

Organisation de Coopération et de Développement Économiques Organisation for Economic Co-operation and Development

28-Jan-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS COMPETITION COMMITTEE

Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Romania

-- Session III --

This contribution is submitted by Romania under Session III of the Global Forum on Competition to be held on 27-28 February 2014.

Ms Cristiana Vitale, Senior Competition Expert, OECD Competition Division Tel: +33 1 45 24 85 30, Email: cristiana.vitale@oecd.org

JT03351567

Complete document available on OLIS in its original format

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Romania --

1. Supply conditions

- 1. In Romania there is, in principle, an adequate and reliable supply of affordable drugs of acceptable quality. This perception is based on the number of marketing authorisations and the effective presence of international and local manufacturers' drugs. Thus, in 2009, approximately 7,000 drugs were on the Romanian market, their situation being constantly changed due to the entry of some new drugs each year and the exit of drugs for which there is no more medical or commercial interest. In spite of a large number of drugs on the Romanian market, there is a limited number of only 50 drugs benefiting from an allocation of large sums of money annually and accounting for about 40% of the total value of the pharmaceutical market in Romania.
- 2. Currently, a significant number of actors are active on the Romanian pharmaceutical market. However, a consolidation process occured in the pharma industry during the past few years. Thus, the first 20 manufacturers held approximately 78% of the market in the year 2009.
- 3. Secondly, strong distribution channels (including importers, national and local wholesalers and retail pharmacies) are active in Romania. However, it's important to highlight also that in 2009 a change in the statutory pricing system came into force. This development led to the lowering of the approved prices for prescription drugs by reference to the minimum price among 12 EU Member States. Therefore, starting with 2009, Romania became a (parallel) exporting Member State for certain prescription drugs.
- 4. In April 2013, there was a shortage on the Romanian market of certain essential oncology drugs, shortage temporarily settled by the Ministry of Health by prohibiting export of a list of 22 drugs in order to preserve public safety objectives. The measure of prohibiting parallel trade had an exceptional character and it was taken only for a limited period of time, i.e. until June, 30 2014.

1.1 Competition enforcement actions

- 5. Regarding the competition law aspects of the parallel trade, the Romanian NCA recently dealt with a complaint from a distributor (Relad) alleging that the producer (Roche) abused its dominant position in order to restrict parallel exports.
- 6. So, in this case, there was an alleged abuse of dominant position not an export restriction agreement. The alleged abuse manifested itself through the refusal to supply, the reason being that the distributor was exporting the pharmaceutical products of the producer.

- 7. The analysis conducted by RCC in the Relad/Roche case was similar to the GSK case, where ECJ concluded that a producer that has a dominant position doesn't abuse it while it delivers the regular orders to the distributors (looking at the previous commercial relation between the parties), taking account of the growth of the national market.
- 8. The Relad/Roche analysis took into account that the prices of pharmaceutical products are regulated at different levels in different Member States, and those differences in prices make them attractive for the parallel trade. Therefore, starting with April 2009, the products of Roche Romania became attractive for the distributors due to the parallel exports, because at that time the prices for drug prescription in Romania were set at the lowest level in the EU.
- 9. Following the analysis, the Romanian Competition Council (hereinafter referred as *RCC*) found that Roche Romania didn't abuse its dominant position because it delivered to the distributors the regular orders taking account of the growth of the market. Furthermore, over half of the Roche distributors, i.e. 6 of 8, exported Roche products in 2010. The exports of the analysed products also increased in 2010 relative to 2009.
- 10. The RCC conducted also four investigations related to parallel trade activities, having as object the ban on export and import of drugs¹ as it follows:
 - Baxter AG Elvetia and its distributors
 - Belupo Croația and its distributor
 - Bayer România and its distributors
 - Sintofarm and its distributors
- 11. The export ban of drugs was the object of the investigations concerning Baxter, Belupo, Sintofarm and their distributors. The export and import ban of drugs concerned the investigation on Bayer and its distributors.
- 12. In the investigations conducted, the RCC found that there are differences among the relevant prices of drugs in different Member States.
- 13. In these circumstances, the price differences make the parallel trade of drugs a business opportunity for distributors, both in terms of export of drugs benefiting from a lower price in Romania than in other Member States and the import of drugs from other countries in Romania at a lower price.
- 14. Regarding the parallel import activities, the RCC has identified certain Bayer products for which the price in Romania was up to 25% higher than in the European target price under the investigation concerning Bayer and its distributors.
- 15. Within the export ban investigations, RCC found that:
 - for most drugs of the Baxter producer, the percentage difference between the highest price in the EU and the price in Romania was in the range of 100% -350%;

The aggregated value of fines applied by RCC was of approximatively 14 million Euros.

- for some of the drugs of the Bayer producer, the price in Romania was up to 30% lower in Romania than the European minimum target price;
- for some of the drugs of the Belupo manufacturer, the percentage difference between the highest price in the EU and price in Romania was in the range of 155% -215%.
- 16. The drugs distribution agreements between a manufacturer and a distributor represent legal trade forms of drugs and therefore they must not contain any form of contractual clauses that would restrain the distributors' right to independently decide on their conduct trade in terms of parallel exports / imports of drugs.

