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Investigating the rules and regulations of the registration process of pharmaceutical products in the Common wealth of Independent States (CIS) in comparison to those in Iran

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Highlights

- The dossier format for pharmaceutical registration differs significantly, with Iran using the Common Technical Document (CTD) format while CIS countries require country-specific (non-CTD) dossiers that only resemble the CTD structure.
- There is considerable heterogeneity in administrative documentation requirements across different CIS countries, creating a complex regulatory landscape for companies seeking multi-country market entry.
- Registration timelines in CIS countries are generally longer (6-24 months) than in Iran (6-12 months), with additional local requirements such as conducting bioequivalence studies within the specific CIS country posing further challenges.

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ABSTRACT

Background: Drug Dossier is a file document submitted based on the requirement of the drug approval process. It is a comprehensive scientific document used to obtained worldwide licensing approval of a drug by diverse health authorities. There are different requirements in different countries for registration of a product. Regulatory agencies require Pharmaceutical Dossiers to gain approval to market drugs. Drug Dossier is a document file which has technical and administrative information. Pharma companies prepare dossier as per CTD / Eu CTD / non-CTD (country specific guideline).

Methods: This dissertation is completely descriptive and it is enough to collect, translate and classify the registration process of the countries under study. Finally, its key steps are compared with Iran's regulations, as well as some guidelines for developing exports in accordance with the regulations of the countries under study.

Results: CIS countries follow their own country specific dossier format. Documentation of Dossier in countries of the CIS countries is different from Iran.

Keywords: CTD-Common Technical Document, Eu- CTD, Non-CTD, CIS countries

Introduction

Drugs have become an essential necessity in public health, people and the government has become willingly to spend more money on the country's healthcare system to restore health, save lives, preventing disease and epidemics. Drugs should be properly regulated throughout development, production, importation and subsequent distribution to ensure it is prescribed with safe, effective and of good quality standards. The structure of drug regulations today has evolved over time. During the process, the scope of legislative and regulatory power expanded in result of a series of disastrous events related to pharmaceutical products, the adoption of more restrictive legislative were put in place for stronger safeguard to the public.

It is vital to have speedy approval process with high standards in safety, efficacy and quality on all approved drugs. If drugs are approved in a rush manner, it will lead to serious adverse drug reactions (ADR), or even deaths in consumption of unsafe, and ineffective drugs. On the other hand, slow approval will make patients suffer and increase the mortality rate to due inaccessibility of appropriate medicines to sustain life and combat diseases.

About pharmaceutical industry of Commonwealth of Independent States (CIS)

In the recent years there has been a phenomenal growth in the pharmaceutical industry of Common wealth of Independent States (CIS). In order to tap the vast potential existing in this region, Islamic republic of Iran is chalking out a slew of initiatives to boost its exports to the region. The CIS region which once was part of erstwhile USSR (United Soviet Socialist Republic) had disintegrated in to several independent countries in the year 1991. Since then all the CIS nations have been focusing on building trade relations with various countries and Iran in particular especially in the field of pharmaceuticals and biotechnology. With the growing salience of Islamic republic of Iran in the field of pharmaceuticals on the global stage, the CIS nations are keenly exploring opportunities for building trade relations with Islamic republic of Iran. The Islamic republic of Iran government is also equally interested in building a long-term relation with the CIS nations. CIS is one region where Islamic republic of Iran has huge potential for growth. At present we are taking part in various forums in CIS countries and conducting exhibitions, networking and touring trade delegations to explore the business opportunities and thereby improving our pharmaceutical and herbal exports to these countries, Among the CIS nations, Iran's pharmaceutical exports have been spread across Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan and Ukraine. Relations between Islamic Republic of Iran and the CIS nations have remained close and cordial since the Soviet era. However, bilateral trade and commercial relations have not grown commensurately with these newly formed countries. At present CIS constitutes only 1.2 per cent share in Iran's total exports. The main reason for this can be attributed to factors Language barrier inadequate transport facility and lack of information about business opportunities. Among the major trading partners, Russia, Ukraine, Kazakhstan, Uzbekistan, Kyrgyzstan and Belarus constitute more than 90 per cent of Iran's total bilateral trade with the CIS countries [1-3].

