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The Compliance Operation and Legal Risk Prevention of Traditional Chinese Medicine Enterprises in the EU Market

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ABSTRACT
The strict regulatory system of the EU market has become a constraint on the development of Traditional Chinese Medicine. This paper explores the path of compliance operation and legal risk prevention of TCM enterprises in the EU. Research on the EU Traditional Herbal Medicinal Products Registration Directive, drug regulatory regulations, intellectual property protection system, advertising and marketing norms, and key risk factors the process of product access, intellectual property maintenance, and market promotion are explored. Specifically, it is proposed to build a compliance management system covering the entire process, involving specific measures such as improving product registration strategies, strengthening intellectual property layout, regulating advertising and marketing activities. The aim is to provide theoretical support and practical guidance for traditional Chinese medicine enterprises to enhance their competitiveness in the EU market and achieve sustainable development goals.

KEYWORDS
Traditional Chinese Medicine Enterprises; EU Market; Compliance Management; Legal Risk Prevention and Control; Traditional Herbal Medicine

1 Traditional chinese medicine enterprises' registration compliance and access risk prevention and control in the EU market

1.1 Analysis of the registration system for traditional herbal medicinal products in the EU

The EU Traditional Herbal Medicinal Products Directive sets a high bar for traditional Chinese medicine products to enter Europe, with the key being the dual of historical use evidence for products. The directive stipulates that registered products must have a history of medicinal use in the EU or other countries for more than 15 years, and least 15 years of that use must be within EU member states. Such high standards pose significant challenges to traditional Chinese medicine enterprises. A well-known pharmaceutical company in Yun applied for registration of its traditional Chinese medicine compound product in the EU, but despite domestic market recognition and good reputation, it failed to pass the registration due to the lack of complete EU proof, missing the opportunity to enter the EU market. In terms of production process supervision, the EU strictly manages products throughout their entire life cycle. The cultivation of medicinal materials follows GACP certification, ensuring that the growth environment, planting, fertilization, and medication are all up to standard, controlling quality from the source. At the formulation stage, enterprises must implement GMP standards, covering the production workshop environment, equipment maintenance, personnel operation, etc. Enterprises need to provide complete process control documents, including the source of medicinal materials, parameter records, etc., to facilitate regulatory traceability[1].The European Pharmacopoeia has strict limits on heavy metals, pesticide residues, aflatoxins, etc., with lead content not exceeding5 mg/kg and cadmium content not exceeding 0.3 mg/kg, which is higher than the requirements of the Chinese Pharmacopoeia. The regulations pesticide residues are also more detailed. When submitting registration materials, enterprises need to provide test reports from authoritative laboratories, explain the detection methods and data traceability, and any such as improper detection methods and incomplete data records during the registration process will lead to registration suspension, increasing the time and financial costs for enterprises.

1.2 Countermeasures and risk prevention and control

Enterprises can build a "regulatory research - technology reserve - multi-party collaboration" trinity response system, set up professional regulatory departments, introduce artificial compliance management systems, use natural language processing technology to capture the dynamics of EU drug regulatory regulations in real time, screen and collate them to establish regulatory databases, and mark regulatory risks intelligent algorithms, new restrictions on regulations mark high risk, and general process adjustment regulations mark low risk, to help enterprises quickly identify and deal with them. At the level of technical reserves, for products with insufficient historical usage evidence, the enterprise has launched a large-scale epidemiological survey in conjunction with European traditional research institutions, collected folk drug use cases

in many places in Europe, and conducted in-depth research and excavation of the value and safety evidence of product use in European folk through methods and big data analysis. For products that need to supplement clinical trials, in accordance with the EU clinical trial regulations, qualified trial bases are selected in EU medical institutions.The trial was designed with a randomized, double-blind, controlled design, strictly controlling variables to ensure scientifically reliable data. Professional monitors were arranged to superv the entire process to promptly identify and resolve issues. In terms of multi-party collaboration, the enterprise has engaged in long-term in-depth cooperation with local contract research organizations (Os) in the EU. The CRO agency has extensive experience and resources in EU pharmaceutical regulatory affairs and clinical trial management, is familiar with the approval processes and preferences of the drug authorities of various member states, and can provide enterprises with registration strategies. A certain Chinese herbal medicine company teamed up with a German CRO agency, which optimized the writing of the's registration materials and the submission sequence based on its understanding of the key points of the German drug regulatory authorities' approval, shortening the registration cycle by nearly 40% successfully obtaining the traditional herbal medicine registration certificate, significantly improving the efficiency of the enterprise entering the EU market.

