Animal Healthcare products in China: A Regulatory Landscape

PEER REVIEWED

Abstract:
Safe and nutritious food products derived from animals are more likely to come from healthy animals than those that are compromised by disease. Veterinary medicine will help in preventing diseases and maintaining good health. Developing countries like China should have more precise veterinary drug regulation and guidelines relating to them. Registration is the precondition for placing a product on the market. The process requires applicants to submit data supporting the safety, quality and efficacy of a product in a detailed dossier, which is reviewed by an independent scientific committee working on behalf of the China governmental agency (Ministry of Agriculture of the People's Republic of China). The scientific review examines all aspects of the product, and includes a detailed risk-benefit analysis. Only after passing this review and being declared safe, of high quality and efficacious, may a product be offered for sale. Therefore, regulations need to be carefully evaluated and follow the proper regulatory path for implementation, regardless of whether it is an investigational or a commercial product. The registration and import of veterinary drug plays an important role in order to market the product. The aim of this article is to provide an overview of the veterinary pharmaceutical market and regulation involved in import and drug registration in China.

Key words - Veterinary medicinal products, Veterinary new drug registration, Premarket approval, Pharmaceutical market, Vaccines market forecast

Introduction:
China, officially the People's Republic of China (PRC, Fig. 1), is a sovereign state in East Asia. It is the world's most populous country, with a population of over 1.35 billion.[1] China borders Eastern Asia in the West and has coastline that extends from North Korea to Vietnam, along the East China Sea, Korea Bay, the Yellow Sea, and the South China Sea.[2]

The PRC is a single-party state governed by the Communist Party of China, with its seat of government in the capital city of Beijing. Covering approximately 9.6 million square kilometres, China is the world's second-largest country by land area. The Himalaya, Karakoram, Pamir and Tian Shan mountain ranges separate China from South and Central Asia.

- Capital - Beijing
- Official language - Standard Chinese
- Country comparison to the world - 1
- Area - 9,596,961 km^2
- Population - 1,376,049,000 (Fig. 2)
- Country comparison to the world - 4 2
- GDP - $18.976 trillion
- Currency - Renminbi (yuan)(¥) (CNY)mn[2]

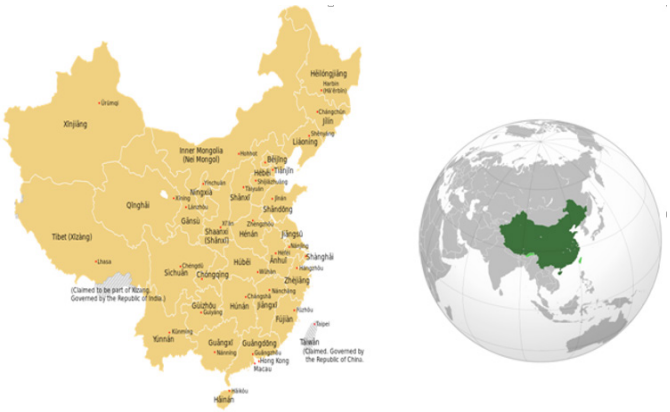


Fig. 1: Bird's-eye view of China[1]

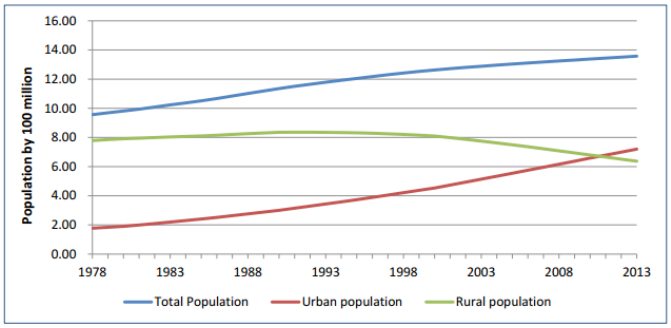


Fig. 2: China population[3]