1.2 Competition advocacy actions

- 17. At the end of 2009 a claw-back system was put into force, by which the manufacturer or holder of the marketing authorisation has the duty to pay a contribution to the financing of the public health system proportional to the revenues related to the drug sales. Mainly the generic manufacturers, but also the originator companies, argued that that burden is so heavy so that would mainly constrain the availability of low-priced drugs on the Romanian market.
- 18. The RCC has been actively involved in the claw-back tax for the purposes of setting out a formula that would not lead to distortions of competition on the market. Starting with 2009, the RCC has held a continuous dialogue both with the pharmaceutical industry and the institutions involved (Ministry of Health and National House for Health Insurance (CNAS)).
- 19. The main proposals of the RCC consisted in the removal of VAT from the base value to which the claw-back tax is applied, encouraging the use of generics through differentiated taxation and the correlation of tax payment terms with the CNAS payment terms.
- 20. Recently, the Constitutional Court established that the application of the claw-back tax to sales value containing VAT is unconstitutional, a position expressed as well by the RCC in its viewpoints delivered on this particular issue to the responsible institutions.

2. Manufacturing level

2.1 The price system set by the Romanian legislation as regards the ex-factory prices

- 21. The Ministry of Health (hereinafter referred as *MoH*) is responsible for price regulation of pharmaceuticals, i.e. the MoH approves the price for each prescription drug which holds a marketing authorisation before it can be marketed in Romania. The time limit within which the MoH issues a price decision is of 90 days from the date of the application². The MoH publishes the approved maximum prices every trimester in the Price Catalogue. Thus, the manufacturer is free, in principle, to sell at a lower price than the catalogue price.
- 22. All prescription drugs (reimbursable and non-reimbursable) fall under the maximum statutory price system, which comprises both internal and external price referencing rules.

The national legislation is in accordance with the Transparency Directive (Council Directive 89/105/EEC).

2.1.1 Originator drugs. External price referencing rule

23. According to the price legislation, a drug's ex-manufacturer price proposed by the producer or marketing authorisation holder cannot be higher than the smaller price among other 12 EU Member States (Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece and Germany). Non-compliance with the pricing rules is sanctioned with exclusion from the reimbursement system for one year.

2.1.2 Generic drugs. Internal price referencing rule

- 24. As regards the ex-manufacturer prices of generic drugs, in addition to the external price referencing rule above, an internal price referencing rule applies. The generic reference price is equivalent to maximum 65% of the originator's price.
- 25. If for a certain drug, the generic reference price is lower than 65% of the originator's price, the original's price of the drug in question has to be lowered accordingly in 60 days. The original's price has to be reduced so as not to exceed the generic reference price with more than 35% (a double referencing rule).
- 26. In principle, due to the existence in Romania of this kind of external price referencing rule, prices of prescription drugs are situated at a low level compared to the EU average statutory prices. The price competition between manufacturers takes place when negotiating with the MoH/submitting the price for approval, but due to the external price referencing rule, there is little space of manoeuvre for manufacturers when applying for a price decision by reference to a minimum price of the established panel of countries. However, price competition may result in discount policies.
- 27. Yet, the RCC did not perform a market study that would inquire into the regulation on ex-factory prices of originator and generic drugs.
- 28. In Romania, there are several important national manufacturers which, in general, provide generic drugs. The share of generics sales is relatively low in Romania, according to the data obtained by the RCC and presented in the Pharmaceutical Distribution Sector Inquiry performed in 2009. The sector inquiry looked at the originator-generic relationship on the markets under analysis (top 50 blockbusters). Among top 50 blockbusters foreign manufacturers are overwhelming.
- 29. However, within the sector inquiry finalised in 2009, the competition authority also conducted a sound research of applicable legislation with impact on the wholesale market of drugs, to identify the possible anticompetitive malfunctions, in four domains, such as the organization and functioning of the national health programmes; the way in which the list of reimbursed medicines is set in the benefit of the insured in the ambulatory system; the way in which drugs are acquired in the benefit of the insured in hospitals; specific legislation in the field of parallel trade.
- 30. Following the assessment done, the RCC made several recommendations to advocate for the improvement of the existent legal framework and for the removal of the regulatory barriers which limit the provision of drugs in Romania. The RCC made the following recommendations on the way of drawing up the lists of reimbursed medicines in the benefit of insured in ambulatory system:
 - The MoH should publish the criteria used to set the three subsequent lists and the degree of reimbursement for the drugs included in these lists. These criteria should also be included in the relevant legislation to provide legal certainty, to insure the needed transparency and to remove

thus the possibility of their discriminatory application (in accordance with the legal provisions of the Article 6 of the Directive 89/105/EEC).

- The automatic reimbursement of a drug should occur after the MoH issues a favourable decision for the inclusion of an international non-proprietary name (INN) in the list. Also, to increase the degree of transparency of the whole process of inclusion of an INN in the List, the Ministry of Health is recommended to publish on its website both the individual decisions and the draft list, according to the legislation in force in the field of decisional transparency.
- The establishment of the legal possibility of appeal in the light of the mentioned Directive and enshrined in the EU case law, respectively the entrustment of an independent body, acting as a court, with powers of evaluation and decision on the claims brought against the negative decisions of the Ministry of Health on the inclusion of an INN in the List.
- 31. The RCC also made recommendations concerning the organization of the procedures for the awarding of the public procurement contracts by hospitals in order to increase the competition during this process:
 - to eliminate the requirement of dealer authorization, document which is not in conformity with the provisions of the Emergency Government Ordinance no. 34/2006 and to use the regulation tools with the same purpose, i.e. the warranty of participation and fine execution. In addition, to prove the distribution capacity, a non-confidential version of the contract on the basis of which the distributor has access to the drugs that make the object of the tender may be required.
 - to insure an adequately competition level playing, the RCC proposed to bid on allotments such to allow the access of small players on the market.
 - in accordance with the existent provisions in the field of public procurement, hospitals should define the technical features at most at the level of INN that is equivalent with ATC 5.
- 32. Taking into account the definition of the relevant market in pharmaceutical sector, the RCC considered that to insure an optimum playing level, in certain instances, the technical features could be defined at a lower level, i.e. ATC4. According to the case practice of the RCC, the ATC 4 level is the most adequate to determine the substitutability of medicines. Nevertheless, taken into account the particularities of the pharmaceutical sector, with regard to the development of new products and the need to insure continuity in the treatment of patients, the RCC stated that the technical features may refer to the commercial name only if those products cannot be substituted and so, competition is not removed if the commercial indication is made.

