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Real-world evidence approach to traditional herbal medicinal products

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There are tens of thousands of traditional herbal medicinal products (THMPs) on the market worldwide but few of them have gone through tests for efficacy and safety in randomized controlled trials (RCTs). THMP regulation is a global challenge. Many countries are faced with this dilemma: a looser regulation could present a significant risk to the public, whereas a tougher regulation might limit the availability of THMPs to the public. In the past two decades, the USA, the European Union (EU), China and other countries have enacted different provisions for THMPs. Different regulatory approaches reflect different cultures, ideology and experience in the regulation of THMPs, and none of them lacks controversy.

US regulatory approach to THMPs

Unlike many other regulatory systems, the USA has no such category as ‘traditional medicine’. A THMP can be marketed as a dietary supplement or a botanical drug, depending in a large part on its intended use. The Dietary Supplement Health and Education Act (DSHEA) of 1994 places dietary supplements in a special category under the general umbrella of foods, not drugs. Dietary supplement products do not require approval from the FDA before they are sold to the public [1]. Consumer Reports found that an estimated 23 000 people every year end up in emergency rooms after taking supplements [2].

The Botanical Drug Development Guidance for Industry was issued in 2004 and revised in