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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Bulgaria

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Bulgaria --

1. General remarks

1. The Bulgarian Commission on Protection of Competition (CPC) has dealt in several occasions with different aspects of distribution of pharmaceuticals in the last five years as part of its competition advocacy powers. In 2006 the CPC adopted Sector inquiry of the pharmaceutical sector in Bulgaria for the period 2002-2005¹. In the following years, reacting on complaints or *ex officio*, the Commission issued a number of opinion decisions on specific legal provisions, regulating the distribution of pharmaceuticals in the country. The main focus of the CPC opinion decisions were competition problems arising from the regulation of the markets (wholesale and/or retail levels) of reimbursable drugs in Bulgaria.

2. Legal framework

2. The Bulgarian legal framework on the use and trade with medicines for human use is quite complex. To a significant extent it is based on and harmonized with the EU legal framework and requirements in the field of medicines for human use, especially as regards the safety of the drugs, the procedures for marketing authorization of drugs, as well as trade aspects relating to the internal market of the EU.

2.1 *Use and trade with drugs in Bulgaria*

3. The medicines that are approved for use in Bulgaria must have either market authorization issued by EMA as part of the centralized procedure at EU level or get such authorization through the national procedure in Bulgaria.

4. All levels of distribution chain of pharmaceuticals is strictly regulated and subject to control. The vertical integration along the chain manufacturer – wholesaler – retailer is prohibited. The existing medicine manufacturing facilities in Bulgaria produce only generics. According to the CPC Sector inquiry of the pharmaceutical sector, at wholesale level there are several leading distribution companies that act nationally, the smaller distributors often act regionally. At retail level medicines could be sold directly to consumers only by registered pharmacies or drug stores (for OTC medicines). Pharmacies sell both prescription and OTC drugs, both reimbursed and paid fully by the patients. Doctors and hospitals do not have the right to sell drugs directly to the patients. For the treatment of the hospital patients the hospitals have pharmacies that are internal structural units, not trade facilities. Doctors prescribe medicines with their trade names. When the prescribed medicines are not reimbursed, the pharmacies may offer generic name to the patients, who decide what trade name to buy. The sale of reimbursable drugs is subject to specific regulation and in this case the pharmacies do not have the right to offer or to substitute the trade names in the prescription of the doctor.

5. Horizontal integration in the retail sector is limited to 4 pharmacies per one owner.

¹ CPC Decision No 303/2006.

2.2 *Pricing of pharmaceuticals in Bulgaria*

6. The prices of the medicines are regulated in Bulgaria.

7. The prices of the reimbursable drugs are composed of manufacturer price, surcharge of 9%, 8% or 6% for the wholesalers, depending on the price category of the medicine and surcharge of 22%, 20% or 18% for the retailer, again depending on the price category of the medicine. General 20% VAT is charged on the total. Thus, for reimbursable drugs, there is a fixed final price, formed according to the described mechanism. The manufacturer price is formed with referencing to the reimbursement price in selected EU Member States.

8. For prescription drugs, which are not reimbursed, but are with the same INN as the one, that is included for reimbursement in the Positive Medicines List (PML), the pricing is done like for the reimbursable drugs, forming maximum price. For the rest of the medicines (prescription/OTC), the market authorization holders or their representative register manufacturer price and maximum sale price (with VAT included).

9. The inclusion in the Positive Medicines List and the level of reimbursement is in the competence of a special commission. The formation of the price of reimbursable drugs is done according to the above mentioned mechanism and this price is entered into the Positive Medicines List. The medicines that are entered into the list must meet the following requirements:

- To be approved for use in Bulgaria;
- To be approved for use for treatment of illnesses, specifically set in a special Ordinance (thus one and a same medicine could be reimbursed when used for treatment of one illness and not reimbursed for the treatment of another);
- To be reimbursed by public health funds in specific EU Member States;
- To receive positive assessment of its therapeutic qualities.