Economy of China:
China's human pharmaceutical market is expected to become the largest in the world by 2050. This is due to a rapidly growing economy and urban middle class sector (520 million people predicted to be of upper middle class status by 2025).[4] The ASEAN-China Free Trade Agreement (ACFTA) is a trade bloc consisting of the ten ASEAN member states and the People's Republic of China. The ACFTA came into effect in January 2010. This organisation is now recognised as the largest regional emerging market in the world, as it dealt with €7.5 trillion of trade in 2010.[4]

China has the world's second-largest economy in terms of nominal GDP, totalling approximately US$10.380 trillion according to the International Monetary Fund. If purchasing power parity (PPP) is taken into account, China's economy is the largest in the world, with a 2014 PPP GDP of US$17.617 trillion.

Graph comparing the 2014 nominal GDPs (Fig. 3) of major economies in US$ billions, according to IMF.[1]

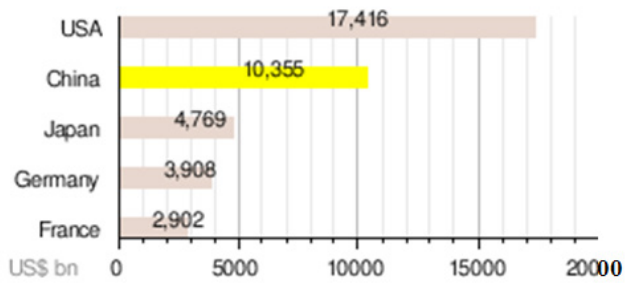
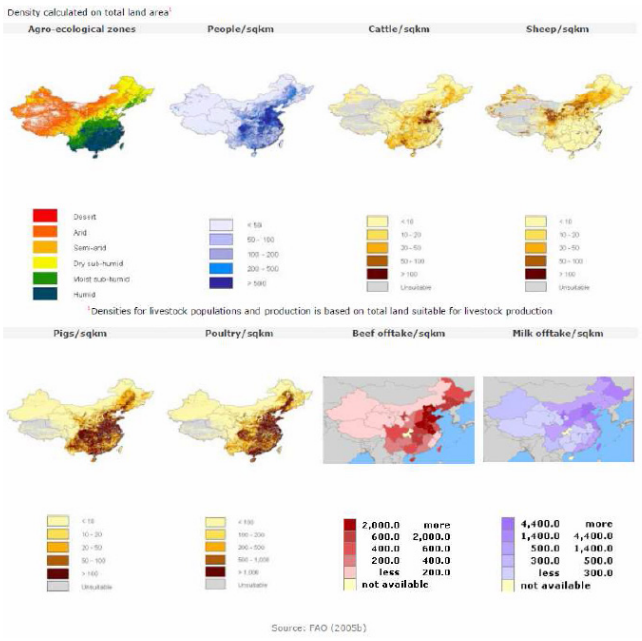


Fig. 3: Graph comparison

Today, "China is the world's third largest economy […] with large potential markets for goods, equipment and expertise, and so it offers many opportunities and challenges. The country is shifting away from resource-intensive manufacturing, resulting in major industrial upgrading in many industrial sectors."[5]



Climatic Conditions:
The FAO data indicates that most of the people, their companion animals and animal farming systems are located in the moist sub-humid and humid zone of the country. Therefore, pharmaceutical products should be proven to be stable in the following conditions: 30°C/65 % r.h., i.e. climatic zone IVa stability testing.[6]

China: Agro-ecological zones and densities of livestock species (2000)

Pharmaceutical Market:
The animal husbandry (AH) industry in China included 1800 companies in 2011. A majority of the produced medicines were live and inactivated vaccines. In that year, 270 billion doses of live vaccines and 60 billion millilitres of inactivated vaccines were produced. Furthermore, China`s industry produces the complete spectrum of veterinary medicines, such as antimicrobial, anti-parasites, disinfectants, antipyretic-analgesic and anti-inflammatory medicines.[7]

With attention to the Chinese regulatory environment, the IFAH Europe noticed a strong local protectionism in China in its last benchmarking report from 2011: "… There is a 2-speed system between local and foreign companies; and China also accepts quality standards from local companies that in some cases are so low that they damage their own industry."[4]

