



Trends
and practical aspects
of development
of the Russian
pharmaceutical
market – 2013



Introduction

This research includes a summarised opinion of pharmaceutical company representatives on the development trends of the market in Russia, its regulation and existing problems arising in the conduct of business.

For the most part, the research was conducted among representatives of foreign companies involved in the production of patented medicines both in Russia and abroad.

The research shows that the Russian market continues to rely on foreign manufacturers. Attempts to influence the situation at government level (the RF Government initiative to restrict access to state tenders for imported medicines, etc.), according to the market players, are thus far difficult to implement and require at least another several years. This is explained by the necessity to localise full cycle manufacturing in Russia, current imperfect legislation and pricing regulations, corruption and many other issues which must also be resolved.

At the same time, our research has shown that despite all the difficulties, the Russian pharmaceutical market has great prospects for development. Almost half of our respondents plan to introduce new medicines to the Russian market, and a third of the participants in the research intend to expand their existing manufacturing capacities or launch new products.

Our investigation offers you the opinions of pharmaceutical sector experts on these and many other issues. We will be delighted to answer your questions, and would also like to thank all participants in this research project for their expert assessment of the current situation and the prospects for the development of pharmaceuticals in Russia over the coming years.

Kind regards,

Oleg Berezin

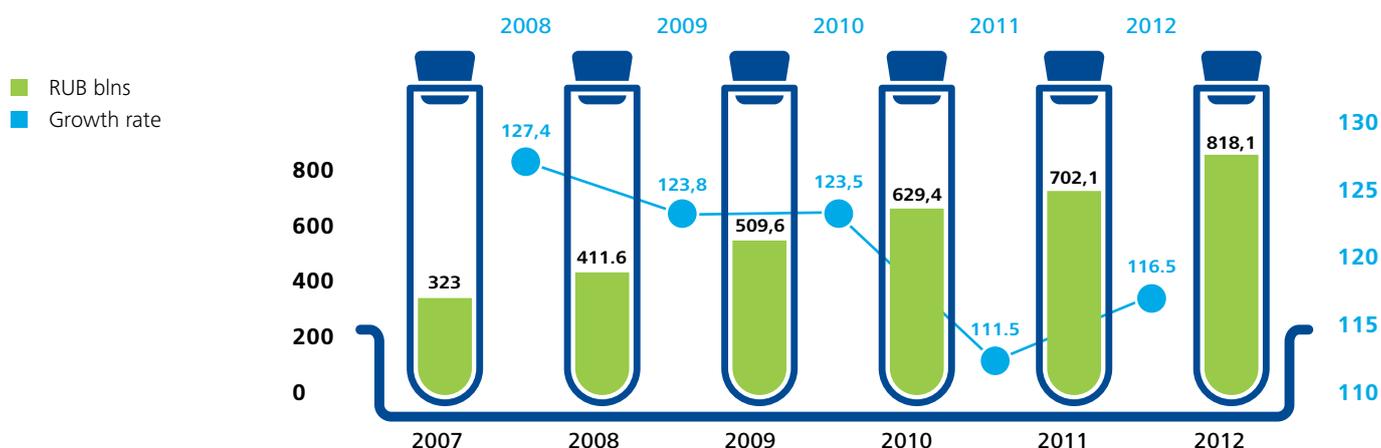
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Share of imported medicines in the Russian market today and tomorrow

The total size of the Russian market for medicines and nutritional supplements in 2012 was 818 billion RUB in the consumer price equivalent (3% of the global market, 8th place globally), in a market where almost 80% of products are imported.



Source: Farmexpert Market Research Centre

In 2012, the market growth compared to 2011 occurred due to an increase in the price of medicines in the non-regulated sector. There was a reduction in the sale of cheap medicines and an increase in the sale of expensive medicines (an increase in the average cost of packaging).

Cheap medicines from the vitally important drug list saw less demand from intermediaries due to a limitation in mark-ups set for wholesalers and retailers.

In volume terms, the commercial sector in 2012 comprised 84% with a volume of 5.1 billion packages and an increase of 5.9% compared to the statistics from 2011 (the volume in 2011 was 4.8 million packages with a share of 84%).