2 Intellectual property rights protection and infringement risk prevention of traditional chinese medicine enterprises in the EU market

2.1 Analysis of the EU intellectual property legal environment

Under the unified framework of the EU, member states enjoy the right of local legislation in accordance with their national conditions and industrial characteristics. The European Patent Office attaches importance to the “technical contribution” in the examination of TCM patents, and the applicant needs to clearly elaborate on the separation and purification technology of active ingredients of drugs including specific processes, equipment, operating conditions, and the synergistic mechanism of compound compatibility, and to demonstrate from a multi-disciplinary perspective [2]. Novartis has invested research and development resources to study artemisinin derivatives, and with the help of innovative patent layout, it has built technical barrier in the EU market to hinder the development of other enterprises. The EU Intellectual Property Office implements a dual system of absolute and relative reasons for trademark examination. The examination of reasons prohibits the use of signs that violate public policies, such as those containing religious discrimination and contrary to public order and good customs. The relative reason examination strictly evaluates the possibility of with similar trademarks, comparing and analyzing from various aspects such as vision, hearing, and meaning. In terms of geographical indication protection, the "Regulations on the Protection of Ge Indications of Agricultural Products and Food" has higher requirements for "authentic medicinal materials". Enterprises need to prove that the quality of their products is closely connected with specific regional (soil acidity and alkalinity, climatic conditions, altitude, etc.) and traditional production processes. When applying for EU geographical indication protection for "Jilin Geng", more than a hundred pieces of materials such as soil component analysis reports, multi-year climate data, and planting historical archives were submitted to prove that its unique quality comes specific regions and traditional processes.

2.2 Analysis of intellectual property infringement risks for traditional chinese medicine (TCM) enterprises

TCM enterprises face two-way infringement risks in the EU market. On one hand, their own intellectual property rights are prone to infringement. If core technologies such as TCM formulas and processing techniques are not promptly patented in the EU, they may be imitated or reverse-engineered by local enterprises. Additionally, trademark squatting can prevent enterprises from using their original brands, thereby damaging their market reputation.

On the other hand, TCM enterprises may also trigger disputes due to unintentional infringement. For instance, they might use technical solutions similar to those already patented in the EU in product packaging or promotion, or fail to verify the intellectual property qualifications of suppliers when sourcing raw materials, leading to infringement of third-party plant variety rights. For example, a TCM enterprise selling health supplements in the EU was sued by a local rights holder for using unlicensed patented technology for plant extracts. The enterprise ultimately had to pay hefty compensation and recall its products, incurring significant economic losses.

2.3 Intellectual property rights risk prevention and control measures

Enterprises should establish a comprehensive management mechanism of "early warning-layout-rights protection". In the early warning stage, the EU market should be monitored in time through the intellectual property big data platform.

The key words early warning system should be set up, and the names of competing enterprises, the names of core products and the technical terms infringement should be set as keywords. The dynamics of patent application and trademark registration should be tracked. Once the system detects relevant situations, it immediately issues an alarm, promoting enterprises to respond quickly. The layout strategy adopts a "core patent peripheral patent combination mode. Traditional Chinese medicine formulas are protected by applying for core patents to protect the unique composition and ratio of the formula, and surrounding the process of refining, the surrounding patents applied for to protect the innovative methods and equipment. The technology of preparation is also patented to protect the new form of preparation and the preparation process. With the help of PCT international application, the protection is obtained in many countries of the European Union, and the scope of protection is broadened. A certain Chinese medicine injection enterprise has applied for 17 patents the production process, from raw material pretreatment to filling sterilization process, which has built a strict patent protection network to resist the infringement of competitors.

Enterprises need to formulate a cross-border intellectual property dispute response plan in the aspect of rights protection, and sign a strategic cooperation agreement with local law firms and agencies in the EU with rich litigation experience. Once they encounter infringement, they will implement the litigation strategy of "quick injunction+ compensation for damages", stop the infringement behavior time through a quick injunction, prevent further loss expansion, and claim economic compensation from the infringing party through legal channels. [3]. After a traditional Chinese medicine brand's EU trademark was preemptively registered, it immediately collaborated with a local law firm to submit an administrative objection to the European Int Property Office, Based on the evidence of prior use and brand influence, legal action can be taken when necessary, and the trademark rights can be successfully recovered through court debate and evidence, ensuring the protection of one's own rights.