Growth prospects in CIS region

It is estimated that pharmaceutical sector in Russia and other CIS nations will have a double digit growth of around 10 to 11 per cent during the year 2012-2017. At present there is no national drug provision insurance system in Russia and CIS countries. This means that 60-70 per cent of all pharmaceutical sales are paid out of the Individual pockets. Large, locally-owned pharmacy chains account for most of the market, but there are still a substantial number of small, independent pharmacies, particularly in the small and medium-sized cities. A national insurance scheme is under development. The hospital drug provision system, meanwhile, is more advanced and will continue to develop in the future. A key factor for pharmaceutical companies to succeed in CIS region would be to balance their portfolio of branded generics, branded ethical products and over-the-counter (OTC) drugs that can be sold primarily at the retail level. A solid pipeline of innovative

products aimed at the developing reimbursement and insurance schemes is also critical.. In order to achieve future growth within these markets, Iran needs to explore its opportunities not only the low cost quality generics portfolio but also move in with innovative drugs. [4]

Aim

1. To examine the regulatory frameworks between CIS countries and Islamic Republic of Iran which affect the evaluation period required for drugs approval.
2. As the first study to examine the drug regulations in CIS countries, the regulatory barriers for drug Dossier submission will be explored and whether the regulatory initiatives from the abovementioned countries may result in an improvement in the overall drug regulation system Islamic Republic of Iran.

Material and Methods

In this research, we do not need materials or equipment that influences the quality of the results. It is not like a laboratory procedure and does not carry out an analysis through a device or a reagent and certain materials. Our research methodology is a data gathering method from valid sources.

This dissertation is a literature review and it will employ concentration in the drug regulation systems in CIS region and Islamic Republic of Iran with varying levels of pharmaceutical regulation capacities. Search engines including Google, Medline, Pub Med (database up to 2017) with key words search of "Department of Health (DoH), Food and Drug Administration (FDA), European Union (EU), I- FDA, Health Sciences Authority, evaluation routes, drug registration requirement, review timeline, Centre for Drug Evaluation, Pharmaceutical Evaluation Reports, risk management systems, pharmacovigilance, drug legislation".

Findings

Although there is a continuous process of harmonization taking place all around the world, still we see a huge challenge, which is yet to be overcome by the Pharmaceutical industry in case of generic drug development and filing. This is due to the heterogeneity in the regulatory landscape of the various countries. Therefore, to meet these challenges, a lot of strategic planning is required before the development of any generic drug product In the emerging markets like CIS countries like Russia, Ukraine and Kazakhstan the registration process is different from other countries. In these countries for generic drug application the bio-stability studies are conducted in their own population only In the emerging markets the common technical document is compared between the CIS countries. The registration process for the generic product is mentioned and compared The regulatory process for the CIS countries is different from the other countries, different stability studies are conducted for different countries.

Table 1. Data requirements between IRAN and CIS

egistration Requirements	IRAN	CIS
Site registration	Yes	Yes
Plant GMP approval	Accepts WHO/EU/PICs approval for FP site.	Audit by CIS member countries of FP site
Stability Zone	Zones I and II	Zones I and II
Stability requirements	25.0± 2.0C 60% ± 5% RH	25.0± 2.0C 60% ± 5% RH
No. of submission Batches	3 primary batches, out of which min 2 are Pilot scale	3 primary batches, out of which min 2 are Pilot scale
Stability data	12 months	12 months
Stability guidelines reference	FDA/WHO/EU/PICs	ICH
BE Study (for Generic)	BE studies are based on the BCS system and are based on the FDA guidance	Reference drug in any Country where BE to be done locally. PE to be done against local reference product in some countries.
Dossier Format	CTD	Country specific (resemble CTD) /non-CTD

egistration Requirements	IRAN	CIS
Site registration	Yes	Yes
Registration time	6-12 month	6-24 months Russia 18 months Belarus-180 working days

CTD is used for Drug products for human use, Biotechnological products, Herbal products and drug filing. CTD is mainly consists of five modules. Ministry of health in Some CIS Countries have also decided to adopt CTD format for technical requirements for registration of pharmaceutical products for human use. In Iran, the requirements for Registration are based on CTD . Implementation of CTD is expected to significantly reduce time and resources needed by industry to compile applications for global registration. Examination of administrative information and prescribing drugs among CIS countries table 2.

Table 2. Comparative Studies of Administrative Requirements for the Registration of CIS Countries.

