NEW PRICING SYSTEM FOR DRUGS IN RUSSIA WITHIN SIGHT

Major pricing reform in Russia's pharmaceutical sector has long been mooted. The necessary legal framework is still being finalised, but amendments to the Pharmaceuticals Law will take effect in June 2019, bringing the reform a considerable step closer to reality.

BACKGROUND

Russia's Essential Drugs List (the "**EDL**") currently contains 735 products and the pricing reassessment campaign (the "**Reassessment**") aims at lowering prices for many or even most of them. The Reassessment is contemplated to begin in the second half of 2019 and be completed by 1 January 2021.

Most importantly, once the Reassessment is finished, pharmaceutical companies will have a new, recurrent obligation to decrease prices following any price decrease for the same products outside Russia.

As a first step for preparing the Reassessment, a price calculation methodology was approved in October 2018 (the "**Methodology**").[1]

Amendments to the framework Pharmaceuticals Law[2] were finally approved by the State Duma on 23 May 2019 and will take effect in June 2019.[3] These amendments will essentially authorise the Russian Government to establish the necessary procedures and deadlines for the Reassessment.

A government decree setting out the details of the Reassessment procedure, deadlines for submissions, the timing when the new prices will take effect, etc. (the "**Draft Decree**")[4] is anticipated to be approved in the next few months and to take effect by the end of 2019. A revised version of the Draft Decree was published on 29 May 2019.

Below we summarise the key requirements of the Reassessment.

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1 Methodology for Calculating the Maximum Ex-factory Prices of Pharmaceutical Products on the Essential Drugs List Upon Their State Registration and Reregistration, approved by Russian Government Decree No. 979 dated 15 September 2015 and amended in October 2018.

2 Federal Law No. 61-FZ "On the Circulation of Pharmaceuticals" of 19 April 2010.

3 Draft Law No. 592388-7 "On Amendments to the Federal Law 'On the Circulation of Pharmaceuticals' Regarding State Regulation of Prices of Pharmaceutical Products on the Essential Drugs List". As of 30 May 2019, the draft law has been passed in three readings in the State Duma and approved by the higher chamber of the Russian parliament, after which it will be passed to the Russian president to be signed into law.

4 Draft Decree of the Russian Government "On Approval of the Rules for Mandatory Reregistration in 2019 - 2020 of Manufacturer's Maximum Ex-factory Prices for Pharmaceutical Products on the Essential Drugs List, and on Amendments to Certain Acts of the Russian Government Regarding State Registration and Reregistration of Maximum Ex-factory Prices of Pharmaceutical Products on the Essential Drugs List"; available at https://regulation.gov.ru/p/89832. Annexes to the Draft Decree include the Rules for Mandatory Reassessment in 2019 - 2020 of Manufacturer's Maximum Ex-factory Prices for Pharmaceutical Products on the Essential Drugs List ("**Reassessment Rules**") and template application documents. The latest version of the Draft Decree was published on 29 May 2019.

REASSESSMENT PROCESS

Duty to apply

Upon enactment of the Draft Decree, holders of a marketing authorisation ("**MA**") for original products[5] will have 40 business days to submit applications for price reassessment to the Russian Ministry of Health ("**MoH**").[6]

Holders of an MA for generics will not need to submit applications. Generics prices will automatically be reassessed immediately after the price of the relevant original product. The revised prices of the reference and generic products will then enter into force simultaneously.

According to the Draft Decree, decisions of the MoH approving a price will enter into force five months after the date of the respective decision.

Consequences of a delayed application

The Draft Decree disincentivises delayed applications for price reassessment. After 70 business days have passed since the enactment of the Draft Decree (i.e. 30 business days after the initial deadline for applications) the MoH will prepare a list of original products for which no application for reassessment has been received. In relation to these original products no price will be approved and the FAS will proceed with calculation of prices for the respective generics. If the MA holder for the original product applies for reassessment later, i.e. after the generic prices have been registered, the price of the original product will be set at a level equal to the highest generic price.

The Draft Decree also establishes a hard-stop deadline for applications: 31 December 2020. Failure to submit an application by that date will result in automatic cancellation of the respective price, meaning that sales of the original product in question will have to stop from 1 January 2021.

No price increases

The Draft Decree does not allow for any price increase as a result of the reassessment procedure. If the price calculated under the Reassessment Rules happens to be higher than the price already registered, the registered price will remain the same.

Exemption for stock in circulation

As mentioned above, decisions of the MoH approving a price will enter into force five months after the date of the respective decision. Batches already released to the Russian market before the date a revised price takes effect will remain in circulation at the unrevised price, i.e. the wholesale and retail prices of such batches will not need to be adjusted.