3 Compliance and legal risk prevention of advertising and marketing of traditional chinese medicine enterprises in the EU market

3.1 Restrictions on TCM promotion by EU pharmaceutical advertising regulations

The EU implements a strictly tiered management system for pharmaceutical advertising. TCM products are classified according to the "EU Pharmaceuticals Law" and the "Directive on Traditional Herbal Medicinal Products," with different categories subject to distinct promotional rules. For TCM products registered as pharmaceuticals, their advertising content must be pre-approved by the Member State's Marketing Authorization Holder (MAH). Only information such as EU-approved indications, dosage, and administration may be presented. Any implication or comparative promotion of efficacy beyond the registered scope is strictly prohibited. For traditional herbal medicines, although the registration process can be simplified, their advertising must not explicitly or implicitly suggest therapeutic functions. Only health-related attributes such as "maintaining health" and "regulating bodily functions" are permitted. For instance, a company was fined heavily and forced to remove its advertisements by Germany's Federal Institute for Drugs and Medical Devices (BfArM) for using the phrase "improving sleep disorders" in social media promotions of a TCM product, as it exceeded the compliant scope for traditional herbal medicine advertising. Additionally, the EU's "Unfair Commercial Practices Directive" and "Misleading and Comparative Advertising Directive" impose stringent requirements on the truthfulness and scientific validity of advertisements. TCM enterprises must ensure that promotional content is supported by clinical trial data or literature evidence; otherwise, it will be deemed misleading.

3.2 Analysis of legal risk scenarios in TCM advertising promotion

TCM enterprises face multiple legal risks in advertising promotion within the EU market. During the content creation phase, violations may easily occur due to cultural and cognitive differences. For example, the use of TCM terms such as "detoxifying and beautifying" or "strengthening the body's foundation" may be interpreted by EU regulatory authorities as unsubstantiated therapeutic claims. When promoting on social platforms, if influencers or opinion leaders are engaged for product recommendations without clearly labeling them as "advertisements" or providing false user reviews, it will violate the "EU E-Commerce Directive." In cross-platform dissemination, discrepancies between advertising information on corporate websites, email marketing, and registered documents, or the promotion of prescription-level TCM products to ordinary consumers, constitute serious violations. For instance, a TCM enterprise triggered an investigation by the EU Consumer Protection Cooperation (CPC) network by pushing product detail pages with therapeutic functional descriptions to EU consumers through cross-border e-commerce platforms. As a result, the enterprise was banned from selling on relevant platforms and included in the list of non-compliant enterprises.

3.3 Advertising and marketing compliance management strategy

Building a compliance operation system of "content review - channel management - effect evaluation" is a key task for enterprises. Content review needs to set up cross-department team, covering medical experts, regulatory specialists, and marketing planners. Medical experts review advertising copy and video scripts from a professional perspective, judging whether they are in line medical principles; regulatory specialists review content based on EU pharmaceutical advertising regulations to eliminate illegal language; marketing planners optimize advertising creativity and presentation forms under the premise of compliance. Third-party medical verification institutions are introduced to verify the scientific basis submitted by enterprises with professional means and standards, ensuring that the relevant expressions are scientific and accurate. In terms of channel management, enterprises the "EU Market Advertising White List", which specifies the compliance publishing criteria for platforms such as YouTube and Facebook in detail. To place TCM advertisements on YouTube, it is necessary follow the restrictions on length and timing; on Facebook, it is not allowed to carry out illegal promotion through user groups [4].For search engine advertising, the negative keyword strategy is applied, setting "cure" and "heal" as negative items to avoid the illegal display advertisements. In the stage of effect evaluation, enterprises use advanced public opinion monitoring systems to analyze the market feedback after advertising in real time. This system collects multi-source information such as media comments, forum discussions, and news reports, and uses sentiment analysis and keyword extraction technology to determine whether advertisements cause controversy. Once there are situations such as consumer questioning of health and media reports of illegal advertisements, it is immediately taken down and adjusted. A certain traditional Chinese medicine and health product enterprise has built an "advertising compliance index" evaluation model, Considering the comprehensive indicators such as the volume of advertising exposure, the frequency of violations, and the rate of consumer complaints, the success in reducing the rate of violations from 12% to 3% has significantly improved the level of compliance in market promotion, ensuring the smooth progress of advertising marketing in the EU market.

4 Conclusionary remarks

The compliance operation and legal risk prevention of traditional Chinese medicine enterprises in the EU market is an extremely important part of the internationalization of traditional Chinese medicine. series of measures, such as precisely understanding the registration and admission conditions, strengthening the protection of intellectual property rights, and standardizing advertising and marketing activities, can help enterprises avoid legal risks the EU market, enhance their competitiveness, and at the same time, lay a solid foundation for the sustainable development of traditional Chinese medicine in the EU market. As a part of strategy of traditional Chinese medicine, the internationalization of traditional Chinese medicine is an important driving force for the globalization of traditional Chinese medicine and is also an indispensable part of the global health welfare governance system. Solving the development problem of traditional Chinese medicine enterprises in the EU market, promoting the extensive dissemination and development of traditional Chinese medicine worldwide, and contributing Chinese wisdom Chinese plan to the global health and welfare cause.

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