	Administrative Documents	Russian Federation	Ukraine	Kazakhstan	Armenia	Azerbaijan	Belarus	Georgia	Kyrgyzstan	Moldova	Tajikistan	Turkmenistan	Uzbekistan
1	Application form	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2	Cover letter	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3	CPP (Certificate of Pharmaceutical Product)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4	Certificate of GMP issued by the authorized body in the country of origin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5	API - GMP certificate	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6	Registration status in other countries	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7	Instructions for medical use of specialists and patients	✓	✓	✓									
8	Qualitative and Quantitative composition of the medicinal product	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9	Art works 1.Carton	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	9.2.Label or Foil	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	9.3.Leaflet	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10	CV of the person responsible for pharmacovigilance	✓	✓	✓	✓	✓				✓			
11	Copies of trademark protection, registered brand names, patents	✓	✓	✓									
12	Guarantee letter that intellectual rights of the third party are not infringed	✓	✓	✓									
13	Guarantee letter that pharmacological vigilance system established and maintained	✓	✓	✓									
14	Guarantee letter in a free form from manufacturer of active substance to inform FP manufacturer	✓	✓	✓									

	Administrative Documents	Russian Federation	Ukraine	Kazakhstan	Armenia	Azerbaijan	Belarus	Georgia	Kyrgyzstan	Moldova	Tajikistan	Turkmenistan	Uzbekistan
15	Certificate of analysis for three manufacturing batches for finished product	✓	✓		✓	✓						✓	✓
16	Summary of product characteristics, labelling and package leaflets/insert	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17	Expert reports on chemical, pharmaceutical, biological, toxicological and clinical documentation	✓	✓	✓									
18	Specific requirements for different types of applications	✓	✓	✓						✓			
19	Information on bibliographic applications in accordance with Article 4.8 (ii) Directives 65/65/EEC	✓	✓	✓						✓			
20	Information abbreviated applications in accordance with Article 4.8 (iii) Directives 65/65/EEC	✓	✓	✓						✓			
21	Assessment of potential hazard to the environment	✓	✓	✓						✓			
22	Medicinal products containing or derived from genetically modified organisms	✓	✓	✓						✓			
23	A detailed description of pharmacovigilance and risk management systems.	✓	✓	✓	✓	✓				✓			
24	Manufacturing facility audit	✓	✓	✓						✓			

Regulatory Challenges in CIS

- Powerful lobby in favor of local manufacturer
- Unclear regulatory guidelines pertaining to new regulation
- Pre-Clinical and Clinical data requirements for Generics
- Delay in CT protocol approval & CT study performance
- Overall slow MA process/ Increased registration timeline
- Russian Government has approved the concept to Develop Russian Pharmaceutical Industry by 2020. It means, more stringent regulations for imported products
- Preference to domestic generic products
- Local manufacturing in Russia has increased due to discriminatory policy between Locally manufactured and imported pharmaceuticals
- Compliance with approved ND

- Post registration amendment –submission and approval pathway unclear
- Compliance with EU Norms (BE and other data)
- CTD documents
- GMP inspection
- Labeling in Ukrainian /Russian
- Each batch has to pass at laboratory
- Lengthy Drug Registration
- Weak IP laws
- GMP Compliance
- Specification compliance with State Pharmacopoeia (prepared based on EP)

Result and Discussion

A total of 112 patients, 56 each in group A and B, enrolled in the study. Other comorbidities observed were With an in-depth evaluation of the CIS Countries' guideline and supporting document required for new drug submission, it is highly recommended that necessary documents at new drug submission (NDA) should be created to facilitate the new drugs approval process.

The regulatory frameworks between all studied countries vary significantly in which implementation of initiatives (e.g. multiple evaluation routes, in-house evaluation system) from individual country affects the standards of new drugs approval and the evaluation timeline required to grant approvals.

process of tapping the markets in other CIS countries.

- Kazakhstan has steadily increased their imports of formulations from India.
- Russian regulatory agency is keep updating their regulatory standards at very fast.
- Kazakhstan is also becoming rigid and it is expecting USFDA level documentations for approvals.
- Countries like Ukraine have so far depended on Indian companies but it is also very rapidly moving towards regulated markets and is also part of PIC/S.

Conclusion

Maintain a balance between ensuring a product is safe, efficacious and of good quality and not delaying public access to the products by Clearly separate the tracks of registration submission into standard review and priority review and reduce the timelines for each step were announced. The Russian healthcare market is attracting increasing global interest – not least because its value is expected to triple within the next decade. However, market access across this vast region is complex and challenging – and has become even more so following the

It is estimated that pharmaceutical sector in Russia and other CIS nations will have a double-digit growth of around 10 to 11 per cent during the year 2012-2016—We are witnessing a robust growth in Russia and have considerable presence in the country. We are also in the

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