Improving access to medicines in the Russian Federation:
The Programme for Supplementary Pharmaceutical Provision

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Summary: In January 2005 the Programme for Supplementary Pharmaceutical Provision (DLO) was implemented in the Russian Federation, enabling, for the first time, uniform, free access to medicines to the most vulnerable social groups in need of extensive pharmaceutical care due to poor health status or disability (federal eligibles). Attitudes towards the programme show increasing levels of satisfaction; utilisation of needed medicines has increased several-fold, particularly in under-provided regions and predominantly for expensive medications, including those for cancer, mental illness, haematology and cardiovascular disease. In order to ensure financial sustainability, further reforms will be implemented aiming at improving efficiency and cost-effectiveness, whilst maintaining quality and equity.

Keywords: Russian Federation, pharmaceutical policy, health care reform, health insurance coverage, access to medicines

Background
Current economic policy in the Russian Federation has become increasingly focused on four priority national projects, Health, Education, Housing and Agriculture. As part of ‘Project Health’, a new programme enabling prescription drug coverage for the weaker segments of society commenced on 1 January 2005 following Federal Law No. 122-Ф3. This Programme for Supplementary Pharmaceutical Provision (Dopolnitelnogo Lekarstvennogo Obespecheniya – DLO) aims to provide prescription drug coverage and free access, at the point of use, to quality medicines within ambulatory care (polyclinic) level (in part also inpatient care, up to a limit) to the most vulnerable social groups of the Russian Federation, namely those who need extensive pharmaceutical care because of poor health status or disability. In this respect, the DLO programme is a major step in the direction of modernising publicly funded health services in the Russian Federation.

Programme provisions
The DLO programme initially enrolled nearly sixteen million eligible citizens in the Russian Federation comprising people of all ages (children, retirees and those aged between 16 and 60). Eligibility is based either on disability status with the ‘disabled’ defined as those severely or chronically ill (more than 90% of all eligible groups), or special social status such as war veterans. The key objective has been to enable access to pharmaceutical treatments for this population at no cost to these insurees.

The key actors in the DLO programme include the Ministry of Health Care and Social Development, which coordinates the activities of all other stakeholders, sets the main rules for programme regulation, including those governing the budget, medications, and flows of funds, as well as establishing the list of reimbursable products. Other actors include the Federal Foundation of Obligatory Medical Insurance (FFOMI), which holds the budget from which it pays for pharmaceutical products supplied and the Federal Service of Health Care and Social Development (Roszdravnadzor), which supervises the implementation of the DLO programme and is also responsible for oversight, pricing policy and overall policy reform. Physicians, pharmacies and regional warehouses, who prescribe, dispense and store and deliver, respectively, pharmaceuticals at the federal level, who purchase and supply pharmaceutical products in the Russian Federation are also key actors.
The implementation of the DLO programme has required the mobilisation of a substantial number of resources and manpower including:

- 233,698 participating physicians
- 26,064 polyclinics, hospitals, and other institutions
- 6,000 pharmacies initially, subsequently increasing to 12,813 pharmacies by the beginning of 2006
- 23 pharmaceutical distributors at federal level, selected through an initial competitive process
- 86 regional warehouses working together with federal level pharmaceutical distributors
- 61 national and 110 foreign pharmaceutical manufacturers

Evaluating programme performance

Undoubtedly, the most important achievement of the DLO programme is that, for the first time, it has enabled free access to essential medicines for the most vulnerable and under-provided segment of the Russian population. Patients have been able to obtain medications on a sustainable basis, without the necessity of having to make any out-of-pocket contribution. Provision has remained, therefore, co-payment-free at the point of use for all eligible patients. Figure 1 illustrates the difference that the DLO programme has made to those who needed to make more intensive use of pharmaceutical care. Prescribed drug provision increased from 87% (April 2005) to 99.5% (January 2006), with the share of prescriptions waiting to be filled decreasing from 11% (April 2005) to less than 1% (January 2006).

