Swallowing bitter pills

China is sprucing up its pharma sector

The changes are helping multinational drugmakers. In time they may boost the domestic industry

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CHINA is home to 1.4bn people. The population is ageing, and thus more vulnerable to ailments. Sustained economic growth is making the country richer, and more able to afford remedies. To foreign pharmaceutical firms, this looks like a winning combination. They are less keen on protracted review times, onerous rules and the reams of paperwork required to sell drugs in China. It can take a decade after approval in America for foreign drugs to reach Chinese patients.

The Chinese authorities at last appear to have acknowledged the problem

—and are administering a cure in doses that have surpassed even optimists' expectations. A reinvigorated regulator is waving through drugs from abroad, and clamping down on unscrupulous domestic companies. The government is spending more on drugs, including foreign ones, as it expands public health care. It is letting market forces weed out frail local firms. In other words, China is becoming a more normal market. Global drugmakers are rubbing their hands. By some estimates China became the second-largest global consumer of medicines in 2017. The market is worth $122.6bn, according to IQVIA, a research firm.

The normalisation owes a lot to the overhaul of the China Drug Administration (CDA). Under Bi Jingquan, who took over the regulator in 2015, the CDA introduced fast-track review for drugs for unmet medical needs, ditched the requirement to perform clinical trials with Chinese patients in state-run Chinese labs and relaxed rules that obliged many firms to invest in local factories. The CDA has also joined a global

body which harmonises the way drugs are assessed. It is adopting international standards for the collection of clinical data. In three years Mr Bi accomplished what would normally take three decades, gushes Lu Xianping, the co-founder of Chipscreen Biosciences, a Chinese biotechnology firm.

For foreign drugs firms this means quicker and cheaper drug approvals. The approval in March last year of AstraZeneca's lung-cancer drug, Tagrisso (osimertinib), came seven months after regulators in developed markets gave theirs—"a very different timeline" compared with the past, confirms Sean Bohen, head of global medicines development at the British firm. On August 20th Roche, a Swiss company, secured Chinese consent for its own lung-cancer drug, Alecensa (alectinib), less than nine months after it launched in the West.

As well as these regulatory changes, China's national insurance scheme has expanded to cover most citizens. Although patients remain on the hook for part of the cost of the priciest treatments, the government is coughing up for more high-end drugs. In May the government extended patent protection for pharmaceuticals by five years, to as much as 25 years. It also removed import tariffs on cancer drugs and cut it on other medicines, despite trade tensions with America.