3. Wholesale distribution

3.1 Organization of wholesale distribution

- 33. In Romania, the wholesale distribution of medicines is performed by Romanian legal entities, named wholesalers, in units called deposits of medicines. The wholesale distribution is carried out based on an authorization of wholesale distribution, issued by the National Agency of Medicines of Romania (ANDM).
- 34. The traditional distribution system is mainly applied. The main feature of this system regards the transfer of the ownership rights from the producer to the distributor. The latter is free to choose its clients and to determine the resale price, in the current regulated framework, bearing at the same time all the

commercial and financial risks inferred from these operations. Next on, the wholesalers sell the products either to other distributors or through the two channels, hospitals or pharmacies, by means of which medicines are acquired by consumers.

- 35. Given that the traditional wholesaler is free to set the resale price within the limits the current regulated framework, its incomes derive from the price margin applied and also from the financial and commercial discounts received from producer. With respect to the price margin, its level is predetermined by the state at the maximum level for prescription medicines and it is freely set for medicines sold over the counter.
- 36. In 2009, an evaluation on a sample of 23 active pharmaceutical chains, representing approx. 80% of the Romanian pharmaceutical market, was performed during a sector inquiry conducted by the RCC. At that time, all 23 groups of undertakings were employing a traditional distribution system.
- 37. Out of the 23 pharmaceutical groups, 19 of them marketed their products on the base of distribution contracts concluded with Romanian distributors, 3 applied general conditions of sale at which interested distributors might adhere and 1 pharmaceutical group applied both methods, i.e. for several products it concluded distribution contracts and for others it determined general conditions of sale.
- 38. This system continued to be enforced in the last years, without being influenced by major changes produced lately. Actually, the changes produced in the last years were of relative minor importance, reflected in the shift of one group from contracts to general sale conditions while another group replaced the general conditions with distribution contracts.
- 39. Lately, starting from 2012, certain active producers on the Romanian market expressed their intention to shift from the traditional distribution system characterized by many distributors either to direct distribution performed by producers³, or to distribution via a small number of wholesalers. It is important to be mentioned that the changes in the distribution system considers only certain medicines and not all the producer's portfolio. In this context, out of 20 top producers, 13 hold authorization of distribution issued by the ANDM for at least one deposit, meaning that these producers might develop a system of direct sales to pharmacies or hospitals.
- 40. Over 30 distributors are active on the wholesale distribution market for pharmaceutical products for at least five years.
- 41. The main activity of the wholesale distributors is the distribution of pharmaceutical products, for which they are granted a marketing authorization. This represents over 90% of the distribution activity. Besides medicines, they distribute para-pharmaceutical products, personal care products and other products, but their share on the market remains lower than 10% of the total turnover. Out of these, para-pharmaceutical products have the highest share in the total turnover of the distributors.
- 42. A large number of undertakings sell the products directly to pharmacies,, the top ten players on this market covering approximately 80% of the sales to pharmacies. The concentration degree of distributors that sell drugs to hospitals market was higher relative to that of direct distribution of drugs to pharmacy market. Thus, the first ten players in the market for direct distribution of drugs to hospitals were covering about 88% of sales, while the first three players were covering over 60% of sales.

Known as "direct to customer", embracing two forms, respectively "direct to pharmacy" – or "DTP" and "direct-to-hospital" – "DTH".

- 43. These data were established during the sector inquiry on pharmaceutical market carried out by RCC in 2009 and they will be updated on the occasion of another sector inquiry in this field currently under way.
- 44. Currently, the pharmacies are still supplied by many distributors, taking into account the mix of products and the trading conditions offered.
- 45. However, there are situations where a few producers have modified the distribution system for certain products (in the sense of working with a single distributor or with a limited number of distributors), so that the pharmacies at their turn acquire products only from that / those distributors supplying the product. These issues are under analysis of RCC in its ongoing sector inquiry.
- 46. The official data held by the RCC results from the sector inquiry carried out in 2009, having a a starting point for analysis the top 50 best-sold medicines in Romania, which cover about 40% of the Romanian market. Given the medicine's substitutability, 92 relevant product markets were identified and analysed.
- 47. After analysing how distributors have access to existing medicines within the 92 markets at ATC 4 level, and at every best-sold medicine on each relevant market⁴, it was found that generally there are no significant problems on the drugs wholesale distribution market.
- 48. Thus, in the case of the 107 best-sold medicines analysed, the distribution is made by over 10 distributors in more than half cases (56%). Approx. 70% of the market is distributed by over 10 distributors relative to the sales value. The distribution of the first 10 medicines of the top 50 best-sold medicines in Romania is generally made by over 10 distributors, more exactly in the case of 7 medicines and by more than 5 distributors in the case of only 3 medicines.
- 49. Following the analysis, it resulted that, overall, the exclusive distribution agreements did not cover a significant share of the market. Thus, in 2009, the sales value of medicines distributed under exclusive agreements represented approx. 8.75% out of the total value of the 92 markets analysed by RCC.
- Moreover, the most part of the exclusive agreements, respectively 48 out of the 77 represents less than 1% out of the market total value, being conjectural due to sporadic sales of some drugs. Out of the 77 exclusive agreements identified, 10 represent less than 5% and 5 represent less than 10% of the relevant markets value. There are 4 exclusive relationships whose share in the total market ranges between 10% and 20% and 10 exclusive relationships whose share in the total market exceeds 30%.
- 51. Out of the 10 exclusive relationships exceeding 30% of the market, 8 of them hold a share between 30 and 55% of the market, and 2 hold a share of over 65% of the total market.
- 52. Therefore, in the situations in which the producers implement exclusive distribution systems although their market share, as defined by the RCC⁵, exceed the threshold of 30%, it is