10. In reality there is only one fund in Bulgaria that reimburses medicines – the National Health Insurance Fund (NHIF), which is the body, responsible for the management of the statutory health insurance fund in the country. The NHIF reimburses the drugs, in the amount set in the PML, for treatment of all insured citizens and for the illnesses set in the Ordinance, as well as for certain medicines for treatment of very serious illnesses to all Bulgarian citizens, regardless of their insurance status. For the latter, the NHIF receives financing from the state budget.

11. There are private health insurance funds in Bulgaria, but they as a rule do not cover the costs for medicines.

3. **Pharmaceutical market in Bulgaria**

12. In its sector inquiry of the pharmaceutical market in Bulgaria for the period 2002-2005, the CPC has noted that this market is strongly regulated in all its segments – manufacturing, distribution and retail trade with drugs. The regulation is both administrative (as regards the legal requirements for performing any activity in the sector) and price regulation. Generally speaking, state regulation, constant increase of the costs for drugs and high level of participation of the patients in the payment of drugs are among the major characteristics of the pharmaceutical sector in Bulgaria. The strong administrative regulation of the sector, the constant and contradictory changes of the reimbursement legislation, as well as the long period

for the administrative procedures, allowing companies to enter the reimbursement market in Bulgaria, are identified by the CPC as risk factors and barriers for entry that restrict marketing authorization holders from entering Bulgarian market and affects them as competitors.

13. In terms of statistical data, based on the information, received by the CPC during its investigations of the sector, the economic background of the pharmaceutical sector in Bulgaria shows the following:

14. Bulgaria takes 20th place between 27 EU Member states (as of 2009) as total volume of sales of drugs (at manufacturer price), with Slovenia, Lithuania, Latvia, Luxembourg, Cyprus^{2 3}, Estonia and Malta being behind it⁴. The public spending for pharmaceuticals per capita in 2005 in Bulgaria was ~35 Euro (with an average of 300 Euro for the EU), with a share of 1,4% of GDP⁵. For the year 2009, Bulgaria holds 25th place among the 27 EU Member states for use of original/innovative drugs and 22nd place, based on the ratio of sales per 100 000 persons⁶. Bulgaria is on 20th place in the EU in the preferences of original/innovative pharmaceutical companies, when choosing when to enter national reimbursement markets of the EU Member States⁷.

15. As regards the share between generic and original drugs, the CPC sector inquiry established that in the period 2002-2005 the share of generics increased from 70% to 84% (as units sold), which is increase from 27% to 49% as volume of sales. The share of original drugs fell in 2005 to 51% as volume of sales and 16% as number of units.

16. According to the data, provided by IMS Bulgaria, the share of generic (prescription) drugs as volume decreased from ~99% in 1989 to ~76% in 2010. For the year 2011, the share between prescription generics and originals for the whole Bulgarian pharmaceutical market was 75% to 25% (as number of units) and 44% to 56% (as volume of sales). The higher share of originals as volume reflects their higher price. The reimbursement market shows similar shares between generics and originals.

17. As of 2012, the data on retail trade with reimbursable drugs shows that out of about 4 000 registered pharmacies in Bulgaria, only about 52% (2076) of them sell reimbursable drugs. Further to this, only about half of the pharmacies, selling reimbursable drugs, offer 100% reimbursed drugs (25% of all registered pharmacies) and in about 15% of all municipalities in Bulgaria there is not a single pharmacy, selling reimbursable drugs.

² Footnote by Turkey:
The information in this document with reference to « Cyprus » relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Turkey recognizes the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Turkey shall preserve its position concerning the “Cyprus issue”.

³ Footnote by all the European Union Member States of the OECD and the European Union:
The Republic of Cyprus is recognised by all members of the United Nations with the exception of Turkey. The information in this document relates to the area under the effective control of the Government of the Republic of Cyprus.

⁴ See <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

⁵ See CPC Sector Inquiry of Pharmaceutical Sector.