According to the Federal target programme "Development of the pharmaceutical and medical industry of the Russian Federation", the following goals have been set, to be achieved by 2020:

- the share of Russian-manufactured medicines in the list of strategic medicines and vitally important medicines must reach 90%
- the share of local medical drugs in the pharmaceutical market in monetary terms must be 50%
- the share of local medical products and medical equipment in monetary terms must be 40%
- 75% of pharmaceutical and 85% of medical companies should be modernised.

The main task that lies ahead of the Russian Government is to satisfy the market with Russian medicines, increase their quality and contain their price increases.

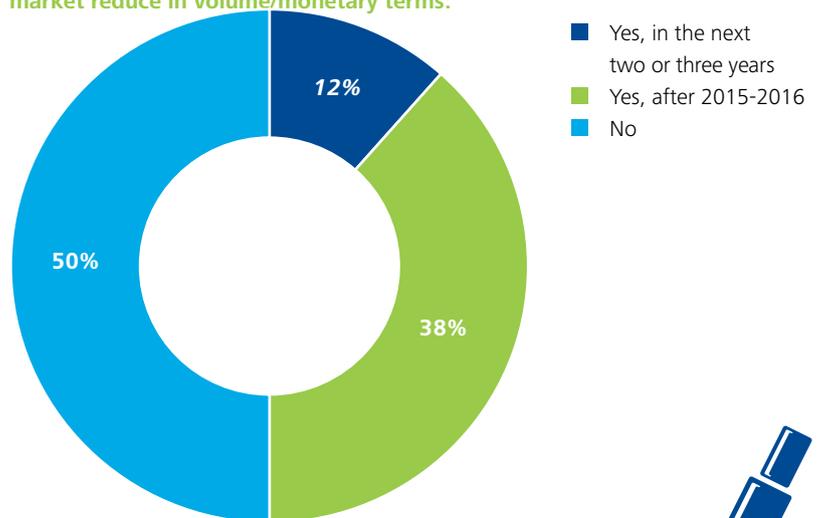
The government has already introduced and plans to add a series of measures to restrict the access to state tenders for imported medicines in order to stimulate local manufacturing. In particular, the following measures are introduced or planned to be implemented:

- in accordance with the draft Resolution of the Government of the Russian Federation "On the establishment of additional requirements for participants in orders for the delivery of medicines", as of 2014 manufacturers of foreign medicines will not be admitted to participate in state tenders where two or more analogues manufactured in Russia or Belarus are registered. Furthermore, in accordance with the draft Order of the Ministry of Industry and Trade of the Russian Federation "On the criteria according to which medicines produced in the Russian Federation using foreign components may be classified as Russian products", only medicines whose substance or prepared form is produced in Russia, i.e. produced at full cycle companies (or, until 2014, medicines whose packaging and labeling are made in Russia) shall be considered as local
- in accordance with the Order of the Ministry of Economic Development of the Russian Federation dated 17 April 2013 No. 211, until 31 December 2013 a preference was established for Russian and Belorussian medicines in the amount of 15% of the contract price when bidding for delivery for state and municipal needs.

It is worth noting that, in accordance with the agreements between the Russian Federation and the World Trade Organisation, WTO principles are not applied to compensation of the cost of medicines or medical products included in packages provided by the state guarantee system of free medical assistance for citizens. Thus, discrimination against foreign manufacturers in the framework of state procurement is not and will not be a violation of WTO principles. Therefore, one can assume that measures to limit the access of foreign manufacturers and medicines to the state procurement market will continue and are likely to become even stricter.

According to 50% of our respondents, the share of imported medicines in the Russian market in monetary and/or volume terms will not reduce up to 2016. More than a third of respondents (38%) predict a decrease in the share, but no earlier than in 2-3 years. The main reason for this forecast is that the establishment of full cycle medicine manufacturing in Russia by foreign companies in a shorter timeframe is considered impossible.

In your assessment, will the share of imported medicines in the Russian market reduce in volume/monetary terms:



Conclusion

In order to increase the share of local medicines in the Russian market, it is necessary to improve the governmental purchase practice and localise manufacturing in the Russian Federation.



Main problems in the pharmaceutical market



The respondents highlighted the three main problems that lie ahead for companies in the Russian pharmaceutical sector:

- Most of the respondents (36%) believe that the main problem of the pharmaceutical sector today is the imperfection legislation regulating the sector.

