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Vol. 24, No. 16 | International Federation of Pharmaceutical Wholesalers | August 10, 2017

GST India: Another Tryst with Destiny

(Source: An article prepared by Dinesh Tarachandani, CEO of Parazelsus Ltd.)

The year 2017 will go down as one of the most significant years in the history of India with Goods and Services Tax becoming a reality from July 1, 2017. The new system is being regarded as the most revolutionizing tax reform in the Indian taxation history.

The result of 17 years of research and multiple political and economic pushes and pulls, the new regime aims to transform the tax scenario of the country by streamlining the system through a single tax for supply of all goods and services across the country. Once implemented, this unparalleled tax reform holds great promise in terms of sustainable growth for the Indian economy. It will help in creating a uniform national market making the dream of "One Nation, One Tax, One Market" a reality.

It is expected that GST will have a constructive effect on the healthcare industry, particularly the pharmaceutical sector. It will help the industries by streamlining the taxation structure since eight different types of taxes are currently imposed on the pharmaceutical industry. An amalgamation of all the taxes into one uniform tax will ease the way of doing business in the country, as well as minimizing the cascading effects of manifold taxes that are applied to one product. Moreover, GST would also improve the operational efficiency by rationalizing the supply chain that could alone add two percent to the country's pharmaceutical industry. GST would help the pharmaceutical companies in rationalizing their supply chain, fostering the need for companies to review their strategy and distribution networks. Furthermore, GST implementation would enable a flow of seamless tax credit, improve the overall compliance, and create an equal level playing field for the pharmaceutical companies in the country. The biggest advantage for the companies would be the reduction in the overall transaction costs with the withdrawal of CST (Central Sales Tax). GST is also expected to lower the manufacturing cost.

One more benefit likely to accrue due to GST is the reduction in the overall cost of technology. Currently, the technical machinery and equipment which are imported into the country by the healthcare sector are very costly. Also, the duty which is levied is not allowed as a tax credit under the present tax regulations. However, with implementation of GST this scenario might change. Under GST, duties charged on the import of such equipment and machinery would be allowed as a credit.

One Market: From a distributors point of view the biggest change being brought about in this reform would be One Market. Since all States come under same tax rules there is no need to check the movement of goods at state border and this allows seamless transportation across country. Unnder GST, a single e-way bill will be generated for the shipment and the same is accepted for movement within and across all states. This immediately creates opportunity for mega logistics parks/hubs that cater to more than one state.

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In Brief...

- **Cardinal Health** announced its Q4 and full-year results. The pharmaceutical segment saw growth from both increased distribution and strong specialty performance. Revenues increased 5% to US$33 billion in the fourth quarter, and US$130 billion (7%) overall for the full year. "While the last 12 months were clearly a dynamic period in healthcare and certainly presented chcallenges for our fiscal '17, it was also a year in which we took important action to strengthen our market positioning, grow our scale, add new long-term drivers of growth, and improve the overall balance of our integrated portfolio," stated Cardinal Chairman and CEO *George Barrett*.
- **Walgreens Boots Alliance** (WBA) announced a partnership with **KKR**, allowing the two companies to acquire **PharMerica**, an institutional pharmacy company. The all cash transaction of roughly US$1.4 billion will make PharMerica a privately-held company. Separately, WBA has terminated its relationship with the troubled **Theranos**. One day prior to the termination, Theranos was forced to acknowledge that more than 10% of the test reports (approximately 31,000) provided to Walgreens customers were null and void. Theranos Wellness Centers were located in Arizona (40 locations) and California (one location.)

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Do Pharma Mergers Enhance R&D Productivity & Innovation?

Source: Edited excerpts from an article by Michael S. Ringel and Michael K. Choy

A new wave of pharmaceutical industry mergers may be on the horizon, in part driven by the $1.3 trillion in overseas cash that U.S. corporations currently hold. If policymakers provide a tax holiday on repatriation of these funds, some experts say that U.S. pharmaceutical companies would be flush with cash and could likely spend a meaningful portion of this windfall on mergers.

While big mergers could have many impacts, on employment at home and abroad, competition, and drug prices, to name a few, one of the most important would be the effect on research and development productivity and innovation.

There are two schools of thought about productivity and innovation resulting from mergers. Pundits at the Institute for Competition Economics in Dusseldorf, Germany, for example, claimed last year in a Harvard Business Review article that previous drug company mergers had "substantially" reduced R&D and innovation, not only at the merging firms but at the merging firms' competitors as well.

On the other hand, another team, this one from Duke University, the University of Toronto, and Baruch College/CUNY, reached a different conclusion with its data-driven approach. The team's review of hundreds of mergers and acquisitions from 1985 to 2009, published in Loyola University Chicago Law Journal, indicated that the correlation between merger and acquisition

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GST (cont.)...

With different taxes in each state and tax exemptions in others, companies will gain from having multiple warehouses across the country to avail of such tax benefits. This creates an effective but inefficient supply chain. With GST bringing a unified tax structure across states, the need for having multiple warehouses has been reduced. A reduction in the number of warehouses also means lesser complexity in supply chain operations and, if rightly managed, better inventory control.

