

# Recent developments in Russian pricing regulation: new challenges for international pharma manufacturers



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# **Overview of recent changes to Russian pricing regulation**

Andrey Odabashian, Associate

## Recent developments

- The Russian Prime Minister V.Putin: Prices for the same pharmaceuticals differ in the Russian Regions twice or thrice. “It describes vividly that there is no order in this business area”
- The major drawbacks of the effective regulations from the standpoint of the Russian state authorities
- Conception of the long-term social and economic development of the Russian Federation for the period up to 2020 (approved by the Governmental Resolution of 17 November 2008 # 1662-r)
- The Resolution # 654 of 08 August 2009 and the Draft Law On pharmaceuticals circulation (amendments are introduced for essential and vital pharmaceuticals included in the Essential Drugs List (EDL))

## State registration of the maximum selling prices of the manufacturers (1 of 2)

- The obligation to register (re-register) the maximum selling price before 1 March 2010 based on the respective Methodology (to be introduced)
- The maximum selling price of a Russian manufacturer will be based on prices for similar (according to international non-proprietary name, form and dosage) pharmaceuticals in Russia
- The maximum selling price of a foreign manufacturer will be based on the minimum price for a pharmaceutical applicable in the country of the manufacturer and other states where such pharmaceutical is registered, and taking into account associated transportation costs:
  - Which “other states” should be taken into account?

Overview of recent changes to Russian pricing regulation

## State registration of the maximum selling prices of the manufacturers (2 of 2)

Transfer from the state registration of maximum selling prices of foreign manufacturers in a foreign currency to their registration in roubles:

- Before 1 January 2010: in a foreign currency and in roubles
- In 2010: in roubles or a foreign currency
- From 1 January 2011: in roubles

## Establishment and application of the maximum mark-ups (1 of 2)

- Application of the maximum wholesale and retail mark-ups only to the actual selling price of a manufacturer (not exceeding the maximum registered selling price)
  - previously application of mark-ups to the selling price of a wholesale trading company was also possible
- Definition of an actual selling price of a foreign manufacturer for application of the mark-ups:
  - the actual price indicated in the supporting documents to Cargo Customs Declarations (not exceeding the maximum registered selling price) including customs duties and the custom clearance fee
  - previously - just the contractual price (not exceeding the maximum registered selling price) including customs duties and the custom clearance fee

## Establishment and application of the maximum mark-ups (2 of 2)

- Draft of the Methodology on determination of maximum mark-ups is already available:
  - The draft Methodology implies existence of at least two distributors (i.e. federal and regional) in the wholesale chain
  - Mark-ups are expected to be differentiated depending on the price of a medicine
- While establishing the maximum wholesale mark-ups the Regional authorities shall take into account:
  - For federal distributors – transportation, commercial and administration costs, their level for the purposes of mark-ups calculations shall be established by the RF Federal Tariff Service, shall be differentiated for particular Russian regions;
  - For regional distributors – the data on results of activities of regional distributors chosen for calculation of the mark-ups based on one of the principles prescribed by the Methodology
- The federal regulation does not establish any particular minimum level for establishing the maximum mark-ups

## Monitoring of the compliance with the price regulations

- As of 1 January 2010 regardless of the regional regulations it is obligatory to formalise a protocol of prices reconciliation between a supplier (a wholesale company) and a buyer (a wholesale or retail company)
- The electronic database of the Roszdravnadzor (Federal Service for Health and Social Development Supervision) is established for Russian manufacturers and importers of pharmaceuticals manufactured abroad
- Information from the Federal Customs Service – for pharmaceuticals manufactured abroad
- The statistical monitoring – for pharmaceuticals manufactured in Russia

## Implications of violation of price regulations (1 of 2)

Starting from 1 January 2010:

- importation license for pharmaceuticals will not be issued if the maximum selling prices of a manufacturer are not registered (amendments to the Resolution # 438 of 16 July 2005)
- compliance with the maximum mark-ups is explicitly established as the licensing requirement for pharmaceutical activities (both wholesale and retail) (amendments to the Resolution # 416 of 6 July 2006)
- non-compliance with maximum mark-ups is considered as gross violation of the licensing requirements that may result in suspension of a license for the pharmaceutical activities and its further cancellation (amendments to the Resolution # 416 of 6 July 2006)

