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中医药在德国

□ 文/Sebastian Jungermann
Kaye Scholer 律师事务所法兰克福代表处的欧洲合伙人

德国是全球化学制药最发达的国家之一，但德国人天性崇尚自然，因此其对天然草药研究的热情也丝毫不减，成为欧洲草药研究的重镇。从1970年至今，德国草药市场增长了1倍，占整体药品市场的28%。因使用天然草药属自我医疗行为，不需医师开处方，所以在德国，除了药店外，超市、卫生用品店及健康食品店均可买到草药制品，而其药费，除非属拒绝支付的特殊规定，一般可由健康保险机构偿还。此外，德国生产的植物药品种很多，如银杏制剂、贯叶连翘制剂等在国际市场有很强的竞争力，有些品种已进入中国市场。

在欧洲专家眼中，中药是世界医药体系中最古老的一派，扎根于中国3000多年的历史文化沃土里。如今的中药已经成为西方医药体系中颇具价值的一派。

中药现已在日本、越南、韩国及其他亚洲国家普遍运用。以中国传统模式为基础，其他模式如日本的“汉方医药”已被开发出来。各国对中药的确切定义避而不谈，只称之为东方医学。

与合成药不同的是，中药从植物、动物和矿物质中提取自然成分。中国草药种类繁多，这些材料既用于处方药，也用于制成药甚至是专利药。

专利药也使用传统药方，制成大剂量的药丸、药膏或补药。绝大多数的专利药在中国生产而销往世界各地，在过去20年里，中药曾是中国出口中销量最好的产品。中国政府及众多其他相关人员希望通过高浓筛选和严格的临床试验来揭开古老草药的神秘面纱，在安全和有效性上所取得的成效给半信半疑的西方科学家打了一针强心剂。

德国的替代药

据发现，中药是替代药的一种。替代药即诸如物理疗法、推拿康复疗法、瑜伽冥想等疗法。自20世纪90年代，替代药已在西方国家迅猛发展。草药疗法是传统医药中最常见的治疗方法，在国际市场盈利颇丰。德国也建立了替代药产业，较知名的公司有Madaus（成立于1919年），Weleda（成立于1921年），Wala（成立于1935年）等。

德国的中药

直到1970年，才有为数较少的几个欧洲专家知道中药的概念。那时的中药从业者要么被称为“神奇治疗师”要么被称为“巫术师”。德国中药产业建立于20世纪90年代，当时无人看好，如今，几乎无人不知中药、针疗或气功究为何物。仅在德国，每年就有30多本关于中药的书出版。

1951年，德国针疗协会成立，另一个活跃的中药协会便是1978年成立于德国慕尼黑的中华医药国际协会。德国有几所中药学校，与上海中医药大学紧密合作的马格德堡中医药国际学院便是其中一所。

德国第一家官方中医门诊成立于1991年，于今年2月成为北京中医药大学教学门诊。德国维藤/海得克大学与中医药刮痧门诊科研机构的合作内容与目的是：（1）诊法研究与比较；（2）理疗程序研究与比较；（3）中药临床研究；（4）德国的医药培训机构和培训研讨会。德国医疗保险也包含中药费用，现在，德国有成千上万个中医药从业者，中医药诊所也遍地开花。

德国专家关注更多的是中药的疗效。在德国，中医药通常和针疗等同起来，实质上，中医药的范畴要宽广的多。

位于伦敦的欧洲医药局

欧盟每年为世界提供1/3的新药。若想进入欧洲医药市场，投资方需要递交上市许可申请，由位于伦敦的欧洲医药局负责对医药产品进行评审。1995年至2004年，该局一直被著称为欧洲医药产

品的评审局。

欧洲医药局对属于权限范围的上千种医药产品进行科学评估。其他医药成品要么根据某国的许可程序在某国上市，要么根据非集中审批程序或互相承认程序在多个成员国上市。欧洲医药局只对使用或授权有争议的药品进行评估。

投资方向欧洲医药局提交上市许可申请后，医疗产品委员会或动物药品委员会将发布一份评估报告。如果委员会对该医药产品的质量、安全性和有效性予以认可，便将评估意见提交给欧盟委员会，欧盟委员会对其出具上市许可。

2007年夏天，欧洲医药局设立了儿科医药立法委员会。2008年夏天，所有新药产品的上市许可申请要么包含儿科医药研究数据，要么提供提交给儿科医疗委员会该研究的弃权证明书或延缓申请书。自2009年1月，该项责任已延伸至所有已授权的医药产品。欧盟成员国的绝大多数现存药由各成员国自行授权，新药则由欧洲医药局授权。欧洲医药局第四大委员会（草药产品委员会）对中药予以评估并对涉及草药产品的程序和条款予以解释协调。

