PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce & Industry, Govt. of India)

REGULATORY & MARKET PROFILE OF UKRAINE

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Eastern Europe bordering the black Sea.
2	Country	Ukraine
3	Capital	Kiev
4	Population	44,033,874 (July 2017 est.)
5	Population growth rate (%)	-0.4% (2017 est.)
6	GDP (purchasing power parity)	$ 352 billion (2016 est.)
7	GDP - real growth rate (%)	2.3% (2016 est.)
8	GDP - per capita (PPP)	$ 8,300 (2016 est.)
9	Epidemiology	Ischemic heart disease, Alzheimers disease, CVS disease & Cancers
10	Population below poverty line	24.1% (2010: No update available)
11	Age structure (%)	0-14 years: 15.76%
		15-24 years: 9.86%
		25-54 years: 44.29%
		55-65 years : 13.8%
		65 & above: 16.3%
Source: CIA World Fact Book updated till July 2017		

UKRAINE- PHARMA MARKET REPORT

Introduction

Opportunities for Pharma companies in Ukraine will be determined by the success of the government's healthcare reform agenda. Increasing public finds have been allocated toward medicine reimbursement and healthcare services, and the imminent implementation of the National Health System is likely boost access to services.

Ukraine's Pharma market in 2017 was of the size $ 2.54 billion is likely to grow to $ 2.86billion by 2018 with a growth of 12.5% after successive high rates of negative growths between 2014 & 2016. The market is forecasted to reach $ 3.94 billion by 2022. This is mainly due to Ukraine's economic issues and steep depreciation of its currency vis-vis USD.

Ukraine's disease burden is dominated by non-communicable diseases such as hypertension, diabetes and cancer, which are the leading causes of mortality and morbidity in the country. Relatively (in comparison to other EU countries) HIV is of higher incidence.

Latest Updates

- In June 2018, the first stage of healthcare reform began with a change in primary healthcare financing resulting in additional funding of UAH8.05bn (USD300mn) for H218.
- In July 2018, the Ministry of Health approved an expansion of the 'Available Drugs' medicine reimbursement program, with an average decrease in price of 6.5%.
- In July 2018, the Ministry of Health held a round table with the Association of International Pharmaceutical Manufacturers (AIPM) to discuss the main aspects of the medicine advertisement bill.

Strengths:

- Ageing population and epidemiological profile to sustain demand.
- Large absolute market (Consumption) and population size.
- Market relatively fragmented, offering low barriers to entry.
- Reliance of the market on out-of-pocket spending limits market opportunity largely to generics and over-the-counter medicines

Opportunities:

- The demand for low cost generic drugs should increase due to low spending capacity and pent-up demand for affordable treatments.
- There is a strong reform agenda and political backing for the need to introduce a national drug policy, specifically including medicine reimbursement.
- The introduction of a mandatory health insurance will increase access to medicines, boosting demand.
- WTO accession and new reform agenda has led to the removal of tariffs on pharmaceuticals, lessened regulatory load and created opportunities for importers.

Generic Market:

Generic medicine sales will be fastest subsector of Ukraine's pharmaceutical market due to the heavy preference for these lower-value drugs. The government's healthcare reforms, including the introduction of rudimentary medicine reimbursement, will ensure sustained robust growth within the subsector as access to medicines increases.

In the year 2017 the generic market was worth $ 1.29 billion accounting for approx. 51% of the total market. The market more or less got stabilised, having negatively grown by 36% in 2015, after negatively growing by 24% in 2014. In the year 2018 the generic market is expected to grow by 12.98% to reach $ 1.461 billion. Generic market is expected to touch $2.046 bn by 2022 with a Cagr of 9.6%.

Rapid expansion of the state healthcare budget and forecasted growth of the private healthcare market, both on account of wage hikes, medicine expenditure is expected to grow significantly in 2018. The introduction of basic medicine reimbursement (April 2017), covering generic medicines to treat cardiovascular diseases, Type II diabetes and asthma, will further boost the generic medicine market. These reforms, which are aimed at increasing the availability and affordability of medicines, will ensure the heavy preference for cheaper generic medicines remains in order to maximise the efficiency of expenditure.

Currently India’s generic companies are able to have a good share of the market and except for top Ukraine’s generic companies rest find it tough to compete with India products. Government is coming up with schemes to help local companies to upgrade themselves to meet the required EU standards of manufacturing as Ukraine is scheduled to Join PICS.