## Implications of violation of price regulations (2 of 2)

Non-compliance with price regulations may also result in:

- Administrative liability under articles 14.1, 14.6, 14.31 of the Russian Code of Administrative Offences
- Liability under the Presidential Decree # 221 of 28 February 1995 and
- Criminal liability under article 171 of the Russian Criminal Code

# **Impact of pricing regulation on international pharma manufacturers' business model**

Evgenia Veter, Director, Transfer pricing

## Transfer pricing (1 of 4)

- Facts
  - pressure on first importers to limit their mark ups
  - commercial issue – importers are dependant on distributors
  - both EDL and non-EDL products affected
- Consequences
  - Mark up left for importers is not sufficient to cover operating costs => losses
  - Cash deficit / funding required
- What to do next?
  - Increase TP on pharma products? Decrease TP on non-pharma products?
  - Consider options to recover losses / fund operations

## Transfer pricing (2 of 4)

**TP should be at arm's length. Both before and after the revision**

### Tax:

- 20% deviation from a market level is accepted
- but should be abolished under new TP rules
- Losses are not welcome, especially if long-term

### Customs:

- no threshold for price deviation under law
- in practice 5-10% deviation is acceptable
- Both financial and business risk (products may be kept at customs)!!!

TP revision – conflict between tax and customs!!!

## Transfer pricing (3 of 4)

### **TP increase** / selling price not changed:

- Tax: decrease of the margin or loss  
→ is new price too high?
- Customs: was old price too low? Risk for historical imports

### **TP decrease** / selling price not changed:

- Tax: increase of the margin  
→ was old price too high?
- Customs: is new price too low? Risk for future imports



Need to explain the rationale for the price revision!

Change in pricing regulations is not good as a reason

Change in functional / risk profile / delivery terms may help

Document the change in the I/C contract, internal documentation, etc

## Transfer pricing (4 of 4)

- TP price revision may maximize the margin, but
- Unlikely to be sufficient to cover operating costs → losses are possible → risks
- Other measures to consider:
  - recharge costs to a supplier / I/C service agreement
  - transfer costs to a RO?
  - other?
- Effectively, a change in a business model - see next!

## **Response to the new legislative environment: changing the business model**

Olga Alexeenko, Manager, Tax services

Anna Ruvinskaya, Senior manager, Tax services

## Back to Representative offices (ROs)?

- The goal is to transfer to the RO marketing, advertising, promotion function (thus, moving the respective expenses away from the sales company)
- Justified only if the RO is able to maintain “non-taxable” status
- The main advantages:
  - obtaining of financing from the head office is easy
  - the operating expenses of the sales company are decreased
- The main disadvantages:
  - necessity to maintain two business units (a sales company and the RO):
  - permanent establishment exposure for foreign company having a RO in Russia
  - structuring regional activities is more difficult as compared to a Russian legal entity
  - other (e.g. necessity to re-structure contractual relationship with partners, transfer of assets and employees from the sales company to the RO, etc.)
  - non-sustainable structure in a long-term perspective

Response to the new legislative environment: changing the business model

## Reallocation of functions – service agreements with manufacturers (1 of 3)

- Functions transferred to the foreign manufacturer may be performed:
  - by the manufacturer's RO in Russia (discussed above)
  - by the Russian subsidiary under a service arrangement
- Implementation of a service arrangement helps to improve financial position of the Russian subsidiary since:
  - promotion and marketing expenses are economically transferred to the foreign manufacturer, and
  - the Russian subsidiary generates additional profit on service operations

and

- Logically leads to increase of transfer prices

Response to the new legislative environment: changing the business model

## Reallocation of functions – service agreements with manufacturers (2 of 3)

### Tax implications

- Profits tax – 20% on profit (service revenue less related deductible expenses)
- VAT – 18% on service revenue (if applicable)
- VAT, if charged on the services to a non-Russian company without presence in Russia, is lost for the Group
- Application of VAT depends on nature of services and VAT place of supply rules

Response to the new legislative environment: changing the business model

## Reallocation of functions – service agreements with manufacturers (3 of 3)

### VAT place of supply rules:

- General rule - services are deemed to be provided in the place of activity of the service provider
- Specific services (e.g. advertising, consulting, marketing, information processing, etc.) are considered supplied at the place of the activity of the service buyer