⁶ According to data collected by IMS on request by EFPIA on the access of citizens of EU Member States to innovative drugs at <http://www.efpia-annualreview.eu/uploads/efpia.pdf>

⁷ See EU <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

18. In several of its decisions the CPC has made the following conclusions on the specific economic characteristics of the Bulgarian pharmaceutical market:

- The national pharmaceutical market is small due to objective economic reasons – population, GDP, small public spending for reimbursement of drugs, low income of the population;
- The share of generic drugs on the Bulgarian market, including the reimbursement market, is significant;
- The small volume of sales in the pharmaceutical market in Bulgaria, as well as the low reference prices of reimbursable drugs make the Bulgarian market rather not attractive for the manufacturers of original/innovative drugs;
- The National Health Insurance Fund is paying for ~35-50% of the drugs (as volume of sales), making the reimbursement market significant factor for all distribution levels;
- Retail trade with reimbursable drugs is not very attractive for significant part of pharmacies and the patients, especially in small cities and villages and distant and mountain areas, do not have direct and easy access to pharmacies, selling reimbursable drugs.

4. CPC case law in the pharmaceutical sector in Bulgaria

4.1 *Vertical integration in the pharmaceutical sector*

19. In 2008, with an opinion *Decision No 1/2008*, the CPC made an assessment of the compliance with the competition rules of the provisions of the Law on Medicinal Products in Human Medicine. One of the issues, analyzed by the Commission, was the ban on vertical integration (manufacturer-wholesaler-retailer). The CPC took the view that even though there are arguments in terms of creating economic efficiencies for the lack of such restriction, there are potential disadvantages of the vertical integration in the pharmaceutical sector. In particular the Commission pointed out that vertical integration could lead to creation/strengthening of dominant position by the integrated undertakings, which could abuse their position by different types of prohibited conduct – restriction of supplies to competitors, applying of discriminatory prices/conditions for sale, restriction of sales to only those products, produced or distributed by the group of undertakings, partition and/or foreclosure of the market(s), etc. Those potential negative effects of the vertical integration in the pharmaceutical sector could in their turn limit or prevent passing the efficiencies of the vertically integrated undertaking to patients, leading to more limited choice and/or higher prices of drugs for consumers, particularly in smaller towns and villages, where there is only one or two pharmacies. Thus, the CPC concluded that the restriction on vertical integration between manufacturer, wholesaler and retailer in the pharmaceutical sector is justified and necessary as it ensures diversity and better meets the needs of the consumers (patients).

20. The prohibition of vertical integration in the pharmaceutical sector is acting provision in the Bulgarian legislation. It should be noted though that in the course of several proceedings before the CPC there were opinions received from various parties with allegations for existence *de facto* of vertically integrated undertakings in the sector, even though strictly obeying the legal requirements for separation of activities.

4.2 *Manufacturing level*

4.2.1 *Criteria for reimbursement and time for start of reimbursement of original/innovative medicines*

21. In 2012 the CPC adopted two opinion decisions (***Decision No 1428/2012 and Decision No 1427/2012***) on the criteria for inclusion of original/innovative medicines in the Positive Medicines List and the effective start of reimbursement of those medicines by the NHIF.

22. The first decision concerned a provision in the Ordinance for the regulation and registration of the prices of medicines, requiring that in order to be included in the Positive Medicines List (PML) the medicine should be reimbursed in 5 out of 17 EU Member States⁸. The claims from the applicant stated, that this provision unjustifiably restrict and delay the entrance of original/innovative drugs to the Bulgarian reimbursement market.

23. The second decision concerned a provision from the Ordinance No 10 on the conditions and order for reimbursement of drugs, setting the period, after which NHIF starts the effective reimbursement of the medicines, included in the PML, of medicines, whose INN has not been reimbursed until then by the NHIF. At the initiation of the proceeding the period was 3 months, in the course of the investigation the period was increased to 6 months. The claimant stated that this longer period delays the access of Bulgarian patients to original/innovative drugs, which often do not have substitutes for treatment of certain diseases.