Recurrent obligation to decrease prices

A key new aspect of the EDL pricing reform which will begin to apply after the Reassessment is finished is the new obligation for pharmaceutical companies to decrease their registered prices in Russia *each time* prices go down in any of the reference countries.

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[5] The Russian Pharmaceuticals Law refers to "reference" pharmaceuticals here, i.e. "a pharmaceutical product that is first registered in the Russian Federation, the quality, efficacy and safety of which are proven based on the results of preclinical and clinical studies… and which is used to evaluate the bioequivalence or therapeutic equivalence, quality, efficacy and safety of a generic or biosimilar product". In this briefing we call these *original products*.

[6] It is also possible to apply for reassessment later, up to 31 December 2020. However, in that case the MA holder will bear the risk that its price will be set at the level of the most expensive generic (see the section "Consequences of a delayed application" below for more details).

There are serious concerns in the industry regarding this approach, as it will create burdensome price monitoring and regular filing obligations for many companies that have an extensive portfolio of products.

However, it is the FAS's firm position that the obligation to decrease the registered price should be triggered *each time* a company decreases its price in one of the reference countries rather than, for example, on an annual basis.

The Draft Decree follows this approach and stipulates that MA holders must file a new application with the revised price within *one month* after a price decrease has occurred in a reference country. A domino effect will apply to generics, so that MA holders for generic pharmaceuticals will be obliged to decrease their registered prices each time a decreased price is registered for the respective original product.[7] The FAS will follow up with MA holders who fail to decrease their registered prices promptly. Then, the MA holder will have one month to decrease the registered price. If the MA holder ignores notification from the FAS, the registered price will be cancelled.[8]

REASSESSMENT METHODOLOGY

Key elements of the calculation

According to the FAS, which is the key driver of the reform, the Reassessment will largely be based on the requirements of the Methodology, as amended in October 2018.

However, the Draft Decree also sets out separate application and review requirements, so the Reassessment procedure will have certain specifics, including:

For original products

- The key instrument in reassessing the prices of original products will be an international benchmarking analysis.[9] Applicants will not be required to submit information on their recent average prices in Russia.
- Foreign currencies will be converted into Russian roubles at the average of the official exchange rates set by the Russian Central Bank for 2017 - 2018.

For generics

- As mentioned above, holders of MAs for generics will not be required to submit applications; new caps for generics will be calculated internally by the FAS.
- No international benchmarking analysis will be run for each generic. Instead, new price caps for generics will be calculated by applying a discount to the price of the relevant original product (as approved by the FAS upon reassessment).
- Since all generics will undergo reassessment in parallel (after the original product), no distinction will be made between the first and any subsequent generics. However, expensive products will be subject to higher discounts

7 Apart from the recurrent obligation to decrease prices, an MA holder for the first generic will be also required to decrease its registered price once the second generic is launched in Russia.

8 The absence of an exhaustive list of sources of pricing information in reference countries which the FAS may use to request a price decrease has been criticised by the business community.

9 Same as under the Methodology, the international benchmarking analysis will be done against the prices in 12 reference countries, including 11 European countries plus the manufacturer's country.

than cheaper ones, as will imported generics compared to local generics (i.e. the same as under the Methodology).[10]

Product forms: general principle and exception

Similar to the Methodology, the Draft Decree provides that:

- in the international benchmarking analysis prices for alternative dosages and/or pack sizes available outside Russia should be included in the calculation if the same dosage and/or pack size is not available in *one or more* of the reference countries;[11] and
- a single price cap should apply in the Russian market for the same quantity of product sold in different packs (including product kits/packaging containing ancillary components).

  An exception is possible for products sold in pre-filled ready-to-use delivery devices (e.g. injector pens) and in packaging compatible with such devices. If it is proved that in reference countries such product forms are priced at least 10% higher than other product forms, separate (higher) price caps can also be approved in Russia.[12] In such cases generic prices will also be calculated separately for each such product form.

Unresolved questions concerning the Reassessment

Based on the latest wording of the Draft Decree as of 29 May 2019, questions remain as to how the Methodology and Draft Decree will be applied together in respect of certain aspects, in particular:

- **Draft Decree vs. Methodology.** In addition to setting out specific requirements on applications and assessment rules (as summarised above), the Draft Decree contains a catchall clause stating that the FAS may reject a proposed price for an original product if it exceeds *calculations made in line with the Methodology* (without reference to any specific sections of the Methodology).[13]

  Hopefully this will be clarified in the final version of the Draft Decree so as to explain the requirements and minimise the risk of unexpected pricing decisions by the FAS due to varying interpretation of the rules by the regulator and applicants.
- **Different brands.** The Methodology provides that if a product made by one and the same manufacturer is marketed in several jurisdictions under different trade names, the prices for all brands of this product are to be taken into account in the calculation.[14] Arguably, this provision targets 'second brand' and similar arrangements in foreign markets, thus putting the lower-priced products within the scope of Russia's international price referencing system.