The legislation changes often. Since its adoption in 2010, the Federal Law "On the circulation of medicines" has undergone more than 90 amendments.

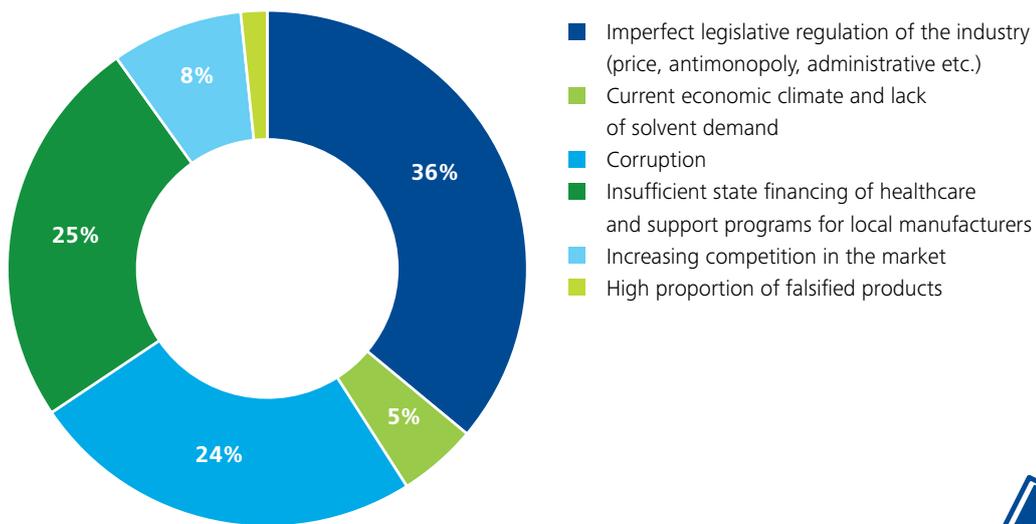
An imperfect pricing system, a lack of companies operating in accordance with the European GMP standard, divisiveness in the creation of a list of vitally-important medicines and the application of preferences, and many other issues remain unresolved.

According to Mr. Sergey Kolesnikov of the Russian Academy of Medical Sciences, member of the RAMS Presidium and President of the National Innovation and Technology Chamber, lawmakers do not consult with experts from the sector when creating new laws or amending existing laws. Their strategy is to create a law and then observe how it works, rather than creating a high-quality law from the outset, which may be useful in the medium-term perspective, creating sustainability for the players of the pharmaceutical industry.

- One quarter of the respondents point to corruption, and another quarter point to the lack of financing of healthcare programmes and support for local manufacturers.
- Other important obstacles preventing the development of the pharmaceutical sector are the growth in competition in the market, the current economic climate and the lack of spending capacity among the population; however, our respondents do not consider these issues to be the most problematic issues in the sector.



The most serious problems that lie ahead of companies in the pharmaceutical and healthcare sectors in Russia include:



Conclusion

A lack of flexibility, imperfect legislation, corruption at all stages from production to distribution, and a weak consolidation of local manufacturers create difficult conditions for the manufacture of medicines in Russia.



State regulation

Almost a third of representatives of companies from the pharmaceutical sector who participated in our research, consider the price regulation procedure for medicines as one of the most problematic aspects of state regulation.



The state regulation of pricing for medicines from the list of vital and essential medical equipment was introduced from April 2010 and includes the control of the establishment of maximum transfer prices for medicines by manufacturers and importers and the control of mark-ups by the sellers of medicines. Before the introduction of the regulation, the prices grew sporadically and in 2009 the prices showed a significant increase: in the outpatient sector by 10.8% and in the hospital sector by 16.1%. In certain regions, the mark-up on medicines, having gone through a chain of intermediaries, reached 200%. Currently, in accordance with the Strategy for the provision of medicines to the Russian Federation population up until 2025, approved by Order of the Ministry of Health of Russia dated 13 February 2013 No.66, the annual increase in the price increase index for vital and essential medical equipment must be no greater than 3%.

- 19% of respondents believe that the procedure for the state registration of medicines needs to be improved, the authorities for which were transferred from Roszdravnadzor to the Ministry of Health of Russia in accordance with the Federal Law "On the circulation of medicines".