4.2.2 *Reference as condition for inclusion in the PML*

24. The motive pointed out for the introduction of this provision was that thus Bulgarian citizens are guaranteed to receive treatment with reimbursable drugs, that have proven to be effective and safe after their marketing authorization.

25. In its decision the CPC based its analysis on the characteristics of the EU market for original drugs, as described in the EC Pharmaceutical Sector Inquiry⁹ and the data on the Bulgarian pharmaceutical sector contained in the EC and the CPC inquiry.

26. The information obtained from the CPC showed, that referencing to other EU Member States as condition for the inclusion of a medicine for reimbursement exists only in Bulgaria and Romania, where the legislation requires that the drug has been reimbursed in 3 other EU Member States for a minimum of 1 year¹⁰. The CPC also analyzed the choice of reference countries as condition for the inclusion in the PML and reached the conclusion that this choice itself could affect the entry of original/innovative drugs to the reimbursement market in the country. The countries, to which the reference was made in the provision in the beginning of the proceeding, included 8 countries, and only one of them was in the first 10 most attractive markets (Spain), 3 were in the second ten most attractive reimbursement market (Greece, Portugal and Czech Republic) and 4 were behind Bulgaria in this list (Lithuania, Estonia, Hungary and Romania). With the amendment to the provision in the course of the provision, the list of the reference countries was extended to 17 and more countries from the top and the middle of the attractiveness list were

⁸ Romania, France, Estonia, Greece, Slovak Republic, Lithuania, Portugal, Spain, Belgium, Czech Republic, Poland, Latvia, Hungary, Italy, Finland, Denmark and Slovenia. It should be noted, that at the initiation of the proceeding before the CPC the provision required reimbursement in 3 out of 8 EU Member States.

⁹ <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

¹⁰ <http://www.musat.ro/pdf/capitoleeng2012/25-Pharmaceuticals.pdf> and a report "Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States" of the Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG), commissioned by the European Commission.

added, which, in the CPC view, made the access to Bulgarian reimbursement market more easily achievable, and therefore useless.

27. The Commission considered that the referencing as condition for the inclusion in the PML could not give additional value added to the assessment of the therapeutic efficiency of the medicine, apart from the other criteria used in Bulgaria, which to big extent are the same as in most of the other countries. On the other hand, having in mind the characteristics of the Bulgarian pharmaceutical market, in particular its small size, low general and public spending for drugs, the low reimbursement prices of the medicines in the country and the small attractiveness of the Bulgarian reimbursement market for the pharmaceutical manufacturers, it could be concluded that this condition might be restricting and delaying the access to the national reimbursement market for originators companies. Further to this, the Commission took the view that this condition favors the originator companies, whose medicines have already been included in the PML, thus creating barriers for entry of new drugs for the treatment of same disease.

28. In the CPC opinion the motive for the introduction of the provision is not based on the established procedures for assessing the efficacy and the safety of the medicines. The existing legal regime, providing both ex ante and ex post mechanisms for control of the safety of the medicines are well functioning and effective, so the referencing could not serve this objective.

4.2.3 *Start of the effective reimbursement of original medicines by NHIF*

29. The motive for the introduction of the provision was that the original medicines are very expensive and the start of their reimbursement by NHIF in the course of the financial year jeopardizes the budget of the fund for medicines.

30. The CPC analyzed in detail the duration of all stages, which should be passed by an original and a generic drug in order to get to point of effective reimbursement by NHIF. The three stages of the procedure include – getting market authorization, inclusion in the PML and start of reimbursement by NHIF. For the original medicines the cumulative time for the three stages takes up to 510 days (270 days maximum for getting market authorization from EMA, max. 60 days for getting included in the PML and 180 days after the inclusion into the PML to start effective reimbursement from NHIF). For the generics, the cumulative time is up to 286, including 240 days for getting market authorization under the national procedure, 30 days for getting the drug included in the PML and 2 to 16 days for the start of the effective reimbursement by the NHIF.