-

In case there is more than 1 drug on the relevant market identified belonging to Top 50. The distribution of every drug part of the Top was assessed so that in the end, 107 drugs were covered by the analysis.

necessary for them to make a self-assessment in order to determine whether the agreements concluded meet the conditions laid down in Article 5 (2) of the Law, respectively Article 101 (3) of TFEU and therefore, whether they would lead to a real increase in efficiency that countervails the reduction in intra-brand competition.

- 53. The analysis of the RCC identified three markets affected by parallel exclusive networks where the exclusive agreements date back at least to 2005, and even to 2001. In 2009, a number of existing exclusive agreements were ended.
- As a conclusion, the access on the wholesale distribution market is not limited to a significant extent by the existence of exclusive agreements or by the distribution through a small number of distributors. It appears that in recent years, a gradual end of exclusive relationships has occurred so that the trend is positive.
- 55. The RCC has continued to monitor the market to ensure that there is no significant restriction of competition. Thus, it has recommended to the producers that continue to use such systems to make a self-assessment of the agreements concluded so to ensure that their positive effects countervail their negative effects caused by competition restriction.
- Vertical integration is rare on the producer-distributor segment; only four producers are active on medicine wholesale distribution market, namely: Glaxosmithkline, Labormed, Gedeon Richter and Daiichi-Sankyo. Even in case of these players, the vertical integration was not due to the interest of producers to expand their activities in the downstream market, but due to the acquisition of some Romanian players that were already active on the wholesale distribution market (data supplied by the 2009 sector inquiry). Also, vertical integration exists on the next segment of the distribution chain, respectively between distributors and pharmacies.
- 57. Both in case of vertical integration between manufacturer and distributor and of products distribution just through distributors, as well as in case of DTP distribution system (using distributors as logistic agents), the question that arises is that, in the case of products for which producers have a dominant position, the main form of possible competition is eliminated, respectively intra-brand competition.
- 58. In the event of multiple distributors, the competition between them may lead both to lower prices and conservation of their interest to develop and make their activity more efficient in order to provide better services to pharmacies or hospitals.
- 59. Reduction of intra-brand competition can lead, although not necessarily, to higher wholesale prices by reducing the commercial conditions offered to the pharmacies and, finally, to higher prices for end consumers.
- 60. Therefore, in case of the implementation of such a system, as a principle, the manufacturers must ensure that a part of the efficiencies obtained will be transferred to the consumers, for example, through the internalization of the double margin resulting from the activities of production and distribution.

_

⁵ ATC 4 Level.

- 61. However, none of these systems should represent a way of restricting the parallel trade. Thus, any undertaking must be able to independently determine its strategic commercial behaviour on both national markets and outside markets.
- 62. Given these concerns, the RCC considered necessary to trigger a new sectoral inquiry in 2013 for gathering information on the pharmaceutical market. During this investigation, RCC will assess, among other things, the impact that the changes in the pattern of distribution may have on the Romanian market of wholesale drug distribution in general. Nevertheless, close attention will be paid to the drugs for which the manufacturer holds a dominant position on the market.

3.2 Price setting

- 63. The maximum price for the RXs (prescription drugs) is established and approved by the MoH who supports it in all or in part, according to the regulations on reimbursement of the drugs.
- 64. After establishment and endorsement, the maximum wholesale and retail prices for RX are listed in the National Catalogue of prices for medicinal products authorized for marketing in Romania (the so called Canamed), which is public. The prices of the drugs authorized by law are reviewed annually or when the macroeconomic conditions require. Also, the prices of the products can be revised when it is found that there are changes in the prices of peer countries.
- 65. In the case of OTCs, consumers make their own choice, while still bearing the price of drugs, which leads to a higher price elasticity of demand. OTCs' price is freely established and modified. The price of new authorized OTC drugs for marketing purpose and the modified price as set by the holder of the marketing authorization or representative shall be notified to the Ministry of Health within 30 days from when it was first introduced on the market.
- 66. Starting with 2009⁶, the maximum level of the margin that may be charged by a drugs distributor increased compared to previous regulations, modifying also the price ranges to which this level applies.
- 67. Currently, the distribution margin is calculated over the producer price, as it follows:

The producer price level	Maximum distribution margin (shares)
0-50,00	14%
Over 50,00-100,00	12%
Over 100,00-300,00	10%
Over 300,00	30,00 RON

- 68. As shown, for the regulated price drugs, the legislation sets both the producer price and the maximum wholesale and retail prices, available throughout the manufacturer-distributor-retail chain.
- 69. Finally, the methodology for the establishment of the maximum retail price will be uniformly applied for all the prescription drugs, according to the formulas established by law.
- 70. This should be seen in light of the availability and accessibility on the market of both the innovative drugs and the generics. The regulations in this regard are not specific to the distribution level, but they apply to the entire chain manufacturer-distributor-retail.