For our respondents, state registration and price regulation on medicines included the following problematic aspects:

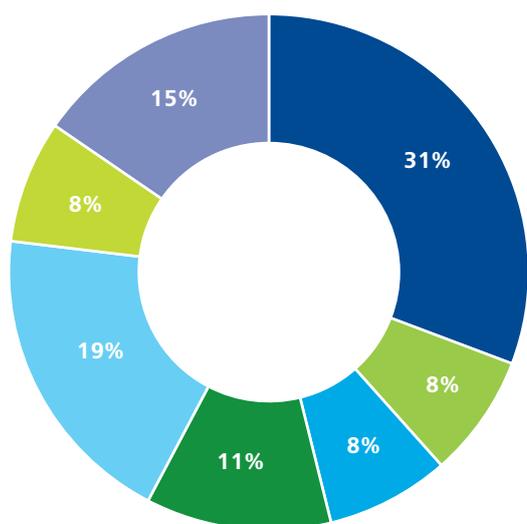
- unlike Russian manufacturers, foreign pharmaceutical companies do not have the possibility to adjust the registered maximum sale price of medicines depending on the level of inflation.
- highly competitive conditions are created in the market;

- a deterioration of the economic climate and the reduction in the financial sustainability of local manufactures are occurring (exit from the market, reduction in investment in the modernization of manufacturing and a deceleration in the movement to GMP standards);
- an additional administrative barrier for entry to the medicine market is arising. When entering amendments to the normative documents for a medicine after the registration of price, the manufacturer is forced to provide a full set of documents for it and to undergo a price registration procedure for the same item;
- an increase in cost and a delay in the medicine registration process are occurring, as in accordance with the Federal Law "On the circulation of medicines", there is no feedback between the expert organization and the pharmaceutical company. If there are comments to documents or difficulties arise, the expert has no actual possibility to address the manufacturer of the medicine and is forced to refuse registration.

Other areas of state regulation requiring improvement include tax regulation of the sector (15% of respondents) and the unification of legislation in the framework of the Customs Union and the World Trade Organization (11%).

In this regard, it is worth noting the absence of GMP certificates among a significant number of companies active on the territory of the Russian Federation, while compliance of production with GMP requirements is essential in the global market for special products such as medical drugs. All manufacturers in Russia must transfer to the GMP standard as from 1 January 2014.

Areas of state regulation which, in your opinion, are in particular need of improvement:



- Pricing regulation for medicines
- Regulations of methods for the promotion of medicines
- Provision of preferences for local manufacturers
- Unification of legislation in the framework of Customs Union and WTO
- State registration of medicines
- Intellectual property protection
- Tax regulation

Conclusion

Half of respondents considered pricing and the procedure of state registration of medicines as the most problematic aspects of state regulation.

This is due to the fact that during state registration and the regulation of pricing for medicines, in particular in the limitation of wholesale and retail mark-ups upon the sale of medicines, there are serious risks for the manufacturers of pharmaceutical products, risks for both Russian and foreign manufacturers.

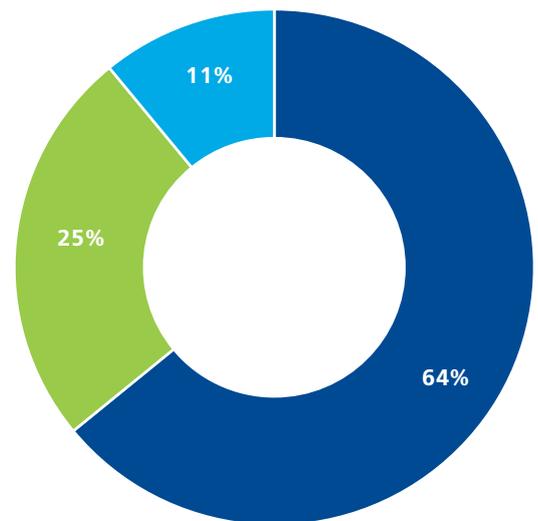


Methods for the promotion of medical products



The introduction of new rules regulating the interaction of the medical community and the representatives of pharmaceutical companies (Article 74 of the Federal Law "On basic health protection for Russian citizens"), in the opinion of almost two thirds of our respondents, turned out to be insignificant to representatives of the pharmaceutical community and did not lead to significant changes in the conduct of business.

How significant did your company find the introduction of new rules regulating the interaction of the medical community and the representatives of pharmaceutical companies, and what are the possible consequences?