31. The data collected by the CPC during the investigation showed that the share of the expenses paid by the NHIF for newly included in the PML medicines is insignificant compared to the total budget of the fund for reimbursable drugs.

4.2.4 *Effects on competition of the two provisions*

32. The CPC considered that the cumulative effect of the two provisions (referencing and start of reimbursement) might lead to foreclosure of the national reimbursement market for new original medicines treating same diseases and discourages originator companies to enter this market. According to opinions received during the investigations, some respected originator companies have withdrawn from Bulgarian market.

33. Thus, the incumbent originator companies could benefit from the lack of competition, maximizing their profit to the detriment of the patients' interests. Moreover, the lack of competition, including price competition between original medicines, compromises the objective for effective spending of public funds for reimbursable medicines. Further to this, the delayed access of new original medicines to the national reimbursement market is directly favoring the potential competition to the originator

companies from the generic companies. Having also in mind that, according to the EC Pharmaceutical Sector Inquiry, the half of the 20 years of patent protection expires by the time the medicine gets market authorization, the originator companies have much less time to benefit from that protection as regards their presence in the Bulgarian reimbursement market. Those considerations led the CPC to the recommendation to the competent authorities to repeal the referencing as condition for inclusion of medicines to the PML and to reconsider the duration of the procedures to start effective reimbursement of original/innovative medicines in Bulgaria.

4.3 *Wholesale level*

34. In 2011 the CPC adopted two opinion Decisions on the Ordinance No 10 of 2009 on the conditions for the payment of the reimbursable drugs. The particular focus of those decisions were provisions, requiring that the market authorization holders should appoint *authorized distributors* for the specific product in the application for that drug to be reimbursed by the National Health Insurance Fund. Based on those provisions, the NHIF was required to create a code for each of the authorized distributors in the software product that is used on mandatory basis by all pharmacies that sell reimbursable drugs. Thus, the pharmacies could not sell reimbursed drugs supplied by non-authorized distributors, as they cannot enter the data for the sale in the NHIF software product and therefore cannot get paid for the specific drug.

35. In its decisions the CPC established that the above mentioned provisions restrict competition on wholesale and retail level in the market of reimbursable drugs. In particular, the Commission pointed out that the provisions in question create opportunities for the market authorization holders to unilaterally affect competition at distribution level, putting the authorized distributors at more favorable position and in fact excluding the other distributors from the wholesale reimbursement market of each particular drug. Thus, the intra-brand competition between the distributors of each particular drug is negatively affected, which could lead to fewer incentives for the authorized distributors to offer better terms and prices to the pharmacies. Further to this, the above mentioned provisions contradicted the general principle in the Law on Medicinal Products in Human Medicine, allowing all registered distributors to purchase drugs either from the market authorization holder or from other registered distributors. Another negative effect from the provisions of the Ordinance was considered to be the possibility for increase of the market concentration at wholesale level as a result of exclusionary conduct by the market authorization holder, leading to market partitioning and/or foreclosure of the market. The provisions in question, besides their direct negative effect on the wholesale level of market for reimbursable drugs, in the CPC opinion, might have indirectly affect the wholesale market of non-reimbursed drugs and the retail level. As regards retail level, the provisions restrict the choice of the pharmacies to get supplied by distributors that offer best terms and price (rebates and discounts). The CPC considered also that the motive, pointed out by the Ministry of Health for the introduction of this provisions, namely to guarantee constant supply and the quality of the medicines sold in Bulgaria, could be achieved not by restrictions of competition, but by stricter control by the competent authorities.

36. As a result of the first CPC decision, the Ministry of Health proposed amendment to the provisions, stating that the market authorization holders should appoint *at least two distributors*. The CPC adopted second decision with the above mentioned arguments, stating that the amendment did not remedy the competition concern. As a result of those two decisions of the Commission, the provisions in the Ordinance on the authorization of distributors for reimbursable drugs were completely repealed.