德国联邦药物与医疗器械所

德国的新药上市许可是由德国联邦药物与医疗器械所授予的。自1978年，药品在投入市场前必须获得上市许可证，医药公司必须提供该医药产品质量、药效和安全性的说明。通常情况下，德国上市许可每隔5年更新一次。

除了德国联邦药物与医疗器械所，其他机构也能授予许可，医疗产品的职能部门是联邦药物与医疗器械所，疫苗、过敏素、抗原等则由位于兰根的德国保罗-埃利希研究所负责。兽药产品则由位于恩波的德国联邦消费者保护及食物安全办事处授权。

欧盟成员国的绝大多数现存药由各成员国自行授权，新药则由欧洲医药局授权。欧洲医药局第四大委员会（草药产品委员会）对中药予以评估并对涉及草药产品的程序和条款予以解释协调。

欧洲上市许可程序

在欧洲委员会的规章和指令的基础上，现已出台新的许可程序。

集中审批程序：集中审批程序许可证是由位于布鲁塞尔的欧盟委员会授予的，组织程序则由位于伦敦的欧洲医药局处理。申请人提交的文件由欧盟成员国的许可证发放机构审查，德国的联邦医药器械机构便是其中之一。

非集中审批程序：为了同时在多个欧盟成员国获得许可，申请人可申请非集中审批程序。如果某个医药产品没在任何成员国上市，可在210天内由其他成员国许可证发放机构予以许可认证。

互相承认程序：当一项上市许可已由某个成员国授权，其他成员国的许可证发放机构可在90天内予以认可。

涉及中药的知识产权策略

随着越来越多来自亚洲的生物科技和制药公司进入全球市场，我们建议他们建立稳固的知识产权策略来保护其全球范围的发展。除了中国，日本及其他亚洲国家，知识产权保护还应涉及北美和欧盟。

专利：只有被授权的专利才有效。德国专利局授权的专利仅在德国有效。如果发明者希望获取其发明专利的多国保护，可以在多国申请专利。如果发明人想在全球获得该发明的保护，欧洲或国际专利申请是个不错的选择。如果涉及到专利诉讼和专利执法，德国在效率和费用上颇具优势。欧洲每年有1400项专利诉讼，德国占66%。

商标：商标区分的是某个公司的产品和服务。好商标是颇具价值的资产。欧洲的商标法对单词、字母、数字、图片、颜色和声音予以保护。德国专利商标局对商标予以保护。如果公司想扩展其产品的保护范围，可向世界知识产权组织申请国际注册。此项申请必须在国家知识产权局备案。如果想在欧盟境内获得保护，可向位于西班牙阿利坎特的欧盟内部市场协调局提交共同体商标申请。IP

（译者：罗先群）

TCM in Europe with a focus on Germany

By Dr. Sebastian Jungermann, KAYE SCHOLER

Introduction

From the European point of view experts describe Traditional Chinese Medicine (TCM) as one of the oldest medicine systems in the world, rooted in more than 3,000 years of Chinese history and culture. Today, TCM is considered as a valuable alternative medical system also in the Western world.

Having its origin in China, TCM has also been used in Japan, Vietnam, Korea and many other Asian countries. Based on traditional Chinese models other versions have been developed, such as the well-known Japanese Kampo-medicine, besides others. In countries like Taiwan, Korea, Japan and Vietnam the definition TCM has been often avoided and TCM very often is being called as Oriental Medicine.

Rather than synthesized pharmaceutical products, TCM uses natural ingredients derived from plants, animals, and minerals. In Chinese herbal medicine literature, 10,000 or so plants are described. These substances are used both in prescription remedies and also in manufactured and even patented medicines. Traditional remedies, which use unprocessed or crude ingredients mixed according to ancient formulas, are generally prescribed by a TCM trained practitioner and sold over the counter in traditional medicinal shops, pharmacies, clinics and even in supermarkets.

Patented medicines use the same formulations as traditional remedies, but they are usually processed into pills, plasters and tonics, and packaged in mass quantities. Most patented TCM medicines are manufactured in China and are exported to other countries all over the world. For the last 20 years TCM has become a best seller for Chinas export industry. The Chinese government, besides many other participants in this market, hope that high-volume screening and rigorous clinical trials will unlock the secrets of ancient herbal remedies. Good results, in particular concerning safety and efficacy, shall convince Western scientists who still remain skeptical.