_

The Order of the Health Minister no. 75 of 2009 on the approval of the Norms for the metodology of setting out the prices of medicinal products for human use.

3.3 Enforcement actions

- 71. At the level of wholesale distribution, RCC did not cope with any case of abuse of a dominant position because none of the active distributors is dominant.
- 72. The distribution of drugs targets three main categories of clients:
 - pharmacies (retail sales);
 - hospitals;
 - sales to other distributors.
- 73. Also, given the different characteristics of these channels, it is possible a market segmentation of the wholesale drugs distribution and a narrower definition of two different markets, namely the market for distribution of drugs to hospitals and the market for drug distribution to pharmacies
- 74. Regardless of the method of defining the relevant market, even a narrower definition does not lead to the existence of a distributor who would hold a dominant position.
- 75. Regarding the possible anticompetitive agreements between distributors, RCC has carried out an ex-officio investigation based on the information published in the media, that the members of the Association of distributors and importers of drugs (ADIM) and the drug distributors Association (ADMR) in Romania have decided to cease deliveries of drugs to hospitals and pharmacies in 2008. According to the representatives of the two associations, this decision was due to the MoH's refusal to adjust, according to the legal provisions in force, the price of medicines, depending on the evolution of the exchange rate. The members of both associations were ensuring over 80% of the distribution of drugs in Romania.
- 76. In the context of the prices freezing by the MoH for prescription drugs, the Romanian drugs distributors concluded, during the period February October 2008, an agreement which had as object and effect the termination of drugs deliveries.
- 77. Following the analysis, the RCC did not find any infringement of the competition law even if the drugs distributors collectively undertook the actions. The retailers' undertakings to cease the deliveries of drugs took place in the context of the lack of updating by the MoH of the exchange rate used for the set-up of the price for the prescription drugs purchased in foreign currency. This caused structural imbalances in the drugs distribution market consisting in the reduction of the quantities sold. It even led to getting out of the market some distributors of lower-size or that were not integrated into a larger group.
- 78. However, the RCC considered necessary to issue some recommendations to the members of ADIM and ADMR, the MoH and the CNAS in order to protect the competition on the drugs distribution market. Thus, RCC pointed out to the members of ADIM and ADMR that the undertakings which are competitors on the same markets should carry out their activities within the professional associations in accordance with the rules of the competition.
- 79. Economic operators, members of the two associations should acknowledge that the performance of protest activities or of specific economic sector lobbying activities will be seen in a restrictive way by the competition authority, so that they would strictly serve the intended purpose and would not be used as a framework for the coordination of the activities by the competitors on the market.

- 80. RCC recommended to the MoH and to the CNAS to take into consideration that no public authority can act out of a well-established framework determined by the legal rules and principles such as the non-harming of the undertakings' activity with which it interacts.
- 81. Thus, there is a general provision in the Health Law, according to which the distributors are required to cover the needs of the patients in Romania, but without distinguishing between classes of patients or their positioning as it follows: "The holder of a marketing authorization for a drug and the wholesale distributors of that product introduced on the market in Romania shall, within the limits of their responsibilities, ensure adequate and continuous stocks in that product to the pharmacies and the persons authorized to supply the drugs so that the needs of patients in Romania to be covered.

4. Retail distribution

4.1 Organization of retail distribution

- 82. In Romania, the population benefits from medicines through different types of outlets, such as closed circuit pharmacies (in hospitals), drug stores or community pharmacies, and their established operating points, called dispensaries. All outlets are allowed to sell only retail and only products which have a marketing authorisation.
- 83. Community pharmacies, their dispensaries and closed circuit pharmacies are allowed to sell prescription drugs and OTC products, as well as cosmetics and parapharmaceutical products. They are run by a pharmacist certified by the Romanian Pharmacists College, and function as trade companies, based on a functioning authorisation issued by the Romanian MoH.
- 84. Drug stores are allowed to sell only OTC products, cosmetics and parapharmaceutical products. Pharmacies are allowed to sell prescription drugs, regardless of the fact that they are included in the national reimbursement scheme or not, provided they have a contract with the CNAS, needed for future reimbursements. The release of the drug will be made only through the pharmacies, and not by doctors, irrespective of the insurance house of the patient.
- 85. The closed circuit pharmacies are publicly owned and established in hospitals included in the MoH's network or in other networks of treatment facilities owned by different institutions or associations. They need to have a different area especially designed to cater to out-patients.
- 86. So far, the Romanian legislation does not allow the selling of prescription drugs by on-line pharmacies.
- 87. At national level, there are approximately 7,000 pharmacies out of which more than 1,000 are part of a chain, the rest being individual ones.
- 88. The establishment of a pharmacy will be made only on the base floor of the building, with a useable surface of at least 50 sqm., and will function only in the presence of at least one pharmacist, thus the functioning programme of the pharmacy will be set considering one pharmacist for every 8 functioning hours. The functioning hours of the pharmacy depend on marketing decisions and the presence of a pharmacist within the premises at all times.
- 89. The most important chains are vertically integrated, the parent companies being Romanian medicine distributors. The first 5 pharmacy chains comprise roughly 1,000 pharmacies. Since

⁷ Art. 792 of the Law no. 95 on the Health reform.

approximately 15% of the total pharmacies are part of a chain, so far there are no worries that the vertical integration may reduce inter or intra-brand competition.