Moreover, the IFAH Europe is concerned about intellectual property (IP) protection issues. Currently, questions are raised on how much detail has to be revealed to meet the requirements of the NCAs. As an illustration, one interviewee of the IFAH report noted that the authorities make every effort to be approachable; a frequent comment sounds like this: "…for biologicals, the Chinese authorities request details and demand strains; this produces a strong internal debate on how to deal with the situation but, as China is the number 2 or 3 market in the world, it is impossible to stay out of it – we need to be sure of the market, but also get into it in a way we don't regret later."[4]

In addition, there have been concerns about the quality of certain APIs of Chinese origin in many countries. In particular, an instance of heparin contamination of an API could be tracked back to China and resulted in recall of the final product in 2008. As a consequence, inspection standards were upgraded in 2009, with the goal of having more rigid and robust technical requirements.[8]

Animal Husbandry

Livestock and Poultry:
In April 2013, three of the four BRIC countries were leading the list of the ten countries with the world's largest cattle populations.[9] The world leader in cattle production was India (327 million animals), followed by Brazil (203 million) and China (104 million). Russia and China reduced their population by -8.3 % and -1.5 %, respectively, during the same time period of four years.[9]

China leads the list, having a pig population of 466 million animals in 2013. The increase since 2009 remains relatively low (+0.8 %), compared to countries such as Brazil that showed an increase of +13.7 % during the same period. An overview of animal husbandry[3] is shown in Fig. 4.

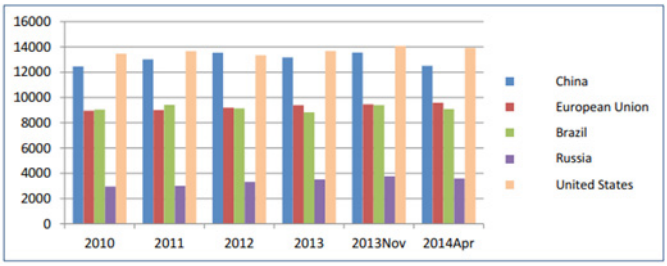


Fig. 4: Animal husbandry

Veterinary Medicine:
This is the branch of medicine that deals with the prevention, diagnosis and treatment of disease, disorder and injury in animals. The scope of veterinary medicine is wide, covering all animal species, both domesticated and wild, with a wide range of conditions which can affect different species. Veterinary medicine is widely practised, both with and without professional supervision. Professional care is most often led by a veterinary physician (also known as a vet, veterinary surgeon or veterinarian), but also by para-veterinary workers such as veterinary nurses or technicians.[10] Substances used as veterinary drugs and biologicals will include chemicals, viruses, sera, antigens, toxoids, immunostimulants, genes or genetic sequences and other substances. Such substances can be ingested, inhaled, absorbed, injected or in some other way exposed to the animal, including through water and food. Veterinary science helps human health through the monitoring and control of zoonotic disease (infectious disease transmitted from non-human animals to humans), food safety, and indirectly through human applications from basic medical research. They also help to maintain food supply through livestock health monitoring and treatment, and mental health by keeping pets healthy and long-living. Veterinary scientists often collaborate with epidemiologists, and other health or natural scientists depending on type of work. Ethically, veterinarians are usually obliged to look after animal welfare.

Traditional Chinese Veterinary Medicine (TCVM)
It is the ancient veterinary treatment of animals based on the same theories as traditional Chinese medicine (TCM). TCM and TCVM have developed over a period of over 3500 years and are practised all over the world. In Western cultures such as the US, TCVM has rapidly grown as an adjunct therapeutic modality for animals that do not respond favourably to typical Western veterinary treatments.

Chinese philosophical truths based on Taoism are the underpinnings that influence the practice of TCVM. The fundamental truth for health in TCVM is balance — balance within yourself, balance with others, balance with your diet, and balance with nature.