- Introduction of new rules did not result in a reduction of the number of medical representatives or change to promotion methods
- Introduction of new rules resulted in a reduction of the number of medical representatives and a change to promotion methods
- Introduction of new rules did not result in a reduction of the number of medical representatives; however, the company is searching for/applying other promotion methods

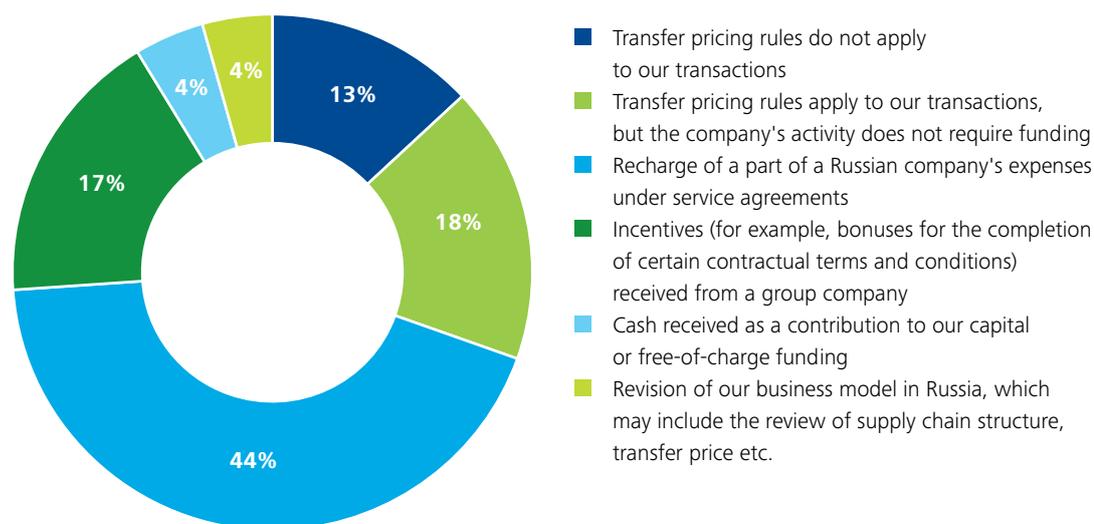
Transfer pricing

According to 44% of the respondents, the most popular way to ensure that the transfer pricing rules are adhered to is for a Russian company to recharge part of its expenses to a group company. The second most popular method (17%) is to receive incentive payments from the group.

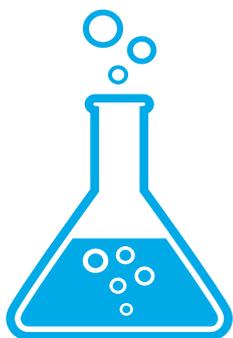
It should be noted that only 4% of respondents intend to reconsider the business model in Russia. This can be explained by the fact that the new transfer

pricing rules have been applied since 1 January 2012, and so far businesses are reacting to these changes for the most part in order to ensure compliance with these rules (preparation of required documentation, accuracy of notifications, etc.). As the experience of other countries shows, the review of the business model and the inclusion of Russian companies in the global transfer pricing strategy will possibly occur later, and with a view on how the state regulation system of medicine prices will develop.

Financing methods that your company applies or plans to apply to comply with transfer pricing rules, active since 1 January 2012:



