Have You Seen The New Opdivo Commercial?

Keith Watts. December 2016

Bristol-Myers Squibb (BMY) has created a very compelling commercial with a strong message that goes something like this: "Ask your doctor about Opdivo for a chance at a longer life."[1] This is very encouraging for anyone who has run out of treatment alternatives and is fortunate enough to live in a country where the product is licensed for commercialization. Unfortunately, if you are in a country awaiting market authorization, as I observed with Opdivo[2] when it was newly approved, you may be out of luck.

Opdivo[3] is only one of many other innovative treatments that are commonly withheld from patients outside the U.S. following FDA approval. This happens for many reasons, but it usually is because the newly FDA approved product is not approved in other countries. Well over 100 countries around the world have recognized that for patients who have exhausted all available treatments in their home country, there is a serious unmet medical need for ethical and regulatory approved pathways. These pathways exist affording temporary rapid treatment access to innovative medicines approved in other countries prior to market authorization (see for example Directive 2001/83/EC, Article 5). These pathways are referred to by many different names, depending on the country and legislation establishing temporary early access (e.g., NPP - named patient program). The key is that early access channels to innovative medical treatments are in place for pre- and post-FDA approved products. These channels are temporary, and even though sale of the product is allowed in the post-FDA approved setting, this route of distribution is not meant to circumvent regulatory approval or market authorization. The channels are in place to protect manufacturers and to allow providers to treat desperate patients who have exhausted all remaining and approved treatments in their home country. Specifically, these temporary paths exist to provide, as the BMY advertisement suggests, "a chance at a longer life"!

One-World Inc. (OWI), a company for which I have direct involvement, is exclusively devoted to serving and securing the specialty supply chain created by host country government legislation authorizing special, temporary distribution of unauthorized medicines. The key point here is to understand that temporary authorization serves an important medical need in advance of market authorization, and exists to temporarily lower barriers to innovative treatments allowing more rapid

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[1] Opdivo commercial. (2016, Nov. 2). Opdivo commercial [Video file] retrieved from https://www.youtube.com/watch?v=FL6b-fexNw4

[2] Opdivo US Approval: 12/22/2014 (see http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125554)

[3] Opdivo EMA Approval: 06/19/2015 (see http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003985/human_med_001876.jsp&mid=WC0b01ac058001d124

access for patients who cannot wait for regulatory approval. These channels should prevent the need for desperate providers and patients to seek out unauthorized distribution for timely product access. It is unauthorized distribution that can jeopardize product integrity and compromises patient safety. Failure by manufacturers to adequately address this channel also misrepresents utilization and sales of products in approved regions. These issues go away when a manufacturer responsibly engages with a company such as OWI or other singularly devoted companies, although I am not aware of similar single focused companies in the U.S.

Oncologists, for example, know that in many cases time is of the essence for their patients, depending on the type of tumor, doubling times, and other factors. Delays, denials, and the oftentimes inefficiency and confusion surrounding compassionate use (CU) programs offered by most mid to large pharmaceutical manufacturers can be a death sentence for desperate patients around the world.

I have personally spoken to numerous administrators of CU programs designed to provide compassionate access to innovative drugs newly approved in the states. It is clear to me that these people really want to help. What I find on the other end of the phone is almost always a passionate individual with no idea how to help, because the provider requesting the needed product is in a foreign country. The usual direction from these good people is to call the headquarters of the country where the request is coming from, or communicating that the manufacturer has licensed the product out, so the licensee may be able to help. One must bear in mind that in countries where providers are issuing requests for needed treatments, a product license or authorization to market has not been awarded. So, no, neither the manufacturer's local division, nor the licensee can help until the product is licensed or receives market authorization. This is the primary reason for special legislation that allows physicians and patients to temporarily access products approved outside a given country (e.g., the U.S. has similar guidance by the FDA to allow for temporary early access to products prior to market authorization). Therefore reputable, early-access specialty distributors are relied on to navigate the regulatory requirements in these unique pathways to ensure compliance and supply chain security.

Stay tuned as we begin a research study that identifies the companies and products with the greatest opportunity to secure these specialty distribution channels. Securing these channels through specialty distribution may not bring back the many patients denied access over the past year, even though temporary regulatory authorization and payment mechanisms were in place, but secure channels may prevent future deaths, or even "offer a chance at a longer life," for many currently without hope.