TCVM practices include four major fundamental branches: Chinese food therapy, acupuncture, herbal therapy, and Tui na ("twee-na"). Its counterpart, TCM, includes other treatments such as herbal medicine (中药), acupuncture, dietary therapy, and both tui-na and shiatsu massage. Qigong and Taijiquan are also closely associated with TCM.

TCVM has evolved simultaneously with the evolution of TCM. TCVM originated thousands of years ago through meticulous observation of nature, the cosmos, and the human body. Major contributing theories that apply to the practice of both TCM and TCVM include: the yin-yang theory, the five-element theory, the human body channel system, Zang-Fu organ physiology, six confirmations, four layers, etc.[11]

Fig 5: Example of traditional Chinese veterinary medicine[12]

Current Situation of Changes in Regulatory Law in the China:
During the last decade, the registration requirements for VMPs in the BRIC countries have been tightened continuously. In China, the regulatory requirements and control mechanisms for pharmaceutical products were amended in order to improve the quality and safety of human medicines and VMPs, since there have been big concerns regarding active pharmaceutical ingredients (APIs) and traceability throughout the supply chain. This was triggered by scandals such as the worldwide contamination of various heparin products with over sulphated chondroitin sulphate, cases of contaminated glycerine originating in China and ending up in products as diverse as toothpaste, cough syrup and antihistamine tablets, and an alarming increase of reports about fake medicines. These amendments of the legislation upgraded the good manufacturing practice (GMP) inspection standards by imposing more stringent technical requirements, quality control and validation procedures.[5]

Competent Veterinary Authorities and Regulatory Legislation in the China:

4.1 Organisation and Responsibilities of Competent Authorities
In this chapter, the author presents the structure and function of the national competent authorities (NCAs) responsible for the evaluation and registration of VMPs in the China countries. For comparative reasons, the organisation and function of the EMA will be briefly discussed.

In general, the organisation of the NCAs, responsible for evaluation and supervision of veterinary medicine, varies from country to country. According to a publication of the Indian Veterinary Journal in 2012,[13] the agencies could be divided into two groups, based on how the control of veterinary medicines is organised:

- NCAs in countries where the veterinary medicine control is part of a "single agency" system that regulates human medicines under supervision of the national Ministry of Health, and
- NCAs in countries where a separate agency regulates the veterinary medicines underthe supervision of the National Ministry of Agriculture.

According to that overall classification, China works in separate agencies under the control of the local Ministry of Agriculture. Hence, the Chinese Ministry of Agriculture (MOA) have their main focus on agricultural issues, such as livestock disease prevention and food safety.[14]

Organisation and Responsibilities of Competent Authorities

Organisation of China:

In China, the organisation for evaluation and approval of

China	China Institute of Veterinary Drug Control (IVDC) / Center for Veterinary Drug Evaluation (CVDE), Bureau of Veterinary Service, Ministry of Agriculture	http://http.ivdc.gov.cn/English/	Chinese and English	Veterinary Desk Address: Administrative Examination and Approval Office Ministry of Agriculture No.11 Nongzhongnan Nanli, Chaoyang District, Beijing, China Postcode: 100125

applications for VMPs is comparable to its neighbouring country, Russia. Also, two different agencies are involved in the evaluation and registration of VMPs, namely the Institute of Veterinary Drug Control (IVDC) and the Veterinary Bureau of the Chinese Ministry of Agriculture (MOA).

In particular, the IVDC is responsible for the assessment of veterinary medicines, quality supervision and inspection of veterinary medicines and appliances. That national institute and one of its subdivisions, namely the Veterinary Drug Evaluation Center (CVDE), share the following duties: monitoring of veterinary medicines residues, collection of veterinary cultures, drafting and revising national standards of veterinary medicines, as well as preparation and calibration of the national standards and reference materials of veterinary medicines.[7] The IVDC is a national veterinary technical support institution, which is directly affiliated to the MOA. The Veterinary Bureau of the MOA comprises of six divisions: the Division of Veterinary Drug and Appliances, the Division of Animal Disease Prevention, the Division of Animal Disease Inspection and Supervision, the Division of Veterinarian Administration, the Division of Science, Technology and International Cooperation, and the Division of General Affairs.[7]

