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2016: Drug-makers seek a prescription to stay alive

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A major event on the global pharmaceutical landscape that will unfold this year is Pfizer's $160-billion deal to buy Botox-maker Allergan. The "tax inversion" deal raised eyebrows as it sought to reduce US drugmaker Pfizer's tax by shifting its legal base to Ireland.

But the transaction also brought home another message – that the big-ticket merger and acquisition (M&A) route to growth is both alive and well.

LEAD STORY

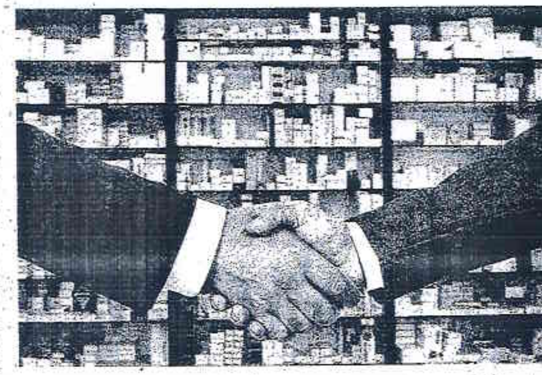
More such deals are expected this year, as companies pull out all stops to stay in the race. A race to survive, that is fraught with risks from drug development to marketing. Companies face the constant challenge of whether their investments in research bring in the breakthrough drugs. And if they do, then comes the pricing predicament – of keeping it viable for the company and affordable to the paying patient.

The scenario is not very different for domestic drug-makers faced with similar pressures. Last year saw overseas acquisitions by domestic drug companies Lupin, Cipla and Sun Pharma, to grow in different markets and strengthen product portfolio. In fact, Lupin's $880-million (over ₹5,600 crore) buy of the US-based Gavis makes it the largest foreign acquisition by an Indian drugmaker.

With the pharma industry fragmented globally and in India, consolidation is in order, observes Ranjit Shahani, Novartis' India Head. In 2015, deal street in pharmaceuticals and healthcare grossed over $600 billion globally, he says, forecasting more "strategic" M&As and asset swaps.

In fact, these "encouraging signs" will resonate into this year too, says Amit Mookim, Country Principal (South Asia) at IMS Consulting Group, pointing also to investments flowing into healthcare projects. (see info-graphic).

But there is also a dark side that the local industry needs to deal with, as even large companies run foul of good manufacturing practice norms outlined by foreign regulators. Companies will need to focus on building a quality culture, not just compliance, observes DG Shah with the Indian Pharmaceutical Alliance.



Regulatory stick

Sun Pharma, Cadila Healthcare and Dr Reddy's Laboratories came in for the stick last year from the US Food and Drug Administration for complaints ranging from lapses in sterility validation systems to manufacturing and quality system discrepancies.

Multinationals and local companies have to comply with the FDA's increasing standards, says Shahani. "I expect more pain in this direction in 2016 given the lack of investments in processes and systems required by the re-incarnated FDA," he adds.

Big deals

Pharma, Healthcare & Biotech 2015

- Number - 40
- Value $1,074 million

Source: Grant Thornton

Shutdowns

The outgoing year also saw pain with employees, in some cases, seeking legal recourse, as companies shut down plants or struggled to keep operations afloat. Pfizer shut its "vintage" Thane plant, eventually selling it. Astra Zeneca shuttered its Bengaluru plant. This year end will see Sandoz closing its finished medicine development centre in Mumbai.

Asset rationalisation is in order, says Shahani. "All companies are reviewing the number of manufacturing sites across locations and any duplication is being rationalised. Sweating assets on the ground will be the order of the day," he adds.

Into this complex scenario, comes price control on medicines. Companies may reassess their India strategies and diversify product portfolios to look at other disease areas, says Mookim, as the government increases its grip on medicine prices. Just last month, the government unveiled its revised list of essential medicines to address diseases that are public health concerns in the country. This year, will see a price control exercise on medical devices as well.

But as traditional drug companies cope with these challenges and new digital solutions attempt to inject fresh energy into healthcare delivery – it will take this and much more to qualitatively and quantitative tackle India's disease landscape, with its alarming levels of heart ailments, cancer, tuberculosis, diabetes and so on.

Here's where the government will have to lead by example, by stepping up its spending on healthcare from one per cent of GDP to the promised 2.5-3 per cent. And the coming Budget will be the judge of whether indeed the government will deliver on this promise.

M&A