, fewer takeovers of smaller medtech companies have been occurring, and the very youngest firms are finding venture investment very hard to come by.

If their technology is eligible for EAP status funders and buyers could see the chance of a more rapid return and ought to be more willing to risk their cash. If the FDA is serious about putting EAP into practice – and it was about breakthrough designation, which has had a marked effect on the biopharma sector – it could benefit innovation indirectly, too.

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow @LizEPVantage on Twitter