### If a Russian subsidiary provides non-VATable services:

- Input VAT is non-recoverable and represents a cost for the Russian subsidiary
- Separate accounting in respect of the VATable and non-VATable activities is required
- Proper documents sufficient to support the non-VATable nature of the services should be in place

Response to the new legislative environment: changing the business model

## Agency arrangement – who is an agent and who is a principal?

All agency arrangements:

- are aimed at exclusion of one of the participants of the supply arrangement (either the Russian subsidiary or the Russian distributor) from the chain of wholesale traders

and

- allow the remaining participants to maximize their possible margin on EDL medicines

## Agency arrangement

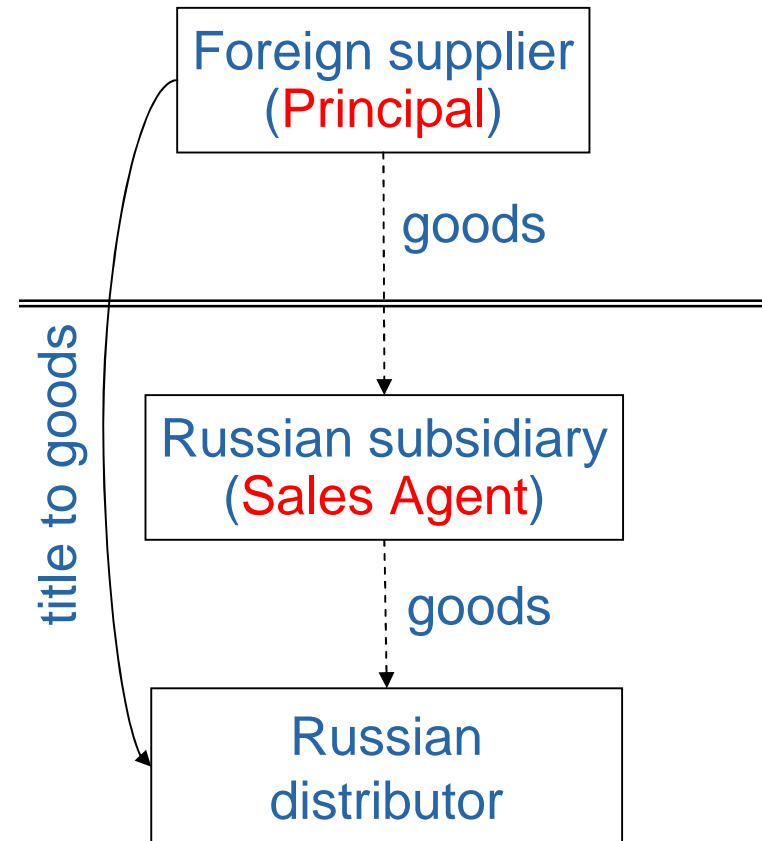
### Option 1. Russian subsidiary acts as a sales agent of the Foreign supplier

#### (1) VAT

- Non-recoverable customs VAT
- VAT on agency fee (cost to Principal)
- VAT on sale from a warehouse located in Russia (recoverable for Russian distributor)

(2) Potential permanent establishment risk for Principal

(3) Agency fee should be at arm's length which may not be sufficient to cover Agent's expenses