  Although the Draft Decree does not contain similar provisions, the FAS might adhere to this approach during reassessment, if the broad reference to the Methodology (mentioned above) remains intact in the final version of the Draft Decree.

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10 The discounts scale is set out in Annex 5 to the Reassessment Rules.
11 While the rationale is clearly to minimise unjustifiable price inflation in Russia, certain exceptions to the rule may be required, e.g. where alternative dosages have different indications (see the section "Unresolved questions concerning the reassessment methodology").
12 If in a reference country the price of a ready-to-use injector form is higher than other forms of the same product by 10% or more, then in Russia a separate price cap can be set for the ready-to-use injector form. However, in Russia the ready-to-use injector form can be no more than 90% more expensive than the less expensive form.
13 Section 17(r) of the Reassessment Rules.
14 Section 28 of the Methodology.

- **Different indications.** Neither the Reassessment Rules nor the Methodology recognise possible differences in indications, which are sometimes associated with different dosages of the same active ingredient. It is yet to be seen how the FAS and the MoH will approach this.[15]
- **Procedure in case of price rejection.** The Draft Decree allows 10 business days for the MA holder for the original product to resubmit a price calculation if the initial application is rejected by the FAS. However, the procedure needs to be clarified. In the current draft, the MoH is not specifically required to publish refusal decisions, but obviously prompt publication will be essential for applicants to be able to react in time.

GETTING PREPARED

Consider impact through product portfolio and distribution chain

- Prices in public sector procurement will be most affected by the reform, due to the combined downward effect of the public procurement mechanism and the Reassessment. In state auctions original products will face competition from generics; if lower caps are registered for an original product and/or for its generics, the actual prices paid by the state for products with the relevant INN[16] will immediately go down.

  However, for many products, there is already now a big difference between the registered price and the sales price that a manufacturer can actually realise when bidding in state auctions. The reason is that the starting price of a relevant auction is normally based on the winning price of the previous auction. Hence, there has been a downward pricing spiral for many products (INNs), while registered prices often remained at their initial levels. For these products (INNs) it must be analysed whether the Reassessment will have any financial impact. In many cases the Reassessment may merely mean a technical adjustment without commercial effect.
- Long-term supply arrangements in the public sector could somewhat balance out the impact of the pricing reform for MA holders with regard to patented products and vaccines. However, recent regulatory initiatives in this area cast doubt over whether such arrangements will be feasible for international companies, given the limited term of proposed supply contracts and priority given to local players.[17]
- For some products MA holders may consider prioritising retail sales over sales in the public sector, due to greater flexibility in setting actual prices and no immediate link in actual prices for original product and generics. That said, the registered price cap cannot be avoided; also, a lower cap determined in the course of the Reassessment will limit possible mark-ups in the distribution chain, which are regulated as a percentage on top of the manufacturer's price.

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15 Similar issue was highlighted in recent FAS clarifications related to the Methodology (FAS letter No. ETs/1156319 dated 18 February 2019 (https://fas.gov.ru/attachment/196286/download?1550749212)).

16 International non-proprietary name of a pharmaceutical.

17 It is anticipated that direct supply agreements for patented products will be signed for a maximum of 3 years, with an early termination option in the event that a generic is launched. For vaccines on the national immunisation calendar, 'single-source suppliers' may be appointed, but it is likely that priority will be given to local players or JVs controlled by them.

- Pricing limitations will no longer apply if a product is excluded from the EDL. However, a decision on exclusion may be hard to achieve, unless the product is fully withdrawn from the Russian market.[18]

OUTLOOOK

The Reassessment is clearly not that far off, and the necessary legislation will likely be finalised in the next few months.

Although quite a few unresolved issues remain, it seems unlikely that the launch of the Reassessment will be postponed for any substantial length of time.

In order to comply with the contemplated strict deadlines for applications, pharmaceutical companies should closely monitor the developments surrounding the Draft Decree and related legislation. For larger product portfolios it will now be advisable to conduct internal assessment and calculations in advance.

[18] The exclusion of a single brand from the EDL is not possible in practice, as the EDL lists INNs and drug forms, not brand names. If exclusion is approved, it will apply to the original product and all its generics. From a procedure perspective, an exclusion proposal would have to pass the Inter-agency Commission under the MoH, which would require elaborated scientific reasoning for the exclusion (including medical aspects and cost of the product as compared to alternative medications that remain on the EDL).

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