Large, multinational generic companies with a presence in Ukraine include Stada, Gedeon Richter, Egis, Teva, Krka and Novartis. Indian generic drugmakers are also present in the Ukrainian market. Ranbaxy gained additional exposure to the Ukrainian market through its acquisition of Romanian generic drugs maker Terapia in mid-2006. Indian firm Dr Reddy's has previously identified Ukraine, along with Kazakhstan, as one of its fastest growing markets in the Commonwealth of Independent States

Local companies such as Farmak and Darnitsa still account for around two-thirds of market by volume due to their low-cost, familiar brands. Most Ukrainian firms are based in the capital, Kiev, as well as some large regional cities such as Lviv, Kharkiv, Odessa and Donetsk.

Local companies tend to produce generic medicines, branded generic drugs and vitamins. At the same time, around 600 foreign companies are currently present in the market, the majority of which are marketing generic and OTC medicines.

Imports accounted for more than 54% of the market in value terms, highlighting the country's dependence on foreign pharmaceuticals. In 2017, imports had a growth of 4.25%.

R &D:

The Institute of Pharmacology and Toxicology is the leading drug-discovery facility in the country, and it has introduced about 13 new medications to the Ukrainian and CIS markets since the country's independence in 1992, including liposome-based cardiovascular and respiratory, anti-tumour, hepato-protecting, analgesic, anti-diabetic, anti-psoriasis, wound-healing and veterinary products. Most of these assets are controlled via the state-owned Ukrmedrpom holding company.

Regulatory:

Registration and testing is handled by the State Expert Centre (SEC), which was known as the State Pharmacological Centre (SPC) until October 2010, and the State Agency for Pharmaceuticals and Medical Supplies.

Since January 2011, Ukraine has been a party to the Pharmaceutical Inspection Cooperation Scheme (PIC/S). This both eases the registration process for foreign manufactured medicines and the acquisition of international certification for medicines produced at certified Ukrainian facilities.

Each batch of imported medicines must be submitted for clinical analysis and the country has at least 28 laboratories for quality control, which the government has said will be technologically upgraded by 2015.The laboratory will enable technicians to determine the quality of medicines on 11 parameters, compared with four elements earlier.

Recent Developments of Regulations:

Much like in the healthcare sphere, the pharmaceutical market in Ukraine is set to undergo significant - and much-needed - reform. Plans To Improve Medicine Access In October 2016, the Ministry of Health (MoH) outlined three key steps that it plans to take to improve the pharmaceutical environment for its population:

- Create and implement a national drugs policy to enable greater access to medicines; rationalise medicine funding; and ensure the quality of medicines within the market and the rational use of medicines.
- Create a comprehensive List of Essential Medicines.
- Establish reference prices for the medicines on the List of Essential Medicines, and the cost of these medicines using a reference-pricing mechanism.

The Ministry of Health approved a National List of Medicines in November 2016. This List contains a number of medicines to treat the most socially significant diseases. Among the 'Main List' are 21 international non-proprietary names (INNs) of medicines to treat cardiovascular disease, Type II diabetes and asthma. Cardiovascular diseases account for 65% of mortality, while Type II diabetes affect over 1 million patients and asthma affects over 200,000 patients. Since the October 2016 announcement, the government has worked to establish a medicine reimbursement system with pricing controls. These were adopted on April 1 2017

Further positive developments in the regulatory by including:

- Granting of licences for medicines that have been approved by the European Medicines Agency in the EU, FDA in the US and regulatory authorities in Australia, Switzerland, Japan and Canada.
- Removal of the re-registration process that required drugmakers to re-submit data to renew marketing licences.
- Declaration by Health Minister Oleg Musiy to rework existing legislation framework to resemble European Directive 2001/83/EC.

Statistics:

India's Exports:

India's Pharmaceutical exports to UKRAINE $ Million						
Category	**2015-16**	**2016-17**	**2017-18**	**GR%**	**contbn%**	**Contbn to Region**
Bulk drugs and drug Intermediates	1.71	2.01	3.43	70.44	3.57	5.23
Drug Formulations and Biologicals	64.52	75.09	85.25	13.54	88.84	13.75
Ayush	2.16	2.08	2.55	22.87	2.66	12.53
Herbal Products	0.08	0.10	0.14	40.05	0.14	12.74
Surgicals	1.07	1.80	2.77	54.28	2.89	24.67
Vaccines	0.00	2.84	1.82	-35.84	1.90	12.18
Total	69.53	83.91	95.96	14.36	100.00	13.09

Ukraine's market as such has grown negatively slightly in 2016 due to devaluation of its Currency vis-à-vis USD. Regulatory restrictions of the country like not renewing the market authorisations which expired and were not approved by agencies like USFDA, EU, EMA, TCG Aaustralia etc as Ukraine has become a member of PICS and harmonising its regulation with EU contributed to some of the barriers for India exporters.

During 2017 India's exports grew slightly faster than Ukraine's local generic market.