4.4 Retail level

4.4.1 Ownership of the pharmacies

37. With its opinion Decision No 1/2008 the CPC made an analysis of the (then acting) provision of the Law on Medicinal Products in Human Medicine, requiring that only master pharmacists have the right to open pharmacy and to perform retail trade with medicines for human use. In addition, the owner master pharmacist should be manager of the pharmacy and should work in it.

38. The CPC considered that the provision gives to master pharmacists the exclusive right to own and manage a pharmacy, which, by its nature is a qualitative restriction of competition. As a rule, the qualitative restrictions of competition aim at ensuring a certain minimum level for the quality of the service provided, but they limit the access to the relevant market. According the Commission, the pharmacies in their capacity of medical facility should ensure to the clients (patients) an adequate and competent information on the proper medicinal product, its use and dosage, side effects, etc. This requires that the activities of the pharmacies need to be subject to strict regulatory control. The control however should be not legal and organizational type of the ownership, but over the activities of the persons, dispensing medicines, therefore the legal provisions should require only that master pharmacists dispense medicines to the patients and manage stocks of drugs in the pharmacy.

39. The CPC held the view that tying the economic nature of the retail trade with drugs (ownership of the pharmacy and the economic risk borne by the owner) and the professional liability (the professional qualification needed to dispense drugs to patients) is inadmissible, as it creates barriers for entry to the market of retail trade with drugs, limiting the number of the pharmacies to the number of master pharmacists.

40. The CPC concluded that the requirement for only master pharmacists to own and manage pharmacies is qualitative and quantitative restriction of competition, which restrict and prevent market entry at the level of retail trade with drugs. Therefore, in the Commission's view, is not justified and objectively necessary in order to guarantee public interest. The more proportionate and adequate legal measures, aiming at guaranteeing public health and the interests of the patients would be providing for strict requirements medicines to be dispensed only by master pharmacists and imposing special rules for and control over the conditions (sanitary, personnel, etc.) for performing retail trade with drugs.

41. In 2008 the Constitutional Court proclaimed this provision is contrary to the Constitution of the Republic of Bulgaria (Art.19), restricting the constitutional guarantee for free economic initiative and protection against abuse of monopoly position and unfair competition, by limiting the entry to the market for new participants. The Constitutional Court also made distinction in this regard between the right to perform specific activity (dispense and sell drugs to patients), and the realization of the ownership rights, concluding that the requirement only master pharmacists to dispense drugs to patients does not contradict the Constitution. The decision of the Constitutional Court made the provision null and void. With an amendment to this provision of the Law on Medicinal Products in Human Medicine later in 2008 the provision was amended, allowing all natural and legal persons, registered in Bulgaria or in the EU, to own pharmacies.

4.4.2 Horizontal integration of pharmacies

42. The provision on the ownership of the pharmacies, discussed above, also restricted the ownership of pharmacy only to one such per person, thus imposing prohibition for horizontal integration in retail trade with drugs. In its Decision No 1/2008 the CPC also analyzed the benefits and negatives of horizontal integration in this market. According to the Commission, the prohibition aims at avowing the risks for

creation or strengthening of dominant position by chains of pharmacies, thus preventing and restricting effective competition in the market.

43. On the other hand the CPC considered, that the benefits of horizontal integration include encouraging investments, more diverse and quality services and products, realization of economies of scale, where part of the benefits, in terms of bigger choice, better services and lower prices would be passed to the patients as final consumers. The Commission also pointed out that the Law on Protection of Competition does include the necessary legal instruments to counteract eventual abuses of dominant position or other forms of prohibited behavior, including ex ante assessment in case of merger control.

44. Based on the above grounds, the CPC proposed the horizontal integration in the retail trade with medicines to be allowed.

45. With the amendment of the relevant provision of the Law in 2008, following the above mentioned decision of the Constitutional Court, the restriction of one owner – one pharmacy was repealed, but the new version limits the ownership of pharmacies to four per one owner, and this limitation is still in force.