The vast majority of medicines (over 75%) consumed by DLO eligible patients in the first half of 2006 were contained within the more expensive medicines categories, costing more than 500 roubles each ($US 18); about 50% of these medicines were very expensive, each costing the system in excess of 2,000 roubles ($US 72) (Figure 1). Prior to the implementation of the programme, patients would either need to purchase these on the commercial market, paying the entire cost out-of-pocket, or obtain some pharmaceutical coverage through in-patient settings, or, simply, forego treatment.

There was also a regional reimbursement system, which provided drugs to so-called ‘regionally eligible citizens’, but the reimbursement list, eligibility criteria, and the level of co-payment required differed greatly from region to region, depending on budgetary constraints. Moreover, no regional reimbursement list could be compared with the current federal reimbursement list. The latter is far more comprehensive, in terms of both the number of INNs (international non-proprietary names) and the new and innovative medicines reimbursed. By contrast, the commercial market has been dominated by lower cost medicines; only about 15% fall into the expensive medicines’ categories.

Receiving its budget direct from the Ministry, the DLO programme immediately became an important player in a system dominated hitherto by a commercial market that experienced regular price instability and price hikes. Indeed, the DLO’s total market share increased from 0% in 2004, to 21% in 2005 and 26% by the first half of 2006 (Figure 2).

Satisfaction surveys conducted at the start of the programme in January 2005 and also towards the end of that year showed improvements in the perception of the programme by eligible individuals; the
proportion of respondents indicating that they were very, or generally, satisfied rose from 38% to 45% over this time period. This is hardly surprising given that the implementation of the programme resulted in a significant increase in the number of prescriptions successfully filled by eligible insurees. On average the number of prescriptions filled in Russia increased two and a half to threefold in 2005 compared with 2004.

In some regions, particularly those which were previously under provided, the increases were even more striking. These included a fourfold increase in Mordovia, fivefold in Amur, more than sixfold in Kaluga and sevenfold in North Ossetia.

The average cost per prescription nearly doubled, from 180 roubles ($6.4) to 340 roubles ($12), between the first quarter of 2005 and the same period in 2006. This was not, however, the result of price hikes, as prices had stabilised and even fallen by 10% across 118 molecules, but rather an indication that more expensive medicines were being prescribed more frequently.

Additionally, in order to monitor and evaluate the programme’s performance, a number of key indicators to be used as benchmarks were developed by the Russian Ministry of Health Care and Social Development and the Federal Service. (The most important are shown in Box 1). These tied in with a series of problems impacting on patients, physicians, pharmacies and manufacturers that arose during the implementation of the DLO programme.

Patients were mainly concerned about the duration of waiting times to see a physician or to fill a prescription at a pharmacy, as well as the shortages at pharmacy level in terms of filling the prescription with the prescribed medicine first time, resulting in delay. Government-led surveys suggested that 27% of all patient-related complaints related to medicines not being in-stock at a participating pharmacy and a further 27% related to (excessive) waiting times in order to see a physician and receive a prescription. 23% of all complaints related to (excessive) waiting times at the pharmacy, whereas in 16% of all cases, patients experienced problems due to a lack of information.

Physicians were mainly concerned with having an excessive workload, seeing many patients without necessarily having the relevant supporting infrastructure. Pharmacists were also sometimes overwhelmed by having to service an increased number of patients, whilst at the same time experiencing shortages in a number of drugs on the reimbursement list. An additional problem was the requirement to prepare dispensing and activity reports; this led to a disproportionate amount of time being spent on administration.

Efficiency measures

While the DLO programme has undoubtedly had a significant positive impact on improving access to essential medicines, it has continued to operate within a fixed budget determined by the federal government. This implies that resources have to be used cost-effectively to maximise both programme impact and value for money. To that end, significant policy changes have occurred during the first two years of the programme [4]. These are intended to ensure that funding is adequate to guarantee continued access to medicines. Of particular attention in the second half of 2006 was a policy shift from simply focusing on the delivery of pharmaceutical products to eligible patients, towards managing resources more rationally.