Imports of Ukraine

Ukraine's Top ten formulation Importing partners $ Million						
Rank	**Country**	**2015**	**2016**	**2017**	**Gr%**	**Share%**
1	Germany	251.83	310.97	338.12	8.73	18.92
2	France	106.07	129.43	139.25	7.59	7.79
3	India	109.55	134.35	134.47	0.09	7.52
4	USA	76.98	93.70	105.90	13.02	5.92
5	Italy	67.04	90.85	103.87	14.33	5.81
6	Austria	74.59	59.19	80.99	36.82	4.53

7	United Kingdom	74.50	65.91	80.66	22.39	4.51
8	Hungary	58.36	62.03	71.42	15.14	4.00
9	Slovenia	58.07	50.12	58.71	17.14	3.28
10	Switzerland	45.61	70.33	57.21	-18.65	3.20
	World	1366.08	1625.10	1787.36	9.98	100.00
Source:UN comtrade						

REGISTRATION AND LICENSING REQUIREMENTS

- Regulatory Authority : **STATE SERVICE OF UKRAINE ON MEDICINAL PRODUCTS AND DRUG CONTROL& STATE EXPERT CENTER OF THE MINISTRY OF HEALTH OF UKRAINE**
- Website of regulatory Authority : http://www.dec.gov.ua/index.php/ua/ www.diklz.gov.ua/control/main/en/index
-
- Fees for Drug Registration : 7500 USD
- Normal time taken for registration : 12-18Months
- Registration Requirement [Dossier Format] : CTD
- Whether plant inspection is mandatory : Yes, if no PIC/S GMP certification available
- Requirement of Local agent/ Subsidiary : Local Agent is sufficient
- Registration Validity : 05 Yrs

Regulation and governance of pharmaceuticals:

The main regulatory functions in pharmaceuticals are currently split between two bodies:

(a) The State Expert Centre (until 27 September 2010 called the State Pharmacological Centre) and

(b) The State Administration of Ukraine on Medicinal Products (SAUMP), both of which are under the Ministry of Health.

The State Expert Centre is a specialized organization which covers:

- The registration and quality control of pharmaceutical products; preclinical, clinical and postclinical research;
- Monitoring adverse drug reactions (although adverse drug reaction reporting by physicians is very low);
- Developing the list of pharmaceuticals that may be bought over the counter and submitting it for approval to the Ministry of Health;
- Authorizing the import and use of unregistered pharmaceuticals; and
- Advising on the content of the National Drug Formulary.
- Moreover, the Centre has the task of standardizing medical services, including pharmaceutical services.

The State Expert Centre is completely funded through fees and charges for services, with no contribution from the state budget.

According to Article 9 of the Law on medicines, drugs are permitted for use in Ukraine after registration by the state (No. 123/96BP, 4 April 1996). To ensure the quality and safety of pharmaceuticals, the registration process requires the presentation of preclinical examinations and clinical trial results. From 2008, the registration process for generics also requires proof of their bioequivalence to their brand-name counterpart.

State registration of medicinal products is carried out by the State Expert Centre on the basis of a submitted application, which, since 2014, has included a good manufacturing practice (GMP) certificate along with a plethora of other specific information.

Upon registration, the applicant receives a certificate that states the term for which the drug is licensed for use in Ukraine.

Intellectual property Protection:

Ukrainian law provides for intellectual property protection for the developers of medicines. A state registration applicant must provide a patent copy or a licence and letter indicating that the patentee's rights are not violated by registration.

Moreover, the Law on pharmaceuticals , which was passed when Ukraine joined the WTO (with several amendments in 2006–2007), prohibits the registration of generics using registration data from another pharmaceutical for a period of five years, regardless of the lifetime of the Page 5/8 Ukraine - Regulation patent.

In linking the registration of generics to the expiration of a patent and giving a five-year exclusive right to the original brand name, Ukraine undertook commitments that are quite stringent in comparison with the WTO and Trade-Related Aspects of Intellectual Property Rights (TRIPS) requirements, and contradictory to the Bolar Provision, which allows manufacturers of generics to submit their products for regulatory approval before the expiry of a patented intervention.