- 90. In Romania, the main problem that pharmacies had to deal with was the payment terms, until the middle of 2013, when the NHIS terms of payment were revolving around 300 days, meaning that pharmacies had to rely on supplier credit for a long time until they collected the money from the NHIS. Therefore, this lack-of-cash situation and delays in payment terms were affecting the whole industry, being transferred to the wholesalers and finally to the producer, thus encouraging parallel exports as a source for quick cash.
- 91. Currently, according to the European Directive 2011/7/EU of combating late payments in commercial transactions, the NHIS terms of payment are of 60 days, steps being taken towards the payment of overdue debts, the overdue payments being expected to be paid in full by July 2014.
- 92. Considering the fact that most of the prescription drugs are on the reimbursement list and their price is regulated, there is little price competition between retail outlets. Therefore, the pharmacies can only compete on the retail margin, which is set in the regulation. There are signs that some retail outlets choose to stock some medicines that have the same active substance, but are cheaper than others on the market.
- 93. The sector inquiry previously conducted has shown that, even if generics penetrate the market, the ones that do are the highly priced ones, not the least expensive ones, the latter showing the lowest degree of penetration.
- 94. Regarding dispensing medicine through pharmacies, there is a general consensus across the industry that this procedure has the advantage of free access of patients to drugs that are granted under national health programs. In addition, medicine dispensing by any pharmacy that has a contract with a health insurer allows patients to choose where they want to pick up their medicine.
- 95. As opposed to national tenders, drug release through open circuit pharmacies provides access to all producers in the market and allows the manifestation of competition between wholesalers, which may lead to the achievement of significant discounts by the pharmacies.
- 96. In addition, it is a system which also takes into account the dynamics of the market. At the moment of patent expiry, generics can legally enter the market and are readily available to patients. Similarly, when an innovative product is found to be more effective than the previous one, it may be prescribed by the doctor and available to the patient immediately, without having to wait for the result of a contract awarded as an auction ends.

4.2 Regulation on prices

97. All prescription drugs in Romania have a regulated price. The computation of the producer and wholesaler prices has been presented in the previous chapters. The margin of the pharmacy is computed according to the price of the products, regardless of the fact that they are innovative or generics, as it follows:

Value of wholesale price	Maximum margin at pharmacy level
0-25	24%
over 25-50	20%
over 50-100	16%
over 100-300	12%
over 300RON	35 RON

98. The margin regulation grants the possibility of a higher margin for cheaper medicines, but in fact for cheaper medicines, although the margin as a percentage is higher, in absolute amounts, the gain is higher for more expensive products; therefore, the pharmacies have the incentives to stock more the expensive medicine, to get bigger gains for fewer packages actually sold. The OTC medicines have no regulated price.

4.3 Enforcement actions

99. There have been some mergers in the field, out of which one was cleared with commitments. The buying party had to engage to sell one of the bought pharmacies, located in a certain area.

4.4 Advocacy actions

- 100. So far, the encouragement of establishing pharmaceutical retail outlets in rural areas is considered to be done through the so-called demographic criterion. This is a provision found in the Romanian Pharmacy Law that settles boundaries for the establishing of pharmacies, according to the size of the city, ranging from 1 pharmacy per 3000 inhabitants in smaller towns and reaching 1 pharmacy per 4000 inhabitants in Bucharest. This provision limits the number of pharmacies that are able to be open in cities, the scope being the establishment of pharmacies in rural areas.
- Between 2005 and 2010, the establishment of new pharmacies in shopping centres, airports and railway stations was exempted from the demographic rule. In 2010, this exemption was eliminated.
- 102. The pharmacies that already have an outlet may open operating points in rural areas not already served by a pharmacy.
- 103. The RCC has done numerous endeavours to eliminate this criterion. In the view of the authority, the demographic criterion represents a barrier to market entry, which leads to the limitation of pharmacies. Therefore, the actors that enter the market are fewer than the ones that would have entered in the absence of the regulation, thus affecting competition on the market.
- 104. The RCC has recommended some possible solutions for encouraging the establishment of pharmacies in rural areas. The establishment of pharmacies in rural areas could be stimulated if the relevant legislation would facilitate access to these areas by establishing less restrictive criteria for establishing conditions compared to those required for the establishment of pharmacies in urban areas, such as: the reduced operating hours, a smaller range of products, eliminate the condition concerning the pharmacy's own laboratory or the opportunity to be served by a pharmacy assistant. Another solution could be to introduce a pilot program for the establishment of mobile pharmacies that serve rural areas with difficult access.
- 105. The RCC has received several complaints from pharmacists that wish to establish new pharmacies but are prevented to do so by the current regulation. This also affects the consumers, because a high level of competition usually for their benefit, though price reductions, increased service quality, encouraging innovation and the growing interest of companies to respond to the ever-changing customer needs.
- 106. Presently, the Pharmacy Law stipulates that the demographic criterion shall be maintained until the end of 2014. The RCC did not endorse this extension.

