

## Lessons from the Chinese defective vaccine case

With the withholding of problematic batches of rabies vaccine, ensuring that they are not placed on the market, judgements of accountability, such as deposing all involved administrators of the China Food and Drug Administration (CFDA),<sup>1</sup> and punishment of Changchun Changsheng Biotech, who were forced to pay about ¥9.1 billion (US\$1.3 billion),<sup>2</sup> by Oct 17, 2018, the Chinese public received an acceptable result in the defective vaccine case.

This incident was first heard of after a tip-off from a member of staff at Changchun Changsheng Biotech on July 5, 2018. However, by this time the company had already been selling defective vaccines for 2 years. In 2016, a batch of rabies vaccine made defective by cold-chain failure<sup>3</sup> and worth ¥570 million was transported from Shandong province to 24 other provinces in China. In the same year, Changchun Changsheng Biotech had also made a batch of defective diphtheria-pertussis-tetanus (DPT) vaccine, which was identified by the CFDA at the end of 2017, but not dealt with until July 15, 2018. The investigation by the CFDA occurred nearly 9 months after a batch of more than 250 000 defective DPT vaccines was sold to Shandong province by

Changchun Changsheng Biotech and a batch of more than 400 000 was sold to Chongqing city and Heilong province by Wuhan Vaccine and Serum Institute.

In China, the public was not familiar with efficient advocacy methods. Although the Chinese Government is open to patient advocacy, and people can appeal to the government through the website of the State Administration for Market Regulation (name of the CFDA as of April 10, 2018), it took the CFDA 2 years from first use of the defective DPT vaccine in Shandong province in March, 2016, to investigate the event.

Few groups or organisations that advocate for patients are well known. Most of the advocacy that occurs in China is a result of individual actions. Generally, it is difficult for people to get instant attention and enough official support for advocacy. Given the slow settlement of the defective vaccine case, a law supporting advocacy channels (especially for public health) in China is urgently needed.

The Chinese medical environment has improved in the past few decades, and the Chinese Government continues to make efforts to improve it further. Since 2001, the National Health and Family Planning Commission of the People's Republic of China has abolished the drug-plus compensation mechanism, intensified the power of health supervision departments,<sup>4</sup> introduced a professional training policy after establishment of a

standardised training system, and showed no tolerance towards violence against doctors.<sup>5</sup> Moreover, after the defective vaccine case, a draft law on vaccine management aiming to tighten supervision of the industry was discussed at the 13th National People's Congress Standing Committee.<sup>6</sup> The most important lesson that we should learn from this incident is that matters such as this need to be curbed before they become a real problem.

We declare no competing interests.

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- 4 National Health and Family Planning Commission of China. China health and health development statistics bulletin 2017. 2018. <http://www.nhfpc.gov.cn/guihuaxxs/s10743/201806/44e3cdf11fa4c7f928c879d435b6a18.shtml> (accessed Jan 28, 2019).
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