State Administration of Ukraine on Medicinal Products (SAUMP):

The SAUMP (previously the State Pharmaceuticals Quality Control Inspectorate) is responsible for quality control once drugs are on the market and it has a network of 27 laboratories across the country to facilitate this; all have completed sector certification and comply with ISO 17025. The SAUMP Central Laboratory has completed the WHO Prequalification Programme, is accredited with the European Directorate for the Quality of Medicines (EDQM) and included in the Europe-wide General European OMCL (official medicines control laboratories) Network (GEON). Moreover, since 2013, Ukraine has been party to the European Pharmacopoeia (as per the Law on the ratification of the Convention on the development of a European Pharmacopoeia as amended by its protocol, No. 5441-VI, 16 October 2012) and, since 2011, SAUMP has been a member of both the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). GMP inspection, as well as the inspection of pharmacies and distributors, is also the responsibility of SAUMP and, as of 2009, the licensing of production, distribution and retail sales has also fallen under its remit. There is no difference in the legal provisions for the licensing of public and private pharmacies (WHO, 2013). Wholesalers and distributors are required to comply with good distributing practices. Since 15 February 2013, it has been illegal to put on sale any pharmaceutical product that has not been manufactured in compliance with GMP.

Ukraine Simplifies the Procedure for Registration of Medicinal Products

On 19 June 2016 the amendments to the Law of Ukraine "On Medicinal Products" became effective. These amendments, inter alia, simplify the procedure for state registration of medicinal products, which were previously registered by competent authority of a country with a stringent regulatory policy ("Country(ies)") for use within such a Country ("Medicine(s)").

Under the Law, the Countries include the United States, Switzerland, Japan, Australia, Canada, as well as the EU member states, provided, however, that the Medicines were registered by the EU competent authority under the centralized procedure.

The amendments are intended to simplify the procedure for state registration of the Medicines and, among other things, provide for the following:

- Fewer documents needed to register the Medicines (the list of required documents no longer includes materials of preclinical studies and clinical trials, as well as certain other documents);
- A decision on the state registration to be made within up to seven business days (instead of one month according to the previous procedure). The amendments also envisage that the master file of a Medicine, which was filed with the regulatory authority that registered the Medicine, shall not be subject to examination. Moreover, the amendments have shortened the term for review of the materials submitted to register a Medicine to ten business days (previously, the examination of the registration materials was to be completed within twenty business days);
- Possibility to file, instead of a copy of GMP compliance certificate or opinion, a manufacturer's written undertaking to produce the Medicines for Ukraine on the same manufacturing facilities that are intended for manufacturing for the Country's domestic market.

Furthermore, the amendments provide for the list of grounds to deny registration of a Medicine. Such grounds include the following: incomplete set of documents filed for the state registration of a

Medicine; unreliable or incomplete information in the filed documents; a discrepancy in the name of manufacturer, its address or the address of its manufacturing facilities specified in the application for state registration of a Medicine, as compared to the information, based on which the competent authority of a Country registered the Medicine.

Also, some of the amendments relate to the procedure for state registration of all other medicinal products. Specifically, the amendments provide for:

- The term for making a decision on state registration of a medicinal product reduced to ten business days (instead of one month);
- The information on applications for state registration of medicinal products, status of review of the filings and the approved decisions to be made public online;
- The State Register of Medicinal Products to include information on prior registration, re-registration, and cancellation of registration of a medicinal product, as well as its registration by the competent authority of a Country for use with the Country's territory.

State registration of medicines and active pharmaceutical ingredients

In order to import and market medicinal products in Ukraine, it is required to conduct state registration of the medicinal products, as well as to meet all the necessary quality requirements.

The Ukrainian legislation on registration and marketing of the medicinal products has been harmonized with the EU legislation since 2005. The general requirements for documentation and expert evaluation process are fairly close to the European directives, although there are many national features which significantly affect all regulatory processes.

Registration of a medicinal product in the EU indicates the compliance with the general requirements for the registration dossier but does not guarantee a quick and simple registration procedure in Ukraine.

Medicinal products include the following types:

- Finished medicinal products;
- Immunobiological products;
- In-bulk products;
- Active pharmaceutical ingredients (APIs).

The legislation on registration of the medicinal products is very closely intertwined with the requirements for safety management (pharmacovigilance) and quality management of the medicinal products. Therefore, in order to obtain and maintain the Registration Certificate for the finished medicinal product, the Applicant has to:

- Conduct state registration by submitting the application to the Ministry of Health of Ukraine and by expert evaluation of the documents of the registration dossier in the SEC;

- Establish and maintain the pharmacovigilance system in Ukraine;

- Confirm or certify the manufacturing compliance with the GMP requirements;

- Register the layouts (artworks) of the primary and secondary packaging in the Unified Automated Information System (UAIS) of the State Service of Ukraine on Medicines and Drugs Control (SMDC).

As for the active substances (APIs), neither the recognition/certification of GMP compliance nor the layouts registration is required.

The Applicant (Marketing Authorization Holder) of the Registration Certificate:

Both a resident and a non-resident of Ukraine (for example, the manufacturer himself) may act as an Marketing Authorization Holder (MAH) for registration. In accordance with the law it is the MAH who has responsibility for the quality, safety and efficacy of the medicinal product during marketing within the territory of Ukraine.