5. Public and private insurers

- 107. So far, the Romanian market only comprises public health insurers, where the contributions are mandatory for every citizen. There are additional insurance types, offered by private insurers that cover a range of services, according to the chosen scheme and the level of payments.
- 108. The Romanian health reform aims at opening the market and letting contributors choose between the insurance funds, thus eliminating the state monopoly. There have been steps taken in this direction, in the sense that some proposals for a health reform have been made and passed through public consultation. It is an ongoing process and an updated version is expected sometime in 2014.
- 109. Public acquisitions have been conducted through several types of procedures, as follows:
 - National tenders;
 - Hospital tenders;
 - Dispersing medicines through open-circuit pharmacies;
 - Single-source negotiation.
- 110. Where **national tenders** are concerned, the RCC stated that the tender should be organised so that it would maximise the bidding of capable undertakings that compete honestly. An effective competition will be present if more participants want to compete. This objective may be achieved by reducing costs of bid acceptance, setting participation conditions that do not unjustifiably hinder competition, finding ways for SMEs to enter even if they cannot bid for the whole contract.
- 111. In accordance with the law, to demonstrate compliance with minimum qualification and selection criteria, economic operators may present certificates issued by a competent public authority or by a public / private body, complying with European certification standards or any other equivalent certification required, to prove the requirements. Therefore, contracting authorities should not ask bidders to present documents issued by other companies, for example by manufacturers.
- 112. The request of such documents may lead to the creation of artificial barriers as it leaves available to a manufacturer to choose which of its distributors will participate in the tender offer. These requests may turn into handy tool for the manufacturers who, according to their own interests, or following an agreement between him and its distributors, either choose to give the authorization in question to only one of the distributors, thus discriminating against others, either grant it to all distributors, but authorise them to bid for different batches of products. Both situations are likely to eliminate competition between distributors. The effect is even more unfavourable if the manufacturer wishes to participate in the auction himself.
- 113. Requiring letters of guarantee of high sums by contracting authorities for both participation and performance results also in limiting the number of participants and thus eliminate small companies in national auctions. Therefore, it is necessary that the contracting authority to determine these amounts at a level that would achieve the desired goal of a securing a guarantee, and not erecting unjustified barriers.
- 114. In preparation for the drafting of standard documentation, the contracting authority may take into account other factors, in addition to the minimum requirements, to increase the efficiency of the outcome of the tender. They can address issues such as the ability of the bidders to submit a joint tender or the possibility to subcontract part of the contract.

- 115. When economic competitors jointly submit a bid, they automatically reduce competition in the proceedings as joint bidding reduces the number of participants. This effect of reducing competition promotes less aggressive bidding and negative effects on competition. Therefore, in some jurisdictions joint bidding is permitted for direct competitors only if the tender has a very high value or if the performance of the contract requires some technical or financial capacity.
- 116. In these circumstances, the joint bidding is the only way to ensure the participation of SMEs in major auctions, as they could not take part individually. However, contracting authorities should not allow companies to jointly bid where each company has the economic, financial and technical capacity that allows it to achieve the contract by itself.
- 117. Also, contracting authorities should allow subcontracting only if the auction has a high value or if the performance of the contract requires some technical or financial capacity. Allowing the winner to enter into subcontracting agreements creates an important potential effect regarding the possibility of bid rigging. In particular, in cartel cases, the cartel participants can be rewarded through a subcontracting agreement by the winner.
- 118. In conclusion, the minimum requirements in the tender documentation and the documents supporting proving that such requirements are met should be limited to those strictly necessary to ensure the optimum performance of the contract, taking into account the specific requirements imposed by the amount, nature and complexity.
- 119. The RCC recommended also that national tenders should be organised regularly, at intervals of maximum 1 year, according to current legislation on the matter.
- Where **hospital tenders** are concerned, the RCC recommended that the tenders should be organised in a way that reduce the risk of bid-rigging, by:
 - reducing barriers to entry and increasing the number of participants when determining the participation conditions for a tender, the selection process itself should not prevent firms to submit bids due to a number of conditions that are not relevant to the acquisition, such as similar experience or financial situation, or those that lead to the removal of operators from other geographical areas.
 - reducing transparency and exchange of information; a high degree of transparency in the market transactions can facilitate collusion as it enables the detection of deviating cartel members and their sanctioning. This is most likely the case for open bids, in which participants can communicate during the bidding process.
 - reducing the frequency of procurement opportunities; collusion is facilitated where competitors meet frequently in procurement procedures. This is due to repeated interaction that facilitates the implementation of sanctioning strategies between cartel members, necessary for an anticompetitive agreement to be effective. By changing the size and timing of the tender, contracting authorities may encourage cartel members to cheat on each other. Reducing the number of opportunities when competitors meet may reduce the opportunities for sanctioning the cartel members and facilitate competition. This can be achieved, for example, by organizing a smaller number of auctions, but larger quantities of products. Tendering after a pre-set program for the same quantities can facilitate rotation bidding.
- 121. In the case of **dispensing medicines through open-circuit pharmacies**, the RCC has proposed the referencing of medicines from the national health programs, resulting in efficiencies in the use of funds

allocated for the treatment for patients in the national health programs and ensuring the patients' access to medicines, when there are several medicines with the same INN or more packaging forms, some of them being more expensive. This proposal was taken up by the Ministry of Health and the regulation entered into force in 2011.

- 122. The **single-source negotiation** is permitted only when necessary, in cases of extreme urgency, when other acquisition procedures cannot be organised, and the urgency is not caused by the contracting authority but by an unexpected event. The authority does not have the right to establish the duration greater than the necessary one, so as to be able to cope with the situation that has triggered this emergency.
- 123. Single-source negotiation is a form of public acquisition that can be done in exceptional circumstances, i.e. when the products are unique, with no substitute drugs in the market. Direct negotiation with manufacturers can prove itself, in the case of single source, very useful in lowering the price offered. In such cases, organizing the auction in the traditional form (distributors), the only competition on the margin of the distributor and possibly the discount obtained from the manufacturer.
- 124. Drugs for which no substitutes exist, granted under national health programs, are innovative drugs that are under patent protection, and therefore very expensive. In accordance with the law, the maximum distribution margin to drugs whose price exceeds 300 Ron is only 35 lei. By negotiating directly with manufacturers significant savings may be achieved, manufacturers being able to offer competitive prices in a direct negotiation process due to the large volumes purchased. Therefore, in such exceptional circumstances, call for tenders does not lead to the best prices and most cost effective procedure may be to negotiate directly with manufacturers.