The Veterinary Bureau differentiates between veterinary medicines and veterinary biologics. Medicines include pharmaceuticals, antibiotics, herb medicines (traditional Chinese medicine) and disinfectants. Biologics include vaccines, toxoids, antisera and diagnostic kits. Furthermore, the Veterinary Bureau is responsible for veterinary medicinal devices.[7]

Laws and Regulations:

In this chapter, key legislation for new, generic and, if applicable, similar veterinary medicines for China and requirements for import of VMPs are presented. Furthermore, main aspects of changes of regulatory legislation that were amended and/or introduced recently, or which will be in force in the near future, are discussed. Web pages publishing recent changes in law are shown to facilitate the efforts of a foreign RA manager to follow the current regulatory legislation in China.

In general, national legislation concerning human and veterinary medicine can usually be distinguished from laws specifically addressed to VMPs (below table). In cases where it is not clear if there is a specific veterinary legislation, the author presents the relevant human laws.[14]

China Legislation:

According to a self-presentation of the MOA in 2013, "China now has a relatively well-established legislation of animal drug laws, regulations, technical standards and norms, a relatively full-fledged drug control system and a rather complete production chain where GMP management is fully adopted."[7]

Today, the Chinese NCAs are looking at established and proven regulatory systems (e.g., Europe and the US), according to TOPRA's assessment of the Chinese pharmaceutical environment in 2010.[5]

However, the above mentioned report from TOPRA points out that it is undoubtedly necessary for China to adapt the existing regulatory legislation to its very specific national situation in the coming years.

China	State Council regulation "Regulations on Administration of Animal Drugs"	Veterinary medicine	11 January 2004	Specific provisions on animal drug producers, control over medicines in veterinary medical institutions, new animal drug approval, management of drug import and export, and supervision, trademark and advertisement of animal medicines.

a) New VMPs

The Chinese MOA distinguishes between:

a) pharmaceuticals and herbal medicines, and
b) biologicals.

Legal basis for point a:

1. Regulations on Administration of Veterinary Drugs (Order No. 404 of the State Council)
2. Measures for Registration of Veterinary Drugs (Order No. 44 of the Ministry of Agriculture of the People's Republic of China)
3. Announcement No. 442 of the Ministry of Agriculture of the People's Republic of China

Legal basis for point b:

1. Regulations on Administration of Veterinary Drugs

General Requirement for Registration:

Requirements / Considerations	China
Time limit for VMP licence	Decree No. 44, article 27: "import veterinary certificate of registration" and "veterinary registration certificate" are valid for five years.
Renewal	Decree No. 44, article 27: On the need to continue to import, application shall be made six months before expiry to the Ministry of Agriculture for re-registration. Decree No. 44, article 29: Review of application for re-registration by MOA: 20 working days to review.
Variations	Decree 404, article 13: Variations of Veterinary Medicine Manufacturing Licence Decree 404, article 24: Variations of Veterinary Medicine Distribution Licence.
Data protection periods for new products	Data exclusivity is granted for six years starting from the marketing approval for new chemical entity products.[15]
Manufacturing licence	Decree 404, article 12: Veterinary Medicine Manufacturing Licence is valid for five years. Re-registration: six months before the expiration of the licence. Decree 404, article 33: On-the-spot inspections are possible. Requirements of GMP for VMPs will be inspected. MOA tests if the foreign company shall have the right to conduct tests on safety and efficacy of the medicine at an institution designated by MOA.
CPP	Yes, CPP is required together with legalisation.[16]
Labelling requirements	Decree 404, article 20: In Chinese, requirements as indicated.
MRL	China maintains a national list of MRLs for pesticides (for VMPs there is no information available). MOA is responsible for establishing and publishing MRL standards; the country does not officially defer to Codex Alimentarius.[19]
Review time	Approx. 27 months for VMPs in total (preliminary review by MOA and CVDE: six months, clinical trials and residue tests: eight months, evaluation by CVDE: six months, quality tests: five months, approval of licence: two months).[17] On the contrary, according to MOA, the promised time frame for evaluation of imported VMPs is: 60 workdays (a maximum of 120 workdays for technical evaluation or experimental evaluation; a maximum of 150 workdays for special testing), for imported veterinary biologicals: 20 workdays.[20] Registration procedure for feed additives (type 1): five months in total (preliminary review by MOA: one month, quality tests: three months, approval of licence: one month).[17]
Stability studies Critical and/ or recent issues	Climatic zone IVa. Import: Conduction of clinical trials and verification tests in designated agencies (by MOA) within the territory of China.[17] Feed additives and VMPs must be registered separately. Moreover, the MOA distinguishes between two types of imported feed additives: Type 1: on the national list of approved feed additives; type 2: *not* on the national list of approved feed additives. Furthermore, there are different rules for a) vet. pharmaceuticals, herbal medicines and b) biologicals.[17] Decree 404: In addition to the medicine approval licence, the applicant needs a licence for manufacturing and medicine distribution.

