Evaluate Vantage

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Vantage Point – New FDA expedited review could halve the cost of device development

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Speeding up the development process for pharmaceuticals by awarding them breakthrough designation has apparently worked so well that the FDA intends to permit devices a similar path to market. The agency is planning an expedited access PMA route which could allow certain devices to be approved on the strength of phase II or even phase I data.

As well as speeding development, the process could also cut the time it takes for FDA review – from the current average of 19 months, according to *EvaluateMedTech*, between applying for and receiving a PMA (see table), to around a year. And faster means cheaper. “I think you could take out potentially a third to half of the cost,” Navid Malik, an analyst at Cenkos, tells *EP Vantage*.

EAP year

The expedited access PMA (EAP) programme is intended to allow patients earlier access to high-risk medical devices that are intended to treat or diagnose serious conditions whose medical needs are unmet by current technology.

Companies developing devices that qualify for EAP will have earlier contact and more interaction with FDA staff, including senior management. The company and agency will collaborate on clinical evaluation and collection of data.

To be eligible for EAP, a medical device must be intended to treat or diagnose a life-threatening or irreversibly debilitating disease. Furthermore, it must satisfy at least one of the following conditions: no other device is approved; the new technology is a breakthrough that provides a meaningful advantage over existing technology; the new technology offers a significant, clinically meaningful advantage over existing devices; or, simply, availability is in the patient’s best interest.

These criteria are increasingly broad, and in practice will cover any device or diagnostic which addresses an unmet or poorly met medical need, Mr Malik says. “A device to diagnose sepsis, a diagnostic to determine the applicability of a cancer drug, anything like that will come under the remit for EAP.”

The closest parallel in biopharma is the breakthrough therapy designation. Earlier this year, *EP Vantage* calculated that the time to market for drugs with breakthrough status was cut by more than a quarter compared with those not known to have received the designation.

Since the beginning of 2005 the FDA has awarded 280 first-time PMAs and has taken an average of 18.8 months to assess the submissions, data compiled by *EvaluateMedTech* shows. If the EAP programme permits a similar reduction for devices as breakthrough status does for drugs, EAP devices could pass through the FDA’s hands in just over a year.

Average review time for PMA approvals by year		
Year	**Number of approvals**	**Average review time (months)**
2014 to date	6	17.0
2013	23	26.9
2012	39	17.9
2011	42	14.5
2010	21	24.3
2009	16	18.5
2008	29	21.5
2007	29	18.3
2006	41	16.5
2005	34	15.6
Total	**280**	-
Average	-	**18.8**

The average speed each year has fluctuated quite widely, with the agency taking an average of 27 months to assess the 23 PMA applications in 2013, but just 15 months to review the 42 it awarded in 2011. This is partly to do with the Poly Implant Prothèse breast implants scandal; two of the five products which took longest to review were breast implants whose eventual approval came in 2013.

These products had an average review time of 89.4 months – seven and a half years – as the agency sought to ensure their safety.

EvaluateMedTech's data further shows that, over the past decade, the therapy areas with the longest FDA review times are drug delivery and wound management at nearly four years, while the fastest are systems in the ear, nose and throat area, which take just eight and a half months.

Average time of PMA approvals by therapy area		
***EvaluateMedTech* device classification – level 1**	**Number of approvals**	**FDA review time (months)**
Ear, Nose & Throat	3	8.4
Gastroenterology	2	10.3
In Vitro Diagnostics	64	12.9
Blood	1	13.2
Cardiology	90	15.2
Diabetic Care	4	16.7
Urology	5	17.1
Ophthalmics	18	17.2
Neurology	13	18.6
Radiology	2	20.1
Diagnostic Imaging	8	22.3
Anaesthesia & Respiratory	4	24.9
Dental	3	25.0
Orthopaedics	28	25.9
Obstetrics & Gynaecology	4	26.0
General & Plastic Surgery	21	30.5
Endoscopy	2	39.5
Drug Delivery	1	45.9
Wound Management	7	45.9
Total	**280**	-
Average	-	**18.8**

Thus companies active in particular areas could benefit to a greater degree from faster review times. But this will require delicate balancing of risk and reward, and safety will be a vital consideration. Approval for EAP devices could potentially come based on early clinical data, with larger trials conducted post-market. Mr Malik says that if concerns emerge after the device is approved, it can be swiftly withdrawn.

“If safety issues or a lack of efficacy is shown in later trials then the FDA can withdraw any permissions it has given for the product to be available on the market. There’s no binding commitment – if the data that comes beyond approval is negative then you’re off the market, no doubt about that.”

Double digits

Getting devices onto the market before conducting large clinical studies will of course benefit developers hugely. “Not only do you save time and money [through faster PMA review], you generate revenues which you would otherwise not have, and revenue generation can offset your burn on the product. Companies can sell the product and fund the rest of the trials from the market,” Mr Malik says.

Mr Malik says it is hard to know how many devices are likely to qualify for EAP once it comes into effect, which he expects will happen within a year.

“If you look at the breakthrough therapy designation, which is the only thing we can really base this on, so far there have been near enough 40 designations granted, and well over 130 applications made,” he says. “I suspect there are going to be quite a few companies applying. I don’t know how many will be granted but I suspect that within 12 months [of EAP coming into force] there will be at least double-digit numbers.

“Approval,” he adds, “is another thing.”

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