6. Generics competition

- 125. A defining feature of the demand for drugs is that the patient is not the decision maker. The demand is the result of complex relationships between patients, doctors, pharmacists and the National Health Insurance Fund. In general, the decision is taken by the prescribing doctors, and possibly the pharmacists who issued the prescription. Neither the patient nor the people who prescribed / issued drugs directly bear most of the costs, as they are largely compensated or reimbursed in full. Therefore, for medicines, the price elasticity of demand is limited for policy makers and patients.
- 126. Starting with 2010, the legal framework governing the prescription and release of generic drugs has improved as a result of the reintroduction of the physician's obligation to prescribe drugs according to the international non-proprietary name, instead of the commercial name. Also, the pharmacies are bound to release the medicine that gives the reference price, respectively the least expensive medicine corresponding to the therapeutic unit with the same dosage form and concentration of the INN. These steps were taken to boost generic consumption. The main beneficiary of this regulation is the state, which, whether the patient chooses one medicine or another, will reimburse the compensation percentage from the reference price.
- 127. Following these developments in the legal framework, generics should have acquired a significant share of the market once entered. However, yet this has not happened. That is why the RCC's sector inquiry currently underway envisages among other things to identify the reasons behind the low penetration of generics.
- 128. The 2008 pharmaceutical sector inquiry of the European Commission revealed that, on average, in the first year after the entry on the market, the generic drugs achieve 30% of the market and in the second year they earn up to 45% of the market (in terms of volume). This situation could not be found but in the 2009 sector inquiry of the RCC. Rather, it was found that there are markets where generic drugs are present for at least five years and innovative drug still holds a significant market share.

- 129. A possible explanation regarding this ratio between innovative drugs / generic drugs could be the intense promotion of the products by the innovative companies. Innovating companies devote a significant part of their budgets to the products marketing through doctors and other professionals specialized in healthcare sector.
- 130. The belief of doctors that they should prescribe or use a certain drug for any therapeutic treatment occupies the most important part of the marketing and promotion activities. This activity is known as "detailing activity": a sales representative of an innovative company visits a doctor to discuss the characteristics of a particular drug and convinces him on the safety, effectiveness and product quality. At European level, in 2007, "detailing activity" accounted for half of the marketing and promotion expenses incurred by innovative companies.
- 131. In Romania, marketing and promotion of drugs are regulated by the Guidelines on the assessment of drugs advertising issued by the ANMDM. Also, the Romanian Association of International Drugs Manufacturers (ARPIM) issued in 2006 "the Code of Ethics for promoting the drugs", code joined by all 28 producers belonging to the association.
- 132. Thus, of the 36 markets in which drugs in the Top 50 best-selling medicines in Romania can be found, 29 markets contain innovative drugs, 4 contain generics and 3 contain both innovative drugs and generics. Further analysis was conducted for markets that contain at least one innovative product.
- 133. Regarding markets where there are only innovative medicines, they contain drugs to treat serious conditions such as diabetes, cancer, HIV / AIDS, rheumatoid arthritis or hepatitis. They are usually granted within the national health programs.
- Regarding markets where also generics are marketed, it is noted that, in most cases, although there is a number of producers in each market, innovative drugs have retained significant market shares.
- 135. The analysis has identified three different situations on the generics position in these markets, namely:
 - Generic drugs are made and sold, but they do not have the same active substance as the innovative bestseller;
 - Generic drugs have the same active substance as the innovative bestsellers, but their market penetration is low;
 - Generic drugs with the same active substance as the innovative bestsellers have been approved only recently and therefore had no way to earn a significant part of the market.
- 136. The RCC has identified the factors affecting the penetration of generic drugs on the market or the gain of significant market shares:
 - regulatory framework;
 - intensive promotion of innovative medicines;
 - the level of competition existing between innovative and generic drugs determined by the producer behaviour.

- 137. Concerning the medicines released through national health programs, the RCC's proposal of a reference system for generics was taken up by the Ministry of Health, starting with 2011. Due to the fact that the patients now bear a part of the medicine's cost, they are interested to request generic drugs or less expensive innovative drugs for their treatment. The pharmacies also have now the incentives to offer discounts for these medicines, now that the state does not reimburse any longer the full price.
- 138. Also, the incentive to buy generics at consumer level derives from the fact that they are less expensive and the state covers only the cost of the least expensive medicine. Therefore, the consumer will have to pay the price difference to get the more expensive medicine.
- 139. The RCC has recommended also that the national regulation should be changed, to include the definition of the amount of gifts to be accepted by the doctors when prescribing medicines. So far, the definition in the regulation is unclear and leaves room for influencing attempts.
- 140. In the new sector inquiry, the RCC will conduct an analysis on these possible attempts and measure the extent to which these actions influence the consumption of innovative medicine in Romania.
- 141. So far, the RCC is not aware of any studies being conducted on the Romanian consumer's perception of generics drugs. The Romanian Association for Generic Drugs is taking steps in this direction, but the common view expressed by the producers' associations is that the Romanian Consumer perceived the less expensive medicine as being of a low quality, and struggles to make a financial effort to get the most expensive medicine. This problem will eventually be solved by sustained advocacy from both public and private bodies through awareness campaigns.