If the MAH and the manufacturer are different entities, it is necessary to include the documentation clarifying association between them in the registration materials.

A non-resident MAH doesn't have to establish a local representative office or another corporate entity within the territory of Ukraine, however, the MAH is obliged to:

- Establish and maintain the pharmacovigilance system in Ukraine, including the necessity to appoint the local contact person (LCP) responsible for pharmacovigilance in Ukraine;

- Appoint the person in Ukraine, who will be responsible for the medicinal product quality.

Fulfilment of MAH's commitments with regard to establishment and maintenance of the quality and safety management system may be partially delegated to a third party under a delegation agreement.

In order to represent his interests, the MAH may issue a Power of Attorney, which describes authorized representative's authority with regard to registration, quality and safety management. The Power of Attorney must be drawn up according to the set of national requirements and legalized appropriately.

General requirements for the registration materials:

The documentation for the standard new registration procedure consists of the following parts:

- Application for registration, completed according to the national application form;
- Registration form (legal and administrative documentation that accompanies the Application);
- Registration dossier in CTD format, consisting of 5 Modules (Modules 2-5 meet the ICH CTD requirements);

- Translation of registration dossier parts into Ukrainian or Russian;
- Specific national documents, namely:

  - QCMs are the quality control methods for the medicinal product that include the medicinal product composition, release and storage specifications, detailed method descriptions, data on the manufacturers, packaging description, shelf-life and storage conditions.
  - Instruction for medical use is the information on use of the medicinal product, which is most often supplied as a leaflet.
  - Layout and description of the packaging is the description of the information on the primary and secondary packaging of the medicinal product.

There is a large number of specific requirements for the registration documents, the most important of which are:

- All the documents should be submitted in a paper form (Application, registration form, registration dossier, specific national documents);
- The registration dossier has strict requirements for execution, namely: the number of pages in the folder, information on the cover, page numbering and table of contents;
- The registration dossier is submitted in several non-identical copies;
- The communication happens both by making a personal appointment, and via correspondence;
- Correspondence during expert evaluation of registration materials is carried out only in paper form, as well as any additional materials (responses to observations);
- Some documents (for example, the instruction for medical use) may be corrected during the process of expert evaluation for several dozen times.

Requirements for packaging and Instruction for medical use:

Labeling text shall be approved during state registration of the medicinal product and is the integral part of the Registration Certificate. Any amendments are allowed only after submitting the appropriate Application, expert evaluation and approval by the MOH of Ukraine.

During state registration the layouts (graphic images) are not subject to approval; their description and text should be only agreed. Packaging material labeling shall be done in Ukrainian, any other languages (for example, Russian, English) may be also present providing the identity to the Ukrainian text.

Subsequently the graphic layouts of the packaging are created based on the approved text and are submitted under special procedure for registration in the Unified Automated Information System (UAIS) of SMDC.

During incoming quality control (at the import stage) the packaging of the medicinal product undergoes very strict assessment of compliance with the layouts registered in UAIS. Even the smallest deviations (font type, text flow, size and position of elements, differences in color gamma, presence of technical symbols etc.) lead to observations, delay in issuing the statement regarding quality, and necessity of corrective actions.

Information on the secondary packaging of the medicinal product must contain information in Braille in Ukrainian (with the exception of medicines that are only used by appropriate specialists: orphan preparations, parenteral preparations, radiopharmaceuticals, specific immunobiological agents). For these groups of medicinal products Braille marking remains at the discretion of the manufacturer.

Instruction for medical use shall be approved during sate registration of the medicinal product and is the integral part of the Registration Certificate. Any amendments to the Instruction are allowed only after submitting the appropriate Application, expert evaluation and approval by the MOH of Ukraine.

Instruction for medical use shall be approved in Ukrainian, any other languages (for example, Russian, English) may be also present providing the identity to the Ukrainian text.

The basis for writing the Instruction for medical use of the medicinal product registered in the EU is the SmPC (Summary of product characteristics). For generic (equivalent) drugs the text of the Instruction should match the text of the originator.

The language of the documentation and correspondence:

Ukrainian language is the only state language in Ukraine.

All official correspondence with competent authorities has to be performed using the state language only.

The Application form, registration form and covering letters have to be submitted only in Ukrainian. Also in Ukrainian all the specific national documents have to be submitted, namely:

- Quality Control Methods (QCM);
- Instruction for medical use;
- text of the packaging material labeling.

