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Inside this Issue

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FOCUS ON: Market Access & Health Technology Assessment (HTA)

Market Access—The Definition Depends on the Viewpoint

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There are several dynamics surrounding the entrance of new drugs, biologics, devices, and diagnostics in the marketplace that have converged in the last five to ten years, including:

- Rising costs of new drugs and biologics coming to market resulting in increased payer control and restrictions
- Increased concern regarding drug safety and the need to ensure that benefits outweigh risks—in the U.S. this has resulted in the Food and Drug Administration's (FDA) implementation of Risk Evaluation and Mitigation Strategy (REMS)[1] requirements, as well as elements to assure safe use (ETASU) requirements
- Creation and validation of survey instruments to demonstrate how patient-reported outcome (PRO) measures serve as meaningful endpoints in demonstrating product effectiveness
- More rigorous technology assessments in the global market that serve to inform decisions around how and when new products will be accessible
- Demand for more evidence that a product is not only safe and efficacious, but that the "value" can be clearly demonstrated, particularly as compared to competitive therapies

These key issues, as well as other dynamics, create an increased need for strategic planning **to ensure that the new products are adopted by key stakeholders and therefore accessible upon approval and launch with minimum barriers to use. This is how market access is defined.**

It is important to remember, however, that different stakeholders view market access each through a different lens. The table below highlights these varying viewpoints.

The key to strategic planning is to not miss any of the stakeholders' perspectives, but instead take the multi- or inter-disciplinary approach

continued on page 2

to ensure all viewpoints have been considered in preparing for access to the marketplace. This can be accomplished by careful planning using a well-defined process, which takes the following steps:

- Designing trials to collect the endpoints that will be meaningful to payer audiences as well as regulatory bodies
- Gathering and generating sufficient evidence to demonstrate value to health technology assessment bodies, payers, and other audiences
- Complying with regulations to assure safe use
- Minimizing administrative burden to providers of care
- Designing support programs to assist providers and patients in gaining access to the needed products
- Tailoring messages to the right audiences at the right time

Audience	Viewpoint
Medical or Clinical Affairs	Will the clinical trial endpoints be met, and if so, will the evidence be sufficient to receive approval by the appropriate governing body?
Product Commercialization Teams	What will product uptake be? How do I remove any potential obstacles to uptake?
Providers	Should I prescribe this for my patients and why? Are there payer-imposed restrictions that make it administratively burdensome to prescribe?
Patients	Is this a good treatment option for me? How hard will it be to gain access to the product? How much will I need to pay out of my pocket?
Health Technology Assessment	Does the evidence support that the technology meets (or fails to meet) the criteria evaluated?
Regulatory Body	Does the evidence prove the product works? Is it safe and efficacious? Do the benefits outweigh the risks?
Payer	Is the product safe and efficacious? What is the cost? What is the value relative to other therapies? What techniques should be used to ensure appropriate utilization?

All of these should lead to successful commercialization of the product or market access and uptake.

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References

[1] Food and Drug Administration Amendments Act (FDAAA) of 2007. http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm