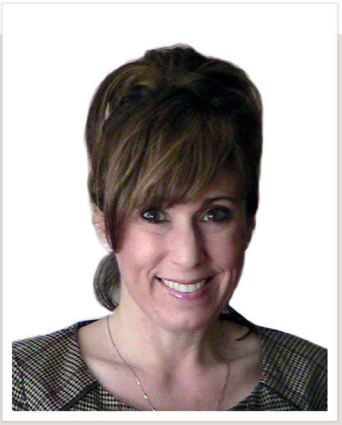
Key numbers drop, but Advisory Committees hold steady in complex year for drug approvals



Oh, what a difference a year makes!

Earlier this year NDA released its 2016 **annual report on drug approvals** in both the EU and the US. One striking finding: US approvals (NMEs) plummeted from 45 (2015) to 19 — a drop of almost 60 percent.

That dramatic number wasn't the only thing that caught our attention though. When we drilled down into all the applications, we spotted some important trends:

- Of the 19 NMEs approved, seven were Fast Track, and seven were First in Class. Five received Accelerated Approval, seven were Orphan, and six were Breakthrough. Our take: **Expedited drug development and nonstandard review approval pathways are increasing in the US.**
- Only two Complete Response Letters (CRLs) were issued in 2015. But that number increased sevenfold in 2016, to 14! In several of them, the FDA explained that **the primary deficiency was failure to comply with Good Manufacturing Practices (cGMPs).**
- **There's been a shift in approvals across drug categories:** Applications waned in biologics, diabetes/metabolic, orphan drugs, and oncology; however, CNS, anti-virals, and immunology saw an increase. The point? **Trends can shift from year to year — and it's the sponsors, and not the agency, that drive the mix of applications** (interestingly, companies outside the top 20 pharma accounted for 47% of new drug approvals— up from 38% in 2015).

Since we excel at preparing teams for high-stakes regulatory hearings, we also wanted to take a closer look at trends in FDA Advisory Committee hearings in 2016.

On this matter, it's interesting to note that, despite the dramatic shifts outlined above, **the number of Advisory Committee hearings held steady — 31 (2016) versus 32 (2015). That suggests that the FDA is continuing to rely on expert advice for complicated development programs.**

Also worth noting: **Smaller and midsize firms seem to increasingly be appearing before the committee.** Companies outside of top 50 pharma appeared in 58% of the hearings in 2016, up from 43% in 2015.

In fact, when we looked at all the foregoing data in total, we realized that **a majority of products moving through the approval pipeline are from smaller to mid-sized pharma companies** — this is a trend that has been occurring for many years.

Bigger companies may, of course, be able to absorb the ongoing shocks of the complex drug approval process. But if your firm is small to mid-size, this process can be very stressful. And those stresses grow even greater if your company is submitting concurrent applications to EMA and FDA.

Add to that a possible FDA Advisory Committee meeting (and formal notice is only given 74 days in advance), and you have an extraordinarily complicated picture that can wreak havoc on both timeline and team.

How NDA can help

You've spent years developing your product. Now you've got just one chance to make your case for it. And the outcome, of course, can make or break your product — even your company.

Whatever regulatory gauntlet your team is navigating – simultaneous submissions, Advisory Committees, or other regulatory challenges — our industry-leading professionals have been there.

We'll help you define and drive strategy. We'll help you bring structure focus to your team. And we'll help you optimize every regulatory interaction and shape the dialogue about your product to create a more direct path to approval — including (and most especially) an FDA Advisory Committee meeting.

PharmApprove has been a member of NDA Group since 2016 and is a leading pioneer in Advisory Committee meeting preparation. Our rigorous approach has been developed over 20 years and more than 150 hearings. Our project leaders are industry professionals and communication coaches with decades of scientific communication experience. They can help you prepare your content ("what you say"), and will train you on persuasive and powerful delivery ("how you say it").

Our suite of services is compressive and easily customizable to meet the needs of your team. We'll guide the process and provide practical methods to sharpen the strategy, argument, and product message to make the strongest case for your product.

It's been an exciting and changing 2016. This year should prove no different. Whatever your product, your company will soon be faced with a regulatory challenge.

And We can help:

NDA and PharmApprove provides support with key activities to make your high-stakes meetings a success.

- Regulatory and clinical critique of the product profile
- Strategy and message development
- Content development and organization of the briefing package and core presentation
- Q&A strategy, development and management
- Speaker, responder and media training
- Slide development and technical execution
- Project management
- Mock panel production
- Onsite services