

# Market Access of Drugs in Russia

*Regulatory essentials,  
entry process and  
marketing options*

## TOPICS

- Regulatory intelligence pathway
- Import regulations and entry process
- Market access strategy
- Partnering and contracting peculiarities
- Timeline of a market entry

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## YOUR SPEAKERS



**Mag. Gerhard Eder**  
EG - CEE Consult  
Mag. Eder Gerhard  
Unternehmensberatung,  
Vöcklabruck, AUSTRIA



**Vladimir Krasnikov**  
Russian Pharmalicensing  
Group, LLC  
Moscow, RUSSIA

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## Aims and objectives

Will your products be sold on the Russian market? Then don't miss this seminar: you will get first-hand information on regulatory and import requirements, as well as useful hints for your market access strategy.

You will also become aware of what to avoid in preparing for your market entry, how to draft a contract with a Russian partner and how to estimate the timeline for market access.

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## Who should attend?

This seminar addresses the needs of healthcare professionals involved in bringing pharmaceuticals to the Russian market. Regulatory affairs, business development and market access experts will particularly benefit from this course.

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## Limited number of attendees

This seminar is limited to 20 participants. This limitation, a feature of all FORUM seminars, enables participants to thoroughly discuss the complex issues covered by the programme.

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## Quality guaranteed!

We follow the IMI quality criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards. An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 01.2019 - 12.2019) produced a result of 1.6 (based on a school grading system of 1-6).

## YOUR SPEAKERS



### Mag. Gerhard Eder

EG - CEE Consult  
Mag. Eder Gerhard  
Unternehmensberatung  
Vöcklabruck, AUSTRIA

Founder, Consultant



### Vladimir Krasnikov

Russian Pharmalicensing  
Group, LLC  
Moscow, RUSSIA

Founder

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## Your benefits

- Two experts with first-hand knowledge of the Russian market
- Information on regulatory affairs, import regulations and market access combined in a single seminar
- Plenty of time for discussion in a small group

## Booking option: e-Learning

If you would like to know the general regulatory affairs principles outside the ICH region, we recommend our "e-Learning: Marketing Authorisation Outside the ICH Region".

This e-learning will show you how to categorise the various regions in terms of regulatory requirements.

Please search for webcode 2012221 on [www.forum-institut.com](http://www.forum-institut.com)

## Your programme 09:00 - 17:00

### Prerequisites for entering the Russian Market

Gerhard Eder

### Regulatory overview of the EAEU

Vladimir Krasnikov

- The main aims and features of the regulatory landscape
- Example: Review of the registration procedure
- Product categorisation and classification

### Regulatory intelligence pathway

Vladimir Krasnikov

- Clinical study requirements
- GMP requirements
- Safety and pharmacovigilance
- Local RA agent

### Import regulations and procedure

Vladimir Krasnikov

- Obtaining mandatory permissions
- Payment of customs duty and VAT

### Overview of stakeholders in rare disease policy and orphan drug circulation in Russia

Vladimir Krasnikov

- The Russian 'Union of Patients and Patient Organisations for Rare Diseases'

### Common mistakes before and during entry

Gerhard Eder

- What to avoid in a market entry into Russia

### Searching for the right market access partner

Gerhard Eder

### Peculiarities of contracts in Russia

Gerhard Eder

- Common misunderstandings in contracts
- Possible solutions shown in cases

### Marketing options and structural peculiarities

Gerhard Eder

### Timeline of a market entry and first delivery

Gerhard Eder

- Sample timeline

# Market Access of Drugs in Russia

## REGISTRATION UNDER

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Fax +49 6221 500-555



## REGISTRATION FORM

Yes, I will attend

- ☐ Market Access of Drugs in Russia  
(Webcode 2009233)
- ☐ e-Learning: Marketing Authorisation Outside the  
ICH Region (Webcode 2012221)
- ☐ Yes, I agree that FORUM Institut may inform me about events by:  
☐ email; and/or ☐ telephone.  
I may withdraw my consent at any time.

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Name

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Position, department

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Company

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Street

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Post code, city, country

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Tel. no./Fax no.

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E-mail

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Contact person at office

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Date, signature

### Date and venue

Monday, 28 September 2020 in Berlin  
08:30 registration; 09:00 - 17:00 seminar  
Adina Apartment Hotel Berlin Mitte  
Platz vor dem Neuen Tor 6 · 10115 Berlin  
Tel. +49 30 2000 32 0 · Fax +49 30 200 767 599

### Fee

€ 1,190.00 (+ German VAT)

The fee includes course documentation (including  
free download) as well as refreshments, lunch and a  
certificate.

### Fee e-Learning

€290.00 (+ German VAT) - e-Learning:  
Marketing Authorisation Outside the ICH Region  
(Webcode 2012221) - This fee is only valid in  
combination with the above mentioned seminar.

### Our quality promise

We are proud of having passed the PharmaTrain  
Federation quality audit with excellence. We are now  
a recognised 'PharmaTrain Centre'.

## CANCELLATION POLICY

Our general terms and conditions (as of 1 January  
2016) apply and are available upon request. We can  
send them to you at any time. Alternatively, you can  
access them online at [www.forum-institut.com/t&c](http://www.forum-institut.com/t&c)

## YOUR CONTACT



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