The Registration dossier is submitted in Ukrainian, or in Russian, or in English. If dossier is submitted in Russian or in English, the following sections of the dossier should be submitted in Ukrainian:

- **Module 1:** fully translated into Ukrainian;
- **Module 2:** experts' reports on quality, non-clinical (2.4) and clinical (2.5) information is recommended (but not obligatory) to translate into Ukrainian;
- **Module 3:** Section 3.3.P. should be partially translated;
- **Module 4:** usually is not translated;
- **Module 5:** statement on bioequivalence may be translated, other sections usually are not translated.

Establishment of new registration

Depending on the type of the medicinal product, its indications, market status and other characteristics, different types of Applications and different time terms of expert evaluation are applied. It should be reminded that Ukraine undergoes the harmonization procedure with the EU, but the country has its own independent legislation and expert evaluation procedure.

The registration process begins from the moment when the Application is submitted to the so-called "single point of contact" of the MOH and ends when the appropriate Order is signed by the MOH and the paper original of the Registration Certificate is issued.

Since the moment when the Application is submitted, there is a strict timeframe, which must be adhered to by both the competent authorities and the Applicant. If the Applicant does not perform a specific action or does not submit all the necessary documents, or the documents are filled in incorrectly, then the registration procedure may be canceled and all paid amounts are not refunded.

In addition to carrying out registration procedure itself, it is also necessary to meet a number of requirements for safety management (pharmacovigilance) and quality management of medicinal products, namely:

- Prior to registration (the information must be indicated in the Application):
  - To assign a contact person responsible for pharmacovigilance in Ukraine, to create and maintain the pharmacovigilance system;
  - To assign a contact person responsible for the medicinal product quality in Ukraine.

- In the process of registration:
  - To obtain the Conclusion or the Certificate of Compliance of the medicinal product manufacturing conditions with the GMP requirements.

- After registration:
  - To register the layouts of the primary and secondary packaging in the Unified Automated Information System (UAIS) of the State Service of Ukraine on Medicines and Drugs Control (hereinafter referred to as SMDC).

Therefore, it is very important to assess the objective situation and manufacturer's capabilities before the start of registration, to plan in advance the chronological order of the necessary actions and the persons involved.

Stages and timelines of new registration:

Registration starts from the moment of submission of the Application to the MOH. Registration procedure may be divided into the following main stages:

I. Preliminary stage.

1. Preliminary consultation – if needed.
2. Submitting the Power of Attorney to the SEC and signing the Agreement for expert evaluation.

II. Submission of the Application and payment.

3. Submitting the Application for registration to the MOH.
4. Submitting the Registration form (Addendum to the Application) to the SEC.

5. Obtaining the positive opinion (or observations) in regard to the Application and Registration form.
6. Obtaining the invoices for payments of government levy and expert evaluation cost.
7. Carrying out payments, obtaining the payments confirmations and submitting to the SEC.

III. Primary expert evaluation.

8. Checking the completeness of the registration dossier materials according to the Application type.
9. Obtaining observations, or submitting the dossier with the registration materials for expert evaluation.

IV. Specialized expert evaluation.

10. Transfer of the dossier to expert commissions, the number of these commissions depends on the Application type:

- Department of expert evaluation activities;
- Department of expert evaluation of instructions and nomenclature;
- Department of expert evaluation of vaccines and immunobiological preparations;
- Department of expert evaluation of materials on bioequivalence;
- Department of expert evaluation of materials on clinical and preclinical trials;
- Department of pharmacovigilance.

11. Obtaining observations, in-person communication with the corresponding expert on the substance of the observations (if needed).
12. Responding to the observations, editing the Instruction for medical use of the medicinal product.
13. Carrying out quality control of samples of the medicinal product in the authorized laboratory.
14. Making the decision (recommendation) in regard to the registration of the medicinal product in Ukraine at the SEC meeting.
15. Verifying and reconciling a draft of the Registration Certificate, QCM, Instruction for medical use of the medicinal product and the text of the packaging material labeling.
16. Transfer of the documentation set to the MOH.

V. Final stage:

17. Obtaining the documentation by the Ministry of Health and including into a draft of the Order on the registration.
18. Signing the Order on the registration of the medicinal product.
19. Including the medicinal product into the State Registry of Medicinal Products of Ukraine.
20. Issuing the original of the Registration Certificate and its Addenda.

NB! It is mandatory to obtain a Conclusion or a Certificate of Compliance of the medicinal product manufacturing conditions with the GMP requirements during registration of the medicinal product. This procedure runs parallel to registration procedure and is performed by the SMDC.

Manufacturers having PIC/S GMP Certificate undergo "simplified" procedure of the Certificate recognition based on specialized expert evaluation of documents. For all other manufacturers the inspection of the production site is required.

During registration process it is necessary to make several payments to the accounts of the public authorities, including:

- Payment of the government levy for registration of the medicinal product to the account of the State Treasury of Ukraine;
- Payment of the costs of expert evaluation to the account of the SEC;
- (if necessary) payment of the costs of the laboratory quality control of the medicinal product samples to the account of the authorized laboratory.