Product Categorization under HSN code: GST also brings with it the concept of Harmonized System of Nomenclature (HSN) for the categorization of goods and identification for transporters while handling them. It significantly helps shipping companies understand the goods being transported and manage the shipment accordingly. Previously the transporter was completely at the mercy of the manufacturer to figure out if certain goods being transported were classified as "dangerous" or not. With HSN, there is complete transparency in this regard.

To be sure, the pharmaceuticals industry has reservations over the impact of GST on free drug samples, existing bonus schemes, inter-state stock transfers and uncertainty on taxation for life-saving drugs. However, overall, GST is likely to have a far-reaching impact on various aspects of the business and how companies actually conduct and operate their businesses. There is every likelihood that companies will optimize their operations to align to the new regime as well as necessitate the crucial need to re-skill the talent pool. While an accurate quantifiable impact of GST is still indeterminate, there is a confidence in the industry that post-implementation GST will be a win-win for both the industry as well as the consumers.

GSK to Significantly Change Its Emerging Market Business Model

Source: Articles prepared by Jung Won Shin and Lucie Ellis, and published by Scrip

GlaxoSmithKline PLC plans sharp changes to its emerging market business model with an eye on long-term profitable growth and being "better" at rolling out innovations in the region, its new CEO Emma Walmsley said. "We are focusing our commercial efforts on driving an improved performance in the US which is, without doubt, the priority market but the biggest change geographically in fact is going to be about being more competitive in our emerging markets business," she said.

Global and local competition has impacted GSK's returns in emerging markets and the company needs to structure more effectively and efficiently for long-term profitable growth. "We need a model that can competitively drive what is today a largely classic branded product business. The new CEO has shocked the market with a long list of changes for GSK, including a total makeover of the group's pharma unit. As a result, more than 30 R&D programs will be terminated and a 2011 commercialization partnership with Johnson & Johnson is expected to end.

"To do this," she stated, "we are going to create a new, single, dedicated, end-to-end operating model for emerging markets spanning commercial, supply and R&D for life-cycle management." The group will have its own dedicated governance model and the right commercial structure for each market whether that is a standalone business, a cluster of similar markets or a distributor-ledmodel. Each market will be resourced accordingly and the company remains very committed to access of its medicines, the CEO said.

Although GSK had some difficult times in recent years in certain countries in emerging markets, it expects the region to continue to contribute to growth for the company. "We just need to have a much more fit-for-purpose operation there, particularly from a cost structure point of view, because 90% of the business is still in branded generics, it is also noticeable that we haven't been as good as we should have been at launching some of our innovations, so I want us to be better at rolling out innovation," she said.

GSK is going to be making some meaningful shifts as well as running it on, basically, an integrated P&L with supply chain. "This is an area where, frankly, our supply chain both in terms of service levels and probably flow and number of factories has not been where it should be, so we are going to be doing a lot of work on that," she said.

Even though GSK has taken a big hit in China, it will continue to invest in the market. "For obvious reasons, it is important that we participate not just commercially but from a manufacturing point of view, and from an R&D point of view, in China, with China, for China. We have to be patient in terms of seeing materiality of the contribution, but we are still very much supporting our progress there," she said.

During the second quarter, the group's turnover in emerging markets grew 11% AER (Annual Equivalent Rate), while its pharmaceuticals turnover grew 10% AER.

Pharma Mergers (cont.)...

activity and FDA approvals of new drugs is "moderately positive," both at an industry level and individual firm level.

Who's right? Are those in need of new lifesaving drugs harmed by consolidation in the pharmaceutical industry, or are they helped? The authors believe that one of the main problems with much of the previous research in this area has been an over-reliance on anecdotal reporting rather than employing systematic data analysis. Even when such analysis has been done, researchers have sometimes focused on research and development spending or patent activity as benchmarks of success, as if these metrics are indicators of, or even synonymous with, actual product innovation. But they aren't necessarily the same. Spending is just an input, measured in dollars or some other currency. The same is true with patents. There is a long distance between the laboratory where new compounds are discovered and the corner drugstore where medicines are purchased.

The authors sought to address this uncertainty by focusing on research and development productivity: the amount of innovation created as measured by the value of new FDA-approved compounds reaching the pharmacy, relative to input. They used the approach that what matters to patients is the creation of quality medicines, not how much a company spends on research and development or the number of patent applications it files.

To determine whether mega-mergers benefit patients, they, the authors, looked at what happened to research and development productivity in all the major mergers going back to 2001, including the last big wave in 2009 that brought together Merck & Co. and Schering-Plough, Pfizer and Wyeth, and Roche and Genentech.

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Pharma Mergers (cont.)...

As expected, the results varied from year to year and company to company. But their report in Drug Discovery Today showed that mergers generally appeared to drive productivity up, and did so significantly.

