HealthManagement.org
The Journal
LEADERSHIP • CROSS-COLLABORATION • WINNING PRACTICES
VOLUME 18 • ISSUE 3 • 2018 • € 22
ISSN = 1377-7629

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Strategic product approval for health companies and regulators

Streamlining regulation for better healthcare outcomes

Rationalising product registration approval by health companies and government regulatory agencies to facilitate improved disease diagnosis and care of patients by healthcare practitioners.

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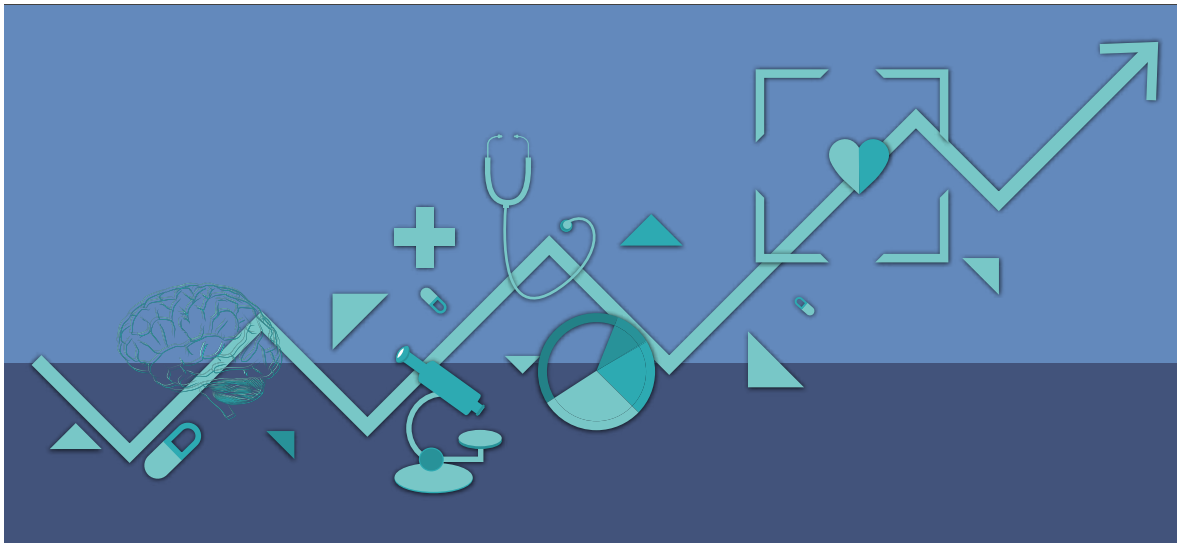

In every aspect of life, being strategic is very important. This is a common word used mainly by businesses with an underlying perception of the effect on their bottom line. Rarely do health companies focus on being strategic with their product registration in conjunction with the regulatory agencies. The reason? Each group generally believes the more products the better. My focus in this article is on how being strategic can be beneficial to health companies, regulators, healthcare practitioners/professionals and ultimately patients or consumers.

First, let us understand what exactly it means to be strategic. In simple terms, dictionaries define strategy as the art of planning and directing actions or policy designed to achieve a major or overall aim. One describes strategy as the art and science of planning and marshalling resources for their most efficient and effective use (Business Dictionary 2018). This is different from being tactical, which is a short-term action to move from one milestone to another in the direction of an overall goal. The focus here is strategic product development, registration and approval as a long-term exercise for the ultimate benefit of the patient or consumer.

What happened to health companies with specialty or specific focus health products? Why does one company think they have to satisfy several disease areas at the same time? Why do healthcare practitioners have to be burdened with the need to make informed treatment choices from so many varieties, mostly purporting to achieve similar patient benefits, when they should spend more time in accurate disease diagnosis for the patient? Health companies can better help healthcare professionals and ultimately the patient by being experts in key disease indication areas. A case in point is the study

of unmet needs in infectious disease management which shows that despite dramatic advances in diagnostic technologies, many patients with suspected infections receive empiric antimicrobial therapy rather than appropriate therapy dictated by the rapid identification of the infectious agent. The result is overuse of our small inventory of effective antimicrobials, whose numbers continue to dwindle due to increasing levels of antimicrobial resistance (Caliendo et al. 2013). Companies are able to dedicate more resources and time to addressing all the grey areas of a particular disease, finding curative and not necessarily only preventive or palliative treatments, or medicines for diseases that improve the quality of life of patients.

> “WHY DOES ONE COMPANY THINK THEY HAVE TO SATISFY SEVERAL DISEASE AREAS AT THE SAME TIME?”

Health regulators also have a major role to play in product registration approvals as applications are submitted by companies. They all have databases and while robustness may vary from one regulatory agency to another, the aim is the same: to track products being registered versus companies and disease indications. They should be able to create a ceiling in the registration of similar products by different companies, working with the individual countries’ government health statistics departments to determine population needs for such medicines. A good example of this is the National Agency for Food and Drug Administration and Control in Nigeria (Federal Government of Nigeria 2018). Working with healthcare professionals, it came up with a list of fourteen drug products for which the country already has more than enough capacity, leading to a ban on further importation by another government group, the Custom. This will encourage healthcare companies to research other disease areas, develop more effective medications, and help reduce the disease burden in the population. The regulators also benefit by appropriate redeployment of their material and human resources to other areas of their jobs that also impact the health of the population they serve, such as enforcement of registered details by these healthcare companies.

There are also a lot of benefits for the healthcare companies. One of these is brand rationalisation and optimisation. A quote aptly explains this: “Firms must invest in creating their own value systems rather than applying generic approaches implicitly derived from a non-applicable value system” (Opeyemi 2014). For companies who take the time to review their inventory list versus operating cost, they have discovered that they gain more competitive advantage with rationalised product inventory management focused on areas of strength and their business mission or vision. A number of books and case studies have been published by the *Harvard Business Review* on supply chain complexity management and how it affects all aspects of the company. This also helps companies create uncontested market space that makes the competition irrelevant.

The proverb that states “The sky is wide enough for all the birds to fly without running into one another’’ surmises the benefit of specificity. The health industry and regulatory agencies are encouraged to focus strategically on development and approval of disease- and patient-specific medications, to help reduce and proactively manage disease burdens in their countries. ■

KEY POINTS

- ✓ Strategic product development, registration and approval benefits the overall wellbeing of the patients
- ✓ Government agencies collaborating in regulating product approvals is beneficial to healthcare
- ✓ The impact of regulation on healthcare companies is positive

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