CAM in Europe and Germany

It has to be noted, however, that TCM is part of other complementary and alternative medicine (CAM), which also includes other practices applied in Europe and elsewhere such as naturopathy, chiropractic medicine, herbalism, Ayurveda, meditation, yoga, biofeedback, hypnosis, homeopathy, and nutritional-based therapies, in addition to a range of other practices. The use of CAM has surged in many Western countries since the 1990s. In many developed countries, 70% to 80% of the population has used some form of CAM. Herbal treatments are the most popular form of traditional medicine, and are highly lucrative in the international marketplace. Germany has a well established CAM industry as well, well known companies are Madaus (established in 1919), Weleda (established in 1921), Wala, (established in 1935), Wala's Dr. Hauschka brand, Hanosan, and many others.

TCM in Germany

Until 1970 only a very few experts in Europe knew what TCM is all about. At that time TCM practitioners were either called "Miracle Healers" or "Voodoo-Wizards". Since the 1990s, TCM is well established in Germany and nobody is smiling at TCM practitioners any more. Today, almost everyone in Germany knows what TCM, acupuncture and Qigong is about. Alone in Germany 30 or more books dealing with TCM are published every year.

In 1951 the German Medical Practitioner Associations for Acupuncture (Deutsche Aerztegesellschaft für Akupunktur e.V.) has been established, another important German associations active in TCM is the

International Association for Chinese Medicine - Societas Medicinae Sinensis, established in Munich in 1978. Several TCM schools have been established in Germany as well, like the International School of Traditional Chinese Medicine in Magdeburg, which closely cooperates with the Shanghai University of TCM, besides others.

Germany's first official TCM-Clinic has opened in 1991. In February 2010 this German TCM-Clinic Koetzing became a teaching clinic of the Beijing University of Chinese Medicine. The contents and general goals of the scientific accompaniment at the TCM-Clinic Koetzing in collaboration with the German University of Witten/Herdecke are (1) research and comparison of diagnostic methods, (2) research and comparison of therapy procedures, (3) research of the medical preparations used in the TCM clinic as well as (4) organization of medical training and training seminars in Germany. For patients in Germany the German health insurance funds usually bear the cost associated with all TCM treatments. Today, Germany has thousands of TCM practitioners and many clinics specialized in TCM.

From the German point of view many experts think that, above all, it is functional illnesses which can be treated with TCM. TCM has to be seen as a supplement to the clinical-morphologically orientated therapy procedure of conventional medicine.

Even though TCM often is equated with acupuncture, TCM is much more than that. The German TCM schools and clinics usually focus on the following TCM disciplines:

- Acupuncture,
- the Chinese medical therapy, which by far represents the most important therapy procedure of the TCM,
- the moxibustion, whose practice in China is inseparably linked to the acupuncture,
- the TUINA therapy, a manual therapy method,
- the meditative breathing and movement exercises of the QIGONG therapy and
- the Chinese dietetics with explicit concepts for nutrition and conduct.

As a mutual basis, all these disciplines have the so-called "theories of TCM", a medical-theoretical conceptual model. Only the use of this within the meaning of the bio-cybernetic and synergetic up-to-the-minute and scientific conceptual model allow a most successful, effective employment of TCM in the daily practice.

The European Medicines Agency in London (EMA)

When it comes to enter the European market and marketing a drug, the sponsor needs to apply for a marketing-authorization. The European Union currently is the source of about one-third of the new drugs brought onto the world market each year. The evaluation and approval of medicinal products for the European Union - which includes 27 Member States as of today - including the three EEA-EFTA states Iceland, Liechtenstein and Norway, is being managed by the London based European Medicines Agency (EMA). Under the so-called Centralized Procedure (CP), biotech and pharmaceutical companies submit a single marketing-authorization application to EMA. From 1995 to 2004, this agency was known as EMEA, the European Agency for the Evaluation of Medicinal Products.

The EMA is involved in the scientific evaluation of hundreds of medicines that fall within the scope of the CP. However, thousands of other medicines that do not fall within this scope are marketed in the European Union either in individual Member States, in accordance with their national authorization procedures, or in multiple Member States through the decentralized or mutual-recognition procedures. The EMA only becomes involved in the assessment of such medicines when they have been referred to EMA due to a disagreement between two or more Member States about the authorization

or use of the medicine, or due to some other issue that requires resolution in the interest of protecting public health.

After a sponsor has submitted its application for a marketing authorization to the EMA, a single evaluation is carried out through the Committee for Medicinal Products for Human Use (CHMP) or through the Committee for Medicinal Products for Veterinary Use (CVMP). If the relevant Committee concludes that quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. This opinion is sent to the European Commission to be transformed into a marketing authorization.