Response to the new legislative environment: changing the business model

## Agency arrangement

### Option 2. Russian subsidiary acts as a purchase agent of the Russian distributor

#### (1) VAT

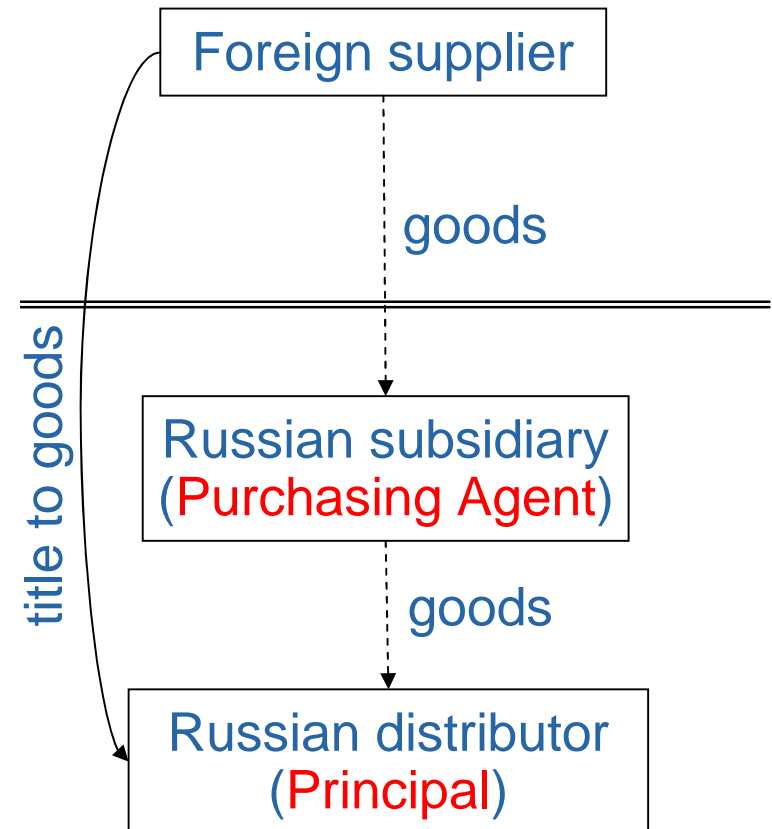
- customs VAT recoverable for Principal (Russian distributor)
- VAT on agency fee recoverable for Principal (Russian distributor)

#### (2) No permanent establishment risk for Foreign supplier

#### (3) Agency fee should be at arm's length which may not be sufficient to cover Agent's expenses

#### But:

- The arrangement may be difficult to negotiate with Russian distributor (unusual)
- A lot of distributors means a lot of agency arrangements



Response to the new legislative environment: changing the business model

## Agency arrangement

### Option 3. Russian distributor acts as a selling agent of the Russian subsidiary

#### (1) VAT

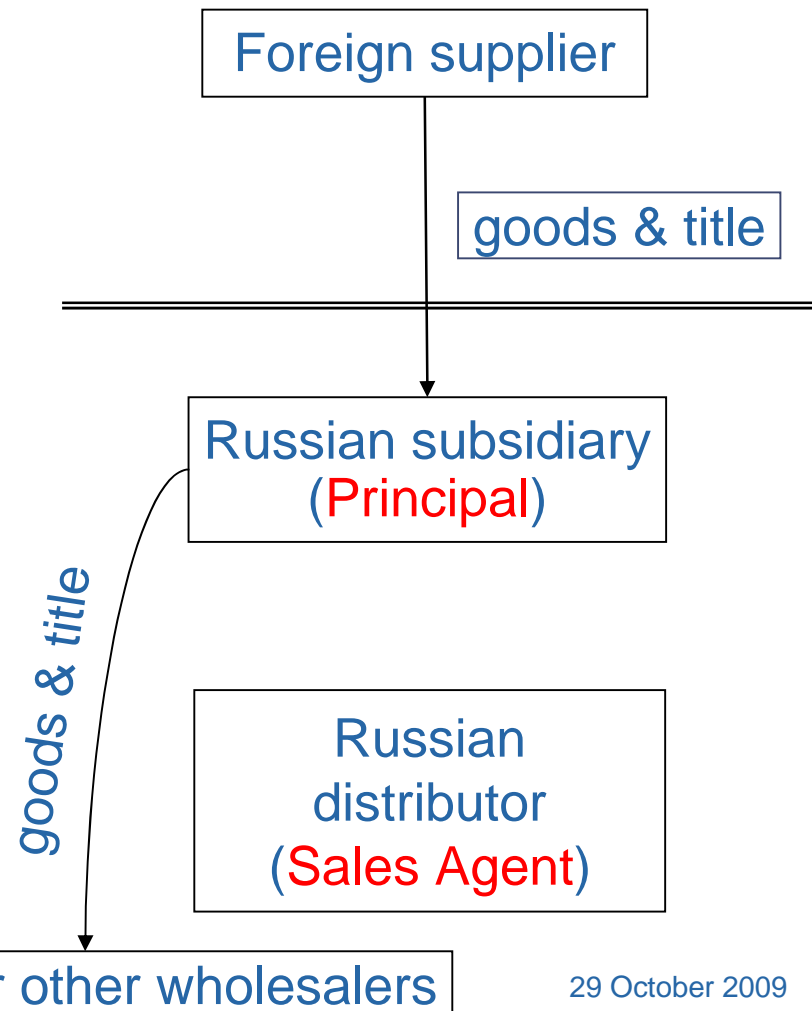
- customs VAT recoverable for Principal (Russian subsidiary)
- VAT on agency fee recoverable for Principal (Russian subsidiary)

