



Dear ladies and gentlemen!

Outsourcing of the registration services is a very interesting opportunity for manufacturers of the medicinal products, as for those who only taking course to Ukraine as well as for those who already established here a representative office.

Obtaining the marketing authorization for medicinal product in Ukraine – is the most complex and expensive part of market entry that requires much time, human resources and time to devote. If you have intentions to enter the market and open the representative office – the first several months you will have to pay fee for renting office and salaries to the staff before your registration managers will finish the procedure and allow the products to be released on the market. Else, if you already have specialists responsible for registration procedure but not so many products that staff is working on the 100% of their efficiency – we can allow you not to make such additional expenses. Registration certificate is valid for 5 years and one product require not more than 4-6 month to obtain state registration.

#### **Company profile: Patern Ltd**

Company foundation: 1998, reorganized twice at 2000 and 2005

Patern Ltd has successfully passed the ISO 9001:2008 audit of the Quality Management System by TÜV Rheinland Group, Germany.

Number of employees: 15 (six MD, two Ph.D., one MBA).

Turnover per year: 500 000 EURO

Average quantity of regulatory procedures per year: 142

Average quantity of registrations (including re-registration) of **medicinal products** per year: 62

Main customers from: Germany, Poland, Turkey, Hungary, Russia

#### **Businesses:**

##### *Regulatory affairs*

Countries: (CIS countries) Ukraine, Russia, Moldova, Belarus, Kazakhstan, Baltic states, etc.

Products: registration of medicinal products, substances, bio-active supplements, medical devices, cosmetics, GMP recognition procedure.

##### *Market studies*

Countries: Ukraine, Moldova, Russia, Baltic states.

Products: study of medicinal products market by molecule/group, advertising.

##### *Clinical and Preclinical Trials*

Countries: Ukraine.

Products: clinical trials phase I-IV, preclinical trials and consulting services.

##### *Optional services*

Countries: Ukraine.

Products: registration of the representative office, human resource.





**Results of 2008<sup>th</sup> - 2009<sup>th</sup> year:**

Registration (renewal, variations) of medicinal products: 82  
Registration (renewal, variations, in-registration clinical trials) of medical devices: 35  
Regulatory affairs on other products (BAS, substances): 17  
Clinical studies (registration of studies and phases I and II): 11  
Registration of the representative office: 1  
Marketing & advertising solutions: 13

**Our customers from:**

**Germany** - 46,67%  
**Poland** - 20,00%  
**Turkey** - 16,00%  
**Russian Federation** - 5,33%  
**Hungary** - 4,00%  
**Other** - 8,00%

**Procedure of registration of medicinal products in Ukraine**

Currently in Ukraine two types of the registration dossier can be submitted for registration – CTD (common technical documentation) and “simple” (local) format. Depending from the chosen structure of documentation the Application is being prepared: for CTD format it is a full Application on 15 sheets, for “simple” format – it is a “reduced” Application that consist from 3 pages.

Dossier must be submitted to the State Pharmacological Center of Ukraine in Russian, Ukrainian or English language. Some information must be submitted in Ukrainian independently of the language of other documentation: AND (analytical normative documentation – control methods of finished product), TND (technological normative documentation – validation and description of the manufacturing process), instruction and leaflet, expert reports upon non-clinical and clinical documentation (bibliography for generics).

At the basis on Power of Attorney issued to the name of Patern Ltd we sign the Contract with State Pharmacological Center of Ukraine (hereinafter – SPC) for expert evaluation of the dossier. After the Contract is signed – we can submit the Application.

After the Application was submitted – SPC issues the Invoices for (1) State fee to Treasury of Ukraine and (2) services of SPC for dossier evaluation.

Those Invoices are being sent via e-mail to Applicant (to you) for finance transfer. Original Invoices (hard copies) are being sent via world courier (DHL, TNT, FedEx etc.).





After the payment is done – the 3 copies of dossier can be submitted to the SPC. Every copy will be directed to corresponding profile commission for expert evaluation.

Also the Letter is being submitted to direct product for quality assurance of the control methods in the control-analytical laboratory. To the laboratory the project of AND is also being submitted for calculation of the quantity of samples (plus active substance and standards), required for analysis.

At the basis of the conclusion of the laboratory regarding the quantity of samples – the Letter for free import of unregistered samples approval is being prepared.

Applicant sends samples by any world courier to the address of Patern Ltd. We take care about delivery of samples to the laboratory (custom clearance is paid additional).

After the positive conclusion of three profile commissions and laboratory – product is included to the list of session of the SPC (session of SPC – every last Thursday of the month). If conclusion is negative, product could be directed to limited clinical trials or returned to applicant for modification of dossier.

During the next 20 days after the product was adopted for State registration in Ukraine at the session of SPC – the original registration certificate is issued. We send it via the world courier to the Applicant.

