LETTER

Pharmacists' role in off-label drug use in China

Off-label drug use is a global issue, which is not uniformly regulated across the world. There is no legislation on off-label drug use in China, while some public media reports in the country said that off-label drug use was illegal and of concern to Chinese healthcare professionals. The Guangdong Province Pharmaceutical Association issued consensus on off-label drug use in 2010 and 2014, which are the first sets of standards for off-label drug use in China, and has done a lot of work to change the perspective on off-label drug use in the country.^{1,2} Now in clinical practice in China, pharmacists play an important role in the management of off-label drug use. After being tested by the severe already existing physician–patient disharmony, we believe that this is a good choice in China.

In a Chinese hospital, off-label drug use requests are submitted to the pharmacy department by the physicians or collected from the physicians by the pharmacists, with the reasons, the evidence and the contingency plans. The pharmacists preliminarily evaluate the evidence and determine the level of evidence by searching the literature, and then making suggestions. The Micromedex database is an important tool in evaluating the evidence. Then the material is submitted to the hospital's pharmacotherapy and hospital ethics committees for approval. The physicians who apply for off-label drug use explain their reasons to the committees. The committee members consider the explanation and the evidence, and the pharmacists' suggestions, then make a decision. A drug clinical trial must be approved by an ethics committee, while off-label drug use may not. If the risk is low, the off-label drug use just needs to be approved by the hospital's pharmacotherapy committee. However, off-label drug use should also be approved by the hospital ethics committee in case the use poses a high risk to patients. After

approval, the drug can be prescribed for off-label use throughout the hospital, and the pharmacists review the orders based on the approvals. However, off-label drug use may be exempt from application for approval in an emergency situation so that treatment is not delayed. During patients' care, off-label drug use must be continuously monitored by physicians and pharmacists, and then progress notes written in detail. As the drug knowledge develops and the drug labels may change, off-label drug uses should be improved continuously by the physicians and the pharmacists.

Off-label drug use is unavoidable in clinical practice and it may pose a higher risk than on-label drug use to patients. In the Netherlands, a doctor must always discuss off-label drug use with the pharmacist in advance.³ Pharmacists have become deeply involved in off-label drug use management in China, improving patients' outcome.

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