Recognition or certification of GMP compliance.

During registration of medicinal products in Ukraine the Applicant has to submit the Certificate or the Conclusion regarding confirmation of manufacturing compliance with the GMP guidelines.

The process of obtaining the Conclusion regarding confirmation of manufacturing compliance with the GMP guidelines is performed in form of expert evaluation of the documentation and doesn't require inspections of the production site. Such procedure is also called "Recognition the GMP Certificate".

Recognition is acceptable only for the manufacturers that already have the GMP Certificate issued by competent authorities of a member state of PIC/S (https://www.picscheme.org/en/members).

Certificates issued by WHO or by other authorities and organizations that are non-members of PIC/S cannot be objects of recognition.

Recognition is not an unconditional procedure and requires preparation and submission of a set of documents, passing through procedure of expert evaluation and obtaining the Decision. The Decision is issued for a period of validity of the Certificate that underwent recognition.

SMDC performs the certification procedure regarding compliance with the GMP guidelines. Such procedure presumes preparation and submission of a set of documents, signing an agreement and making the payment for expert evaluation by the competent authorities, conducting inspections (performed usually by two or three inspectors), expert's report preparation and correction of the observations, issuing the Certificate of compliance with the GMP guidelines.

As Ukraine since 2011 is a member state of PIC/S, locally issued GMP Certificate can be recognized by other members of PIC/S according to their legislative requirements.

Time terms of expert evaluation of the registration dossier of the medicinal product, depending on the type of Applications:

- 210 working days: the medicinal product submitted for registration in accordance with the full (autonomous) dossier; medicinal immunobiological products; biosimilars;

- 90 working days: for other types of medicinal products (Applications for generics, well-known medical use and a number of other types);

- 45 working days: for orphan products and medicinal products for treatment of socially dangerous diseases (HIV, viral hepatitis, tuberculosis, oncological diseases);

- 10 working days: for medicinal products registered by competent authorities of the United States of America, Switzerland, Japan, Australia, Canada and medicinal products registered via the centralized procedure by the European Union competent authority;

- 5 working days: for medicinal products, which are supposed to be purchased by specialized international organizations.

Registration Certificate:

After the first registration, the Registration Certificate is issued for a period of 5 years. After the re-registration, the Certificate of unlimited duration is issued (unless the MOH decides to conduct an additional re-registration after 5 years for justified reasons related to pharmacovigilance).

The Registration Certificate consists of:

- The Certificate itself issued on the special form with a hologram;
- The Addendum to the Certificate: QCM (quality control methods for the medicinal product);
- The Addendum to the Certificate: the Instruction on medical use of the medicinal product;
- The Addendum to the Certificate: packaging materials labeling.

All the changes (of any type) are also the integral parts of the Registration Certificate.

Maintenance of the Certificate and its amendments:

There are no monthly or annual payments associated with maintaining registration in Ukraine. At the same time, the Applicant must maintain the pharmacovigilance system and quality management system in Ukraine. Therefore, the Applicant must ensure:

- The constant presence of the person responsible for pharmacovigilance;
- The constant presence of the person responsible for the quality, safety, and efficacy.

The fulfillment of Applicant's obligations with regard to maintaining quality and safety may be transferred under a Contract to a third party

All changes to the Registration Certificate are made by submitting the Application and the set of documents, payment of the expert evaluation costs, approval by the Order of the Ministry of Health of Ukraine.

The Applicant must submit the Application for safety changes to the Instruction on medical use of the medicinal product no later than 60 calendar days from the date of receiving the information on the need to make such changes.

The types of changes are similar to the types of changes in the EU:

- Correction of a technical error: correction of inconsistencies appeared during registration, re-registration or amendment procedure;

- New Applicant (Owner) of the Registration Certificate;

- Type IA: minor changes that do not have a significant impact on the quality, safety, and efficacy;

- Type IA_{IN}: type IA changes with immediate notification;

- Type IB: minor changes which are neither of type IA nor of type II;

- Type II: changes that affect the quality, safety, and efficacy;

- Changes which lead to new registration.

The term "notification" in Ukraine differs from the one in the European practice: in fact, "notification" changes do not imply any mistakes or questions from the competent authorities, as long as issuing an observation means a refusal to conduct an expert evaluation.

Re-registration:

Not later than 90 days before the end of registration, the Application for re-registration may be submitted (**the recommended deadline is 10-11 months**). After the re-registration, the Registration Certificate of unlimited duration is issued (unless the MOH decides to conduct an additional re-registration after 5 years for valid reasons related to pharmacovigilance).