### **Description of the cooperation procedure**

First of all we require the sealing of the Confidential Agreement.

After the CA is signed – you send us dossiers for chosen products by any world courier. We receive the dossiers and perform the internal expertise of the documents. As a result of the procedure we send you the list of the missing documents, our comments regarding quality and quantity composition of the dossier etc. – the Protocol of the dossier internal expertise. Procedure of internal expertise is free.

Simultaneously with Protocol we send you the price offer.

If the suggested price is suitable for you – we start the registration process. If the price or other circumstances do not suit you – we send the dossier back.

After the Contract and Order(s) for registration of products are signed – we send you the Invoice for the first payment of the services of Patern Ltd – 20% of the total sum.





Some documents are directed for translation, specialists of the company prepare the Application, AND, TND, instruction and leaflet. Dossier is being combined in accordance with Ukrainian legislation. Package design is being adopted with Applicant. After the dossier is ready - 3 copies are prepared.

After the Application is being submitted – we receive the Invoices for the State fees and send them to you. Simultaneously with Invoices for the State fees – we also send you the Invoice for the second part of Patern Ltd service – 60% of the total sum.

We accompany the dossier after submission to the State Pharmacological Center. In the case of any questions or comments from State Authorities – we try to answer them by ourselves or request information from you.

We receive the approval for import of the samples, adopt the process with you, and perform delivery to the laboratory (custom clearance as additional service). Invoice for the services of laboratory will be delivered scanned via e-mail and original via world courier.

After the dossier was adopted by profile commissions and control methods were evaluated on samples – the product is included to the log of the nearest session of SPC.

Registration certificate will be sent by courier with the 3-rd invoices for the services of Patern Ltd – 20% from the total sum of the Contract.

### **Our service fee includes**

- Translation of the dossier (required parts) and notary translation of documents (Power of Attorney etc.);
- preparation of the Application, instruction, leaflet, AND, TND;
- preparation of the package design;
- combining of the dossier in accordance with Ukrainian legislation;
- copying of the dossier in 3 copies;
- submission of the Application to the SPC of Ukraine;
- submission of the dossier to the SPC of Ukraine;
- accompanying of the dossier in profile commissions, defending the interests of the Customer;
- receipt of the import approval and delivery of the samples to laboratory (custom clearance not included);
- all world courier expenses (DHL) from Patern Ltd. to you;
- lobbying of the interests and terms in State Authorities;
- all other expenses.

Actually, our fee defrays all expenses that are required for registration of the product excluding the State fees.





**Prices (approximate)**

Registration of the **original** product or **fixed combination** (active substance or combination has never been registered in Ukraine before)

	State fees	Patern Ltd fees
Registration of the original product	6755 EURO	app. 7000 EURO
Additional dosage/strength	+10%	+10%
Additional package (#10, #20 etc.).	+10%	+10%

State fees includes: payment to the State Treasury of Ukraine, services of the State Pharmacological Center of Ukraine, payment to the State laboratory for methods assurance.

Registration of the **generic** product (active substance is already present on the market)

	State fees	Patern Ltd fees
Registration of the generic product	5760 EURO	app. 6000 EURO
Additional dosage/strength	+10%	+10%
Additional package (#10, #20 etc.).	+10%	+10%

State fees includes: payment to the State Treasury of Ukraine, services of the State Pharmacological Center of Ukraine, payment to the State laboratory for methods assurance.

Registration of the **substances** (API)

	State fees	Patern Ltd fees
Registration substance	≈400 EURO	3000 EURO

State fees includes: payment to the State Treasury of Ukraine, services of the State Pharmacological Center of Ukraine.

**Renewal** of registration

	State fees	Patern Ltd fees
Renewal of registration	2305 EURO	app.4000 EURO
Additional dosage/strength	+10%	+10%
Additional package (#10, #20 etc.).	+10%	+10%

State fees includes: payment to the State Treasury of Ukraine, services of the State Pharmacological Center of Ukraine. Quality assurance is not carried out during renewal of registration.

**Other regulatory services**

	State fees	Patern Ltd fees
Variations - type Ia	200 EURO	500 EURO
Variations - type Ib	300 EURO	500 EURO
Variations - type II	500 EURO	700 EURO





### Other services

	State fees	Patern Ltd fees
Registration of medical devices and equipment	varies	from 2500 EURO
Registration of BAS	varies	from 1000 EURO
Registration of cosmetic products	varies	from 1000 EURO
GMP-recognition procedure	from 1500 EURO	2500 EURO

Please, inform us whenever you need Confidential Agreement, Contract Draft and Power of Attorney from us to continue co-operation and start regulatory procedures.

Please, do not hesitate contact us anytime if you have a question.