While mergers undoubtedly bring disruption to research and development, they also can be catalysts for addressing the fatal flaw of most research and development enterprises: the high cost of failure. More than 90 percent of pharmaceutical industry spending on research and development goes into projects that never reach the market. Any intervention that helps reduce this waste can be a real boon to productivity. There are only two ways to fix the industry's cost-of-failure problem: 1) start with better science, so you have fewer failures; and 2) employ better decision-making about when to stop projects so you can reallocate that capital to more-promising opportunities.

Mergers can help with both dimensions. They bring the best combined science of the merged organizations to bear on the difficult questions of which pathways, modalities, and molecules to pursue. Mergers also trigger reviews that drive the leadership of the new company to take a fresh look at research and development. These reviews can offer the leadership an opportunity to soberly and objectively reassess its scientific hypotheses in each disease area and reevaluate the combined research and development portfolio, eliminating those projects least likely to produce advances in treatment.

The combination of the two factors, fresh science and a fresh look at the portfolio, can create a renewed research and development enterprise better able to bring new medicines to patients. The authors are not suggesting that all mergers are good. Even from the perspective of research and development productivity, some mergers in their study appeared to have depressed the flow of new medicines to patients by slowing down or stopping promising projects.

Overall, however, the evidence indicates that large mergers increase, not decrease, the productivity of pharmaceutical research and development — good news for those in need of new therapies.

Michael S. Ringel is a Boston-based senior partner of The Boston Consulting Group and global leader of its research and product development topic. Michael K. Choy is a New Jersey-based partner at BCG. Both work in the firm's health care practice area, which funded the research for this article.

In Brief (cont.)...

- **Parazelsus Ltd. Afghanistan** announced their merger with **786 Pharma Ltd**, Afghanistan's first international-standard pharmacy chain with 20 pharmacies in Kabul. The companies will combine under a new name, **786 Parazelsus Afghanistan** (786 PZAF) and aim to become the leading pharmaceutical/ wholesale and retail company for pharmaceutical, healthcare and medical products in country. In addition, 786 PZAF will be working to expand the number of international brands it carries. *For more information on Parazelsus or Parazelsus 786, please contact Dinesh Tarachandani at dinesh.tarachandani@ parazelsus.com.*
- **Teva Pharmaceutical Industries, Ltd.** is the latest casualty in what has been a difficult and challenging earnings season for drugmakers and other companies due to lower generic drug prices. Teva stock (listed on the NYSE TEVA) fell 17.8% after the company announced that generics revenues were below expectations. Shares of TEVA rivals also fell, including Mylan, Perrigo, Celltrion, Taisho Pharmaceutical, Teligent and Dr. Reddy's Laboratories. The negative effects also hit stock prices of U.S. wholesalers including Cardinal Health and AmerisourceBergen.
- **AmerisourceBergen Corporation** announced third quarter results with revenues of US$38.7 billion, an increase of 4.9%. Gross profits declined 2.5% to US$1.1 billion. The company attributed the decline to a US$121 million decrease in gains due to litigation settlements and a decrease in the pharmaceutical distribution services segment. **AmerisourceBergen Specialty Group** posted a 10.3% revenue increase, the 14th consecutive quarter of over 10% growth. Combined revenue for ABC's consulting services business, **World Couriers** and **MWI Animal Health** was US$1.7 billion, and an operating income of US$95 million.
- **McKesson Corporation** has agreed to sell its hospital and system IT business to **Allscripts** in an all cash deal of US$185 million (subject to adjustments for net debt and working capital.) The sale of the unit should close in Q4. Separately, McKesson reported Q1 2018 results. Revenues were up 3% year over year at US$51.1 billion, and adjusted earnings per diluted share were down 22% to $2.46 (compared with $3.15 one year ago.) North America pharmaceutical distribution and services segment were up 4% to US$43 billion (and 5% on a constant currency basis.) International pharmaceutical distribution and services were at US$6.4 billion, up 1% on a reported basis (6% on a constant currency basis.) This was driven by acquisitions and market growth.
- The government of India has announced it will issue its first set of marketing rules for drugmakers. Under the new guidelines, gifts and trips offered to doctors and pharmacists will be limited to 1,000 rupees (US$15) according to a draft proposal obtained by the news agency Reuters. Currently India has voluntary guidelines for drugmakers, but critics say that they are ineffective. "In India, corruption and bribery of doctors is widespread," stated *Samiran Nundy*, one of the country's leading gastrointestinal surgeons. "I've seen a range of ways in which this works, from presents to doctors, to paying for them to attend conferences." Failure to abide by the rules would result in a marketing ban on the offending drugmaker for up to a year or more, depending on the degree of the violation. Drugmakers may also opt to pay a penalty in lieu of an imposed ban.
- Japan's Prime Minister *Shinzo Abe* has appointed *Katsunobu Kato* to the position of Health Minister as a result of a shuffling of cabinet positions. Prior to the appointment, Mr. Kato served as minister in charge of reform of working practices.

Sources: Company Press Releases, Drug Store News, Marketwatch, Pharma Japan, and Reuters News Service