Re-registration begins from the moment of submitting the Application to the Ministry of Health of Ukraine, ends with the approval of re-registration by the Order of the Ministry of Health of Ukraine and the issue of the new Registration Certificate. At the same time, the Registration Certificate number remains the same.

For re-registration significantly fewer documents are required, compared to new registration. During re-registration the main focus is on the management of the medicinal product safety, that is, on the documents of the pharmacovigilance system and the Instruction for medical use of the medicinal product.

Before submitting the Application for re-registration, it is necessary to submit separate Applications for all of the changes. These submitted Applications (changes and re-registration) are examined in parallel, and independently of each other.

Import licensing

Since 1 March 2013 it became mandatory to obtain an Import License for all importing companies of medicinal products. These requirements are set by the Law of Ukraine "On Amending Certain Laws of Ukraine on Import Licensing of Medicinal Products and the Definition of an Active Pharmaceutical Ingredient" dated 4 July 2012. The import licensing terms are approved by Order of the Ministry of Health of Ukraine No.143 dated 20 February 2013 "On Approval of the Licensing Terms for the Economic Activity of Medicinal Products Importation", and the procedure for conducting the inspection before issuing the License is approved by Order of the Ministry of Health of Ukraine No. 168 dated 27 February 2013.

In March-December 2013 all importers wishing to receive Import Licenses were able to receive them under the declarative principle, on the basis of the submitted Application and the List of the medicinal products planned to be imported, which subsequently became the Attachment to the License. As promised, the issuance of Licenses was conducted under the "express method" without any additional questions concerning the documentation and without any inspection of the warehouse itself.

Validity term of the License for import of medicinal products is unlimited, and it allows to import into Ukraine only the medicinal products listed by the importer. In order to obtain the License to import medicinal products it is necessary to have the License for wholesale and retail trade of medicinal products. When marketing narcotic substances or precursors it is required to have the corresponding License.

Since December 1, 2013 the State Administration of Ukraine on Medicinal Products started to conduct scheduled and unscheduled inspections of subjects to check the fulfillment of the licensing requirements. The first stage of inspections involved the fulfillment of the licensing requirements for personnel, premises and equipment, compliance with the storage rules, quality control, complaints and recall handling, compliance with the rules for issuing the sales authorization, and the availability of importer's dossier.

Taking into consideration the long-running process of reorganization of the State Service of Ukraine on Medicines and significant shortage of personnel, not all importers were verified on a scheduled basis to date.

The Import License is issued on the basis of the submitted Application (Appendix 1) and the package of documents in a 10-day period (without inspecting importer's warehouse). The cost of issuing the License is 17.00 UAH (approximately 1 (one) USD).

Reissuance of the Import License for medicinal products occurs in the following cases:

- change of the name of the legal importer;

- change of location of the legal importer.

In order to reissue the License it is necessary to submit the Application (Appendix 6) for reissuance within 10 days. The cost of issuance is 85.00 UAH (approximately 4 USD). The previous license is to be canceled.

Each branch of a legal importer of medicinal products must have a copy of the License and the Attachment. When a new branch is created it is necessary to obtain a License copy, which is issued on the basis of the Application (Appendix 5). The cost of issuance is 17.00 UAH (approximately 1 USD).

Amendments to the list of the medicinal products allowed for import, which are specified in the Attachment to the License, are made upon written request in free format by the licensee, with submission of the updated list.

Taxation:

The following VAT rates apply for medicinal products:

- **General case**: a preferential VAT rate of 7% for all registered medicinal products and APIs;
- **Exception 1**: VAT rate of 20% for unregistered medicinal products, or for medicinal products with the expired validity of the Registration Certificate;
- **Exception 2**: VAT rate of 0% for the supply of medicinal products for humanitarian assistance.

All medicinal products are imported with a custom duty of 0%.

Advertising and promotion:

It is allowed to advertise non-prescription (OTC) medicinal products only. Advertising the prescription medicinal products in non-specialized media is prohibited.

There are rigorous restrictions regarding the OTC medicinal products advertising, most of which are described in Article 21 of the Law of Ukraine "On Advertising", and there are also other legislative restrictions.

The promotion of prescription medicinal products is allowed in specialized publications intended for medical institutions and doctors, as well as for distribution at seminars, conferences, symposiums on medical topics.

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Details of importing country embassy in India: https://india.mfa.gov.ua/en

Contact details of Indian Embassy abroad: www.eoiukraine.gov.in/index.php

List of Local Pharma Associations:

Pharmaceutical Association –PHARMUKRAINE	farmukraine@ukr.net www.pharmukraine.org
Association of International pharmaceutical manufacturer (aipm Ukraine)	http://aipm.org.ua/en/