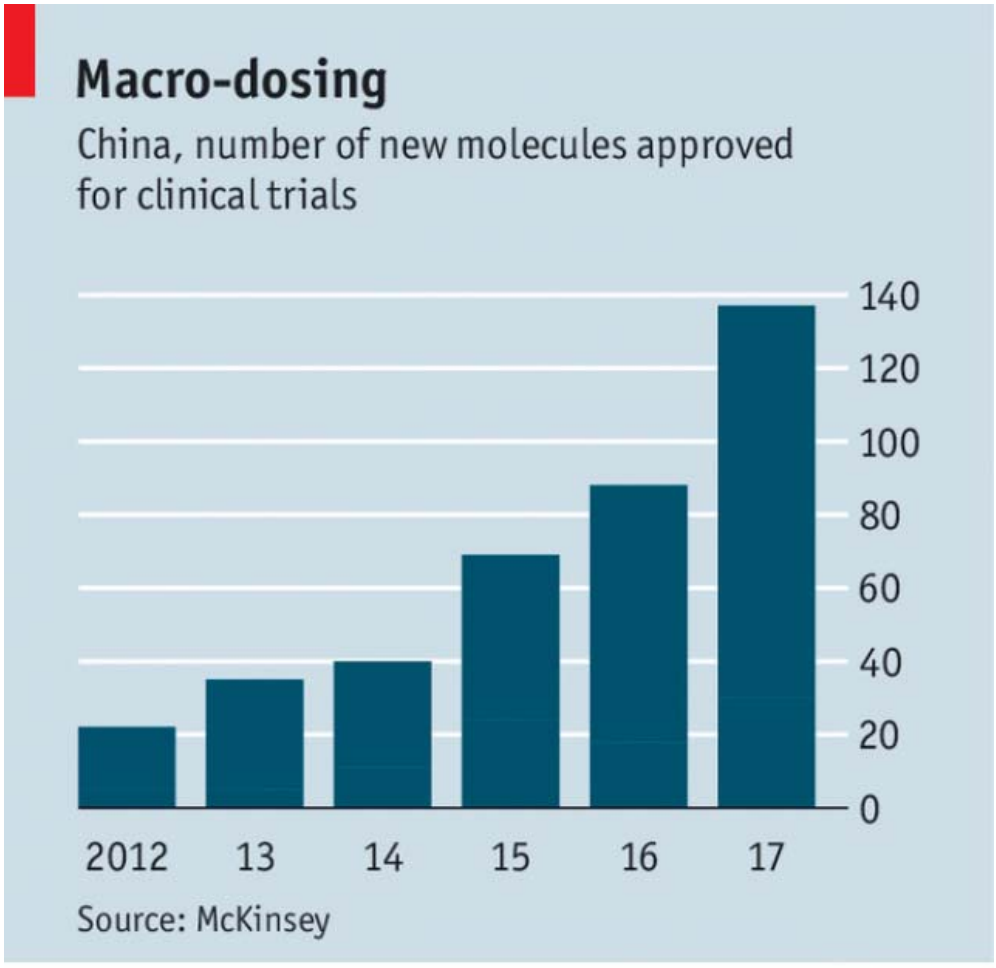
The Chinese authorities do demand steep discounts on the prices of expensive treatments. Across 36 premium drugs that were included on the national reimbursement list last year, producers had to swallow price cuts of 44% on average, relative to the previous year's average prices, calculates IQVIA. But firms are making up for lower margins with mammoth volumes. Deutsche Bank reckons that in the first quarter of 2018, the top 20 global pharma firms saw Chinese sales grow by 18% compared with last year. This was chiefly thanks to newly approved drugs.

Big Pharma thus has reason to cheer the shake-up; local drugmakers less so. Chinese producers of low-quality copycat drugs have been slow to meet the CDA's tougher new manufacturing standards and the requirement to prove that their pills are biologically equivalent to the original drugs. Unblocking the backlog of 22,000 applications for approval for sale (by foreign and domestic firms) will stiffen competition, which weaker firms may struggle to withstand. A programme to verify clinical-trial data appears to have curbed flaky applications. Mr Lu thinks that in the next five to ten years, half of China's 4,000 pharma companies could die as a result of the changes.

That appears to be the point. Hong Chow, general manager of Roche in China, reports that she has heard a government official say: "Better short-lived pain than a long one." The tough love is meant to let laggards wither and innovators flourish. It is having an effect: perhaps 50 local generics firms are transforming into research-driven ones and more biotechnology companies are being founded, often by

Chinese returning from stints at foreign companies. A decision by the Hong Kong stock exchange earlier this year to allow firms to list before they turn a profit will encourage Chinese biotech startups to seek capital at home rather than abroad.

In the longer term that should spell stiffer competition for foreign drugmakers. Mr Bohen says that it is only a matter of time before a Chinese discovery in basic science leads to a new drug sold by a Chinese firm. Mark McDade of Qiming Venture Partners, a big health-care investor in China, points to top-notch Chinese research in cancer therapies known as CAR-T. The number of molecules approved for clinical trials in China has ballooned (see chart).



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The speed of change is not guaranteed. Developing new drugs is an uncertain, lengthy process. Mr Bi, the regulator who championed drug quality, was ironically one of those forced to resign in August after hundreds of thousands of children were discovered to have been given ineffective vaccines. Reforms to the CDA still have a long way to go. The agency has only just begun harmonising its rules with those of foreign counterparts. The goal of having 289 generics pass bioequivalence tests by the end of the year is optimistic.

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