(2) No permanent establishment risk for Foreign supplier

(3) Agency fee should be at arm's length which may not be sufficient to satisfy Russian distributor

#### But:

- The arrangement may be difficult to negotiate with Russian distributor (unusual)
- A lot of distributors means a lot of agency arrangements
- Documentary support of agency services should be obtained from distributors (may be difficult in practice)



Response to the new legislative environment: changing the business model

## Other considerations - bonus arrangements with foreign suppliers

- An arrangement where foreign suppliers pay cash bonuses to the sales company for achievement of certain targets established in the buy-sell agreement (i.e. purchases of the agreed volume of goods during the period)
  - May be potentially viewed as a price adjustment
- Relatively easy to implement
- Tested in practice
- For Russian profits tax purposes bonuses received by the sales company should be treated as non-sales income subject to profits tax
- Not subject to VAT if properly structured

# **Alternative approach: setting up manufacturing facility in Russia**

Alexey Belyi, Manager, Tax services

Alternative approach: setting up manufacturing facility in Russia

## 1. Strategy

- The following entry strategies may be considered:
  - Greenfield
  - Brownfield
  - Acquisition
- Key issues that need to be addressed at this stage:
  - Potential costs (one-off and recurring CAPEX)
  - Legal and tax implications (to be discussed further)
  - Timing impact (e.g. quick entry)
  - Quality and costs of production
  - Fit with long-term strategy of the Group in the region (e.g. potential to expand capacity)

Alternative approach: setting up manufacturing facility in Russia

## 1. Strategy (continued)

- Sample tax and legal issues associated with choosing the strategy:
  - Legal and tax due diligence
  - Permits and approvals, registration issues
  - Ecological expertise
  - Public utilities
  - Profits tax treatment of acquisition / construction costs
  - VAT implications on construction / importation of equipment
  - Customs implications
  - Historical tax and legal risks inherited by the Russian entity
  - Options for financing the project and their tax implications
  - and many others

Alternative approach: setting up manufacturing facility in Russia

## 2. Site selection

- Key factors when choosing location:
  - Geographical (e.g. Western/European part)
  - Relationships with local governments
  - Infrastructure (i.e. highways/railroads main lines/seaports availability)
  - Labor force and wages (quality and availability)
  - Local suppliers
  - Foreign investors present
  - Availability and cost of land
  - Cost of electricity/gas/water, etc
  - Tax/other incentives (Special Economic Areas, availability of regional tax incentives, subsidies and subventions)

Alternative approach: setting up manufacturing facility in Russia

### 3. Operational structure

- Closure or transition of existing entities
  - Pros and cons of using the existing company (“Oldco”) v. newly established company (“Newco”)
  - Tax and legal historic risks of Oldco
  - Timing and administration of setting up Newco / closure of Oldco
- Determining the correct legal structure
  - Pros and cons of using single entity v. multiple entities (e.g. property co, operating co, trading co)
  - Transfer pricing and other tax considerations
  - Tax consolidation?
  - Legal form of companies

Alternative approach: setting up manufacturing facility in Russia

## 4. Importation of the equipment

- Options of importation of the equipment
  - Buy-sell arrangement
  - Charter capital contribution
  - Special Economic Zones
- Issues to consider
  - Documentation requirements
  - Customs clearance and VAT implications
  - Valuation issues

Alternative approach: setting up manufacturing facility in Russia

## 5. Funding the Russian operations

- Comparison of the financing options
  - Loan financing
  - Equity contribution
  - Financial aid
  - Contribution into property
- Issues to consider
  - Legal requirements (incl. net assets, currency control)
  - Profits tax and VAT treatment
  - Limitations (e.g. thin capitalisation, etc.)
  - Complexity of repatriation

Alternative approach: setting up manufacturing facility in Russia

## 6. Other issues

- Intercompany charges
- Employment of personnel
- Tax & accounting
- Logistics
- Compliance
- Repatriation techniques

# Thank you!

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