(Order No. 404 of the State Council)

b) Generic VMPs

Today, China has only a few regulations for human generic products, but the term "generic product" is commonly used inside the country, according to the regulatory legislation platform IDRAC (which only gives information for human medicines). In detail, the China's Food and Drug Administration has published guidelines for bioavailability and bioequivalence studies of medicinal products for human bodies in 2005. In addition, chapter 5 of order no. 28: regulations on medicine registration administration, from 2007, governs the application of generics in China.[15]

Regarding VMP legislation, the author has not found any regulation for generic and/or similar products in China. Thus, special regulations for generic VMPs in China may not exist at the moment.

For human medicines, the term generic product refers to a medicine that has been granted MA and been sold in the Chinese market for years without having patent protection in China.[15] Moreover, the term "essentially similar product" is defined for human medicines. If two pharmaceuticals have the same amount of APIs that qualify for the same quality criteria, have the same pharmaceutical form, and have proven bioequivalence, they can be regarded as "essentially similar products".[15]

In general, the following requirements for registration of a generic human medicine should be met:

- No violation of the patent rights of the reference medicinal product (RMP)
- Specifications should be comparable to or beyond those of the RMP
- Clinical efficacy and safety data should be comparable to those of RMP and should comply with Chinese specific guidelines.[15]

The author assumes that, as long as there are no specific regulations for generic VMPs, the provisions for human medicines may be applicable for a generic application in the country.

c) Import Requirements

For import, the Chinese MOA distinguishes between:

a. Pharmaceuticals and herbal medicines, and

b. Biologicals.

Legal basis for point a:

1. Regulations on Administration of Veterinary Drugs (Order No. 404 of the State Council)
2. Measures for Registration of Veterinary Drugs (Order No. 44 of the Ministry of Agriculture of the People's Republic of China)

3. Announcement No. 442 of the Ministry of Agriculture of the People's Republic of China

Legal basis for point b:

1. Regulations on Administration of Veterinary Drugs (Order No. 404 of the State Council)
2. Administrative Measures for Imported Animal drugs (Order No. 2 of the Ministry of Agriculture of the People's Republic of China)

In general, the applicant for an import licence must have Chinese nationality or, if the applicant is foreign, a Chinese legal representative must be authorised.[16]

In addition, clinical trials and verification tests must be conducted in designated agencies (by MOA) within the territory of China.[17]

At the end of the registration process, a "Certificate for Imported Veterinary Drugs" is issued for each new medicine. Revised specifications, instructions and labels for those medicines are included and enter into force on the day of their issuance.

In addition to the above mentioned procedures for VMPs import, the MOA distinguishes between two different types of imported feed and feed additives. For both types of imported products, there exist different requirements and authorisation procedures.

Type one:
The products were previously approved by MOA, and therefore the requirements for import include only quality aspects.