At the beginning of 2006, INN prescribing was introduced, although it remains to be seen how the policy will be taken up by prescribing physicians. A further policy measure, introduced in April 2006, was a new reimbursement list, comprising 2276 trade names and which reduced the prices of 178 trade names. In addition to these selective price reductions, 103 branded products were excluded while 46 new branded products added to the list. The Ministry of Health Care and Social Development anticipates that the total efficiency savings from this fine tuning measure will be in the region of 14% of total spend.

“If manufacturers refused to decrease prices, their products would be automatically delisted”

Subsequent reforms on the operational side of the programme have included the introduction of further restrictions to the list of reimbursable products in October 2006. Some 74 INNs and 62 product formulations, mainly products financed from other programmes within the health care system (HIV, tuberculosis, some oncology drugs), as well as INNs and product formulations for in-patient use, were excluded from the list. In addition, prices for the most frequently prescribed INNs were reduced to the level of the lowest generic price, plus a supplement of 20%. If manufacturers refused to decrease prices, their products would be automatically delisted. In total, these price cuts affected 122 individual products. As a result, a total of 834 positions (both INNs and product formulations) were affected (due to both INN list shortening and demands for price cuts for individual products or product formulations).

A new tender system was announced for
four groups of the most expensive INNs, (three each from oncology, haemophilia and multiple sclerosis and eight for diabetes (insulins)). These seventeen INNs put together account for 40% of total DLO spend. The objective was to decrease wholesale markup from the current per-region fixed rate (35% on average) to a significantly lower rate. The 2007 tenders are now being published by FFOMI.

Total anticipated savings from these measures, calculated on the basis of next year’s projected DLO budget, have been estimated at 15% of DLO total spend, or $230 million. 7.2% and 7.8% respectively will be saved by the exclusion of INNs and branded products (Figure 3). This is expected to be achieved without adversely affecting the level of access to medicines, or the quality of products supplied. It should also allow room for innovative products to be included in the 2007 DLO programme.

Future policy directions
While the Federal Government remains committed to providing continued access to essential medicines and improving the health status of the population, it must also ensure that the DLO programme provides coverage in a rational and cost-effective way. In order to do this, a number of reforms are necessary. In addition to the already existing INN prescribing, the Federal Government has requested that options such as internal reference pricing and cost-sharing also be considered. Reference pricing would imply that patients would have to pay out-of-pocket if a medication’s price were in excess of the reference price. This might encourage physicians to prescribe cheaper, but equally efficacious alternatives.

“There has been an increase in the confidence of patients in the health care system”

While some of these reforms, such as INN prescribing and, if introduced, reference pricing, are aimed at rationalising both physician prescribing habits and patient utilisation patterns, others are aimed at rationalising the programme’s type of coverage. To date, the DLO programme, being a prescription drug insurance scheme, covers both outpatient and some inpatient use drugs. However, proposals are already in place to shift certain categories of medications to other programmes. For instance, HIV and tuberculosis drugs, which were included in the DLO controlled list until September 2006, and available to patients with doctors’ (specialists or heads of polyclinics) authorisation, will now be shifted to other parts of Project Health and reduce the burden on available DLO funds.

In addition, products for oncology, psychiatry, diabetes and hypertension patients intended for in-patient care, may be shifted, for example, to the ‘Federal Dedicated Programme’, which aims to provide integrated care for patients requiring these interventions; this will also include pharmaceutical care. Finally, the ‘High Technology Medical Care’ project, being part of the President’s ‘Project Health’, is intended to improve access to hospital and high technology medical care, including hospital drugs reimbursed under the project.

Suppliers will compete to provide medicines via a tendering mechanism. This measure should reduce the demands placed on DLO resources. It should also provide an opportunity for the programme to expand its outpatient coverage and tackle the potential under-use of medications in key diagnoses, whilst at the same time, generally enhancing access to improved pharmaceutical care.

To date, the DLO programme has provided free access and comprehensive coverage to the federally eligible population. Its first two years have been accompanied by an increased confidence in the system from a patients perspective while there has also been an accumulation of expertise in terms of establishing infrastructure, administering the programme, addressing its shortfalls and initiating policy changes aimed at a rational and efficient use of resources.

REFERENCES

Notes: INN = international non-proprietary name; TN = trade name
Source: The authors based on data from the DSM Group, 2006.