4.4.3 *Minimum servicing time of prescriptions for reimbursable drugs*

46. With an opinion Decision No 507/2013 the CPC assessed the compatibility with the competition rules of the Sample Contract between the National Health Insurance Fund and the pharmacies, selling reimbursable drugs. Under Bulgarian national legislation, the NHIF annually, together with the representative organization of pharmacists in Bulgaria – the Bulgarian Pharmacist Union, agrees and adopts Sample contract to be signed with all pharmacies, willing to sell reimbursable drugs. The Sample contract includes general conditions, applicable to all pharmacies that cannot be further negotiated and changed.

47. The Sample contract for the year 2013 included new provisions requiring from the pharmacies to apply minimum time for servicing prescriptions for reimbursable drugs, providing that reimbursable drugs sold that exceed the quantities calculated according to a formula would not be paid by the NHIF to the pharmacies. The formula contained minimum time for servicing prescriptions and protocols for reimbursable drugs (6 and 9 min.), the number of master pharmacists, working in the pharmacy, their working time, depending on the fact if they were owners of the pharmacy or hired.

48. In its analysis the CPC established that applying the above mentioned provisions in fact impose quota limitations on retail trade with reimbursable drugs, as applying the formula actually sets *de facto* a maximum number of prescriptions for reimbursable drugs that could be served by a particular pharmacy in a month. The Commission pointed out that such limitation contradicts the core of the concepts of free competition, which is based on the autonomous behavior of the undertakings in the relevant market and competitive fight between them, aiming at gaining higher market share. The provisions in question lead to partitioning of the market, depriving the more efficient pharmacies from the possibility to benefit from their efforts and increased sales and favoring inefficient competitors, which would enjoy reserved volume of sales, regardless of the quality of their services. Thus, the provisions in question would administratively redistribute the retail market for reimbursable drugs between efficient and non-efficient pharmacies. Bearing in mind that patients tend to buy all drugs (reimbursable and non-reimbursable, prescription and OTC drugs) from the pharmacy of their choice, the provisions of the Sample contract might negatively affect not only retail market of reimbursable drugs, but free prescription and OTC markets as well.

49. In addition, the differentiation in the formula between the hired master pharmacists and the master pharmacists, who are both owners and working in the pharmacy (coefficient 1 for the first and 1,5

for the latter) in fact favor certain pharmacies depending of their ownership. The CPC considered that such discriminatory regime contradicts the competition rules. Furthermore, in case a single pharmacy, owned by a master pharmacist, proves to be efficient, the natural economic logic would lead this owner to widen its activities, opening other pharmacies (up to the legally set limitation of 4 pharmacies) and realizing economies of scale. The formula in question however would deprive this undertaking from the economic incentives to do so, as the next three pharmacies could not gain from the benefits of the 50% increased quota for sales.

50. The CPC evaluated the effects on the patients of the provisions in the Sample contract. The Commission considered that those provisions would deprive the patients from their right to choose pharmacy and would make their access to reimbursable drugs more difficult, as they would have to search for a pharmacy that has not reached the monthly quota of sales.

51. The Commission also discussed the motives for introducing the provisions in question, which could be summarized as follows: ensuring high quality of service (consulting, etc.) for reimbursable drugs, including through hiring more master pharmacist, and counter fighting some reported practices of selling drugs not by pharmacies. The CPC took the view that the above mentioned objectives could be achieved by more stringent control over the activities of the drug retailers, but not with restrictions of competition.

52. The provisions of Sample contract for 2012 between NHIF and pharmacies never came into effect, as in a parallel proceeding they were appealed before the Supreme Administrative Court, and finally repealed by the court, about a month after the CPC decision, but based on procedural grounds.

4.4.4 *Payment to pharmacies for 100% reimbursed drugs*

53. With opinion Decision No 676/2012 the CPC evaluated the compliance with competition rules of a provision of the Ordinance on the regulation and the registration of the prices of the medicines. The provision in question sets that the retailers of 100% reimbursable drugs receive a payment from NHIF for the sale of those drugs only 2 BGR (