Type two:
The products are not listed as previously approved, and therefore, feeding studies and safety data, in addition to quality tests, are mandatory.[17]

d) Recent Changes in Legislation
Over the past few decades, China has seen large changes in regard to its human healthcare system, its regulated healthcare industry and its governing institutions. For instance, since fake medicine scandals had become a major political issue in the western part of the world, China introduced good clinical practice and good laboratory practice based on international guidelines. Furthermore, the goal is to increase the GMP inspection standards by imposing more stringent technical requirements, quality control and validation procedures.5 Also, the veterinary legislation has been updated during the last years and the regulations are still under development.[5]

Concerning VMP control, the MOA has increased the quality control of vaccines against major animal diseases, and the review and approval of VMPs and GMP in 2011. Since then, the MOA has examined medicine quality through random inspection and rectified the Chinese medicine market. In this regard, the MOA plans to implement a so-called "Good Sales Practice for Animal drugs". In addition, the Chinese Veterinary Pharmacopoeia 2010 had officially taken effect in July 2011.[7]

The quality standards for VMPs were also tightened. In 2010, three laws were issued in this regard:

- Inspection and Acceptance Measures for Quality Management Standards in Production of Animal Drugs (issued: 09.01.2010),
- Norms for the Business Operation and Quality Management of Animal Drugs (issued: 03.01.2010),
- Administrative Measures for Labels and Instructions of Animal Drugs (issued: 03.01.2010).

e) Publication of Current Law
In general, the IVDC publishes novel registrations and renewals for veterinary medicines on its web page: http://www.ivdc.gov.cn/English/RegulatoryInformation/Legislation/201009/t20100903_34368.htm[18]

General Challenges for Marketing Authorisation Applications in China:
In this chapter, the author provides the reader with a short overview about the national requirements for registration of foreign VMPs in China. In general, the indicated review times are highly variable and unpredictable, depending on local agency resources, reviewer's perspective, number of rounds of questions from agency, speed of answers from applicant, and if the deadline to reply is specified by the NCA.

In general, for an MA submission it is recommended to submit a dossier in accordance with the following structure:

Part 1: Administrative and legal information
Part 2: Quality information
Part 3: Safety (pharmaceutical and toxicological studies)
Part 4: Efficacy (clinical studies)

In addition, a summary of product characteristics (SPC) and information on labelling and
package inserts should be added.[15,16,17,19,20]

General Requirement for Registration: See table on page 30.

Legislation / Guidelines / Other Legal Texts
China:
- Regulations on Administration of Veterinary Drugs (China). Decree No. 404. Adopted at the 45th Executive Meeting of the State Council on March 24, 2004, promulgated by Decree No. 404 of the State Council of the People's Republic of China on April 9, 2004, and effective as of November 1, 2004.
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- SFDA Order No. 28: Regulations on Drug Registration Administration, October 1, 2007
- The Technical Guidelines of Bioavailability and Bioequivalence Study of the Medicinal Products for Human Bodies, March 18, 2005
- Announcement No. 442 of the Ministry of Agriculture of the People's Republic of China. Registration requirements for imported veterinary drugs in China.
- Administrative Measures for Imported Animal drugs (Order No. 2 of the Ministry of Agriculture of the People's Republic of China)
- Administrative Measures for Labels and Instructions of Animal Drugs (issued: 03.01.2010)
- Inspection and Acceptance Measures for Quality

Management Standards in Production of Animal Drugs (issued: 09.01.2010)
- Norms for the Business Operation and Quality Management of Animal Drugs (issued: 03.01.2010)[14]

Conclusion

This brief write-up aims to increase the understanding of regulatory consideration and regulatory pathway for registration of new and generic animal healthcare products and traditional Chinese veterinary medicine in China.

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19. China Pesticide MRLs Market Information Page. March 2013. International Maximum Residue Level Database. A service of the Foreign Agricultural Service, United States Department of Agriculture. (last visit: 29.01.2014) http://www.mrldatabase.com/results.cfm
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