Since summer 2007, the EMA also has a committee dealing with the new pediatric legislation in Europe (the PDCO). Since summer 2008, all new applications for the marketing authorization of new pharmaceutical products will have to either include data from pediatric studies (previously agreed with the PDCO), or to demonstrate that a waiver or a deferral of these studies has been obtained by the PDCO. Since January 2009, this obligation will extend to most variations of already authorized products (for example, for new therapeutic indications).

The majority of existing medicines throughout the European Union's member states remain authorized nationally, but the majority of genuinely novel medicines are authorized through the EMA.

If TCM is involved, very often the fourth committee of the EMA will be active, which is the Committee on Herbal Medicinal Products (HMPC). The HMPC assists the harmonization of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework.

The German Federal Institute for Drugs and Medical Devices

In Germany, the national authorization procedure is being handled by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). Since 1978, finished medicinal products have been required to undergo an authorization procedure before they can be placed on the German market. The pharmaceutical companies must provide proof of the pharmaceutical quality, efficacy, and safety of the product. In general, the German marketing authorization must be renewed after a period of 5 years.

Besides the German BfArM other agencies might be competence for the approval. The competent authority for human medicinal products is the BfArM, while sera, vaccines, test allergens, test sera and test antigens as well as blood preparations are the responsibility of the German Paul-Ehrlich-Institute (PEI) in Langen. Veterinary medicinal products are authorized by the German Federal Agency of Consumer Protection and Food Safety in Bonn (BVL).

The Marketing Authorization Procedures in Europe

As mentioned above, new authorization procedures have been created on the basis of regulations and directives of the European Commission.

Centralized Procedure (CP): The CP effects a license throughout the 27 EU Member States as well as for the EEA-EFTA states Iceland, Liechtenstein and Norway. An authorization under the CP is not granted by a national agency but by the European Commission in Brussels; only the organizational process is handled by the EMA in London. The submitted documentation is reviewed by the scientists from the licensing agencies of the EU Member States, among them those of the German BfArM.

Decentralized Procedure (DCP): In order to obtain a license within more than one EU Member State at the same time the applicant may initiate a so-called “Decentralized

Procedure" (DCP). If a medicinal product has not yet been marketed in any EU Member State it may be recognized by the licensing authorities of other Member States within 210 days. Thereafter, the authorization will be granted unless one of the concerned Member States determines "serious risks to public health" for the product.

Mutual Recognition Procedures (MRP): In case a marketing authorization has been already granted by one EU Member State it can be recognized by the licensing agencies of other Member States within 90 days, unless there are major objections against doing so.

IP strategy concerning TCM

As more and more biotech and pharmaceutical companies from Asia with patented new drug discoveries enter the global market place, they are well advised to establish a solid strategy to protect their IP on a worldwide basis. Besides China and Japan and other countries in Asia, the protection of their IP should also cover at least the most important markets of North America (US and Canada) and the European Union. TCM may be protected by trademarks and patents, besides other IP, while patents are only available for new technical inventions, though.

Patents: Patents are only valid in the country for which they have been granted (principle of territoriality). Patents granted by the German Patent Office only have effect in Germany. However, if an inventor wishes to obtain protection for its invention in just a few countries in addition to the country of first filing, it might be useful to file individual applications in the respective countries. In case the inventor seeks broad regional or worldwide protection, a European or an international patent application might be the right choice.

If it comes to patent litigation and patent enforcement it should be noted that due to efficiency and fees Germany is the place to fight in Europe. While roughly 1,400 patent cases per anno are litigated in Europe, approximately 66% thereof are being litigated in Germany, especially in Dusseldorf, Mannheim, Frankfurt, Mannheim and Munich.

Trademarks: Trademarks identify products and services of an company. Strong trademarks are very valuable assets. In Europe, trademark protection is available for words, letters, numbers, pictures, and even colors and sounds. In Germany trademark protection arises from the entry in the register of the German Patent and Trade Mark Office and is subject to a prior application. However, trademark protection may also arise from an intensive use of a sign in the course of trade or from the fact that a sign is very well-known. As with patents, German registered trademarks are exclusively effective in Germany. If a company wishes to extend protection, it may apply for international registration at the World Intellectual Property Organization (WIPO/OMPI); such application must be filed at the national industrial property office. In case a company seeks protection in the EU Member States, it may file an application for a Community Trade Mark at the Office for Harmonization in the Internal Market (OHIM) in Alicante, Spain.

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