Business development

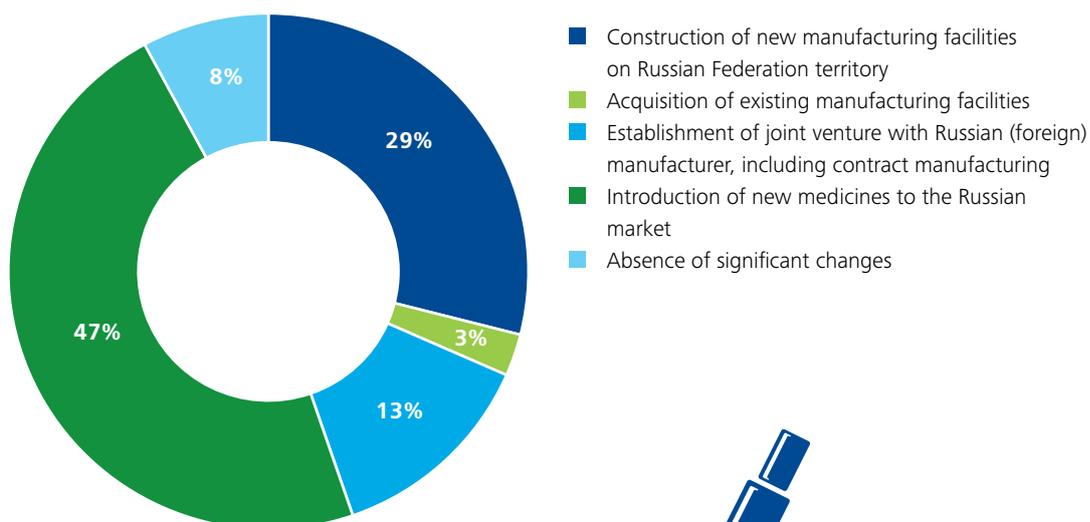


Most of our respondents have significant plans for business development over the coming years:

- almost half of the respondents plan to introduce new medicines to the Russian market in the coming years
- 29% of the respondents are planning the construction of new manufacturing facilities, which should undoubtedly lead to an increase in the share of local medicines
- 13% of the respondents plan to expand their business by establishing joint ventures.

It is worth noting that only 3% of the companies interviewed by us plan to acquire existing manufacturing facilities, which is confirmed by existing practice: the majority of foreign manufacturers prefer to construct their own manufacturing facilities or contract Russian partners to manufacture in Russia. This fact may be explained by the shortage of Russian manufacturers that would qualify in terms of capacities and needs the demanding of foreign companies and that would operate in compliance with GMP.

Your business development plans for the coming years:



Conclusion

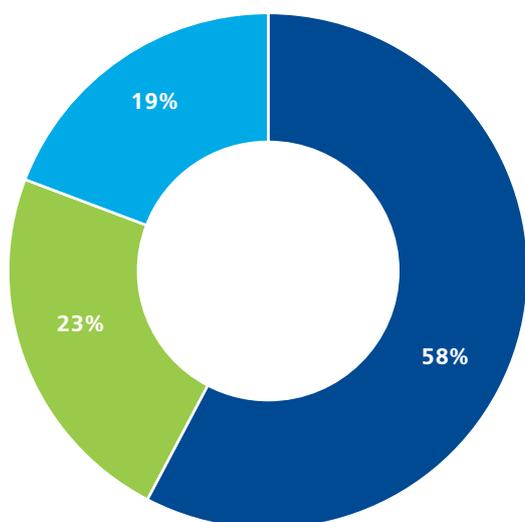
Manufacturers intend to introduce new highly-profitable medicines to the market to increase profit and compensate for their expenses. There is also a trend for the creation of clusters of foreign manufacturers, with local companies constructing factories for the manufacture of medicines in the framework of the replacement programme.



About our respondents

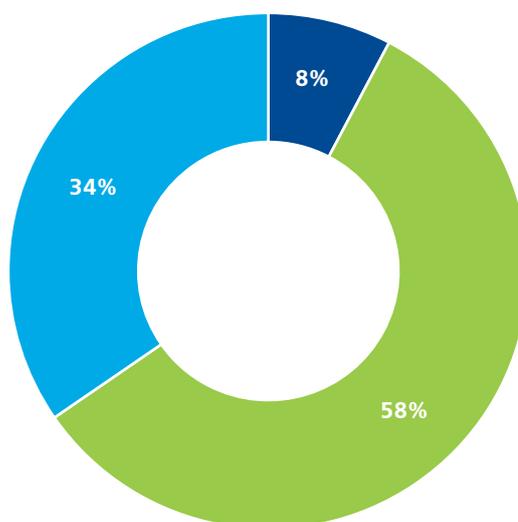
Over 50% of the participants in the investigation are representatives of foreign companies, mostly without localised manufacturing in Russia, and which specialise in the production (including abroad) of original drugs.

Main activities of your company:



- Manufacturing exclusively or mostly of original drugs, including abroad
- Manufacturing exclusively or mostly of generics, including abroad
- Distribution of medicines

Your company is:



- Russian
- Foreign without localization of manufacturing
- Foreign with localization of manufacturing (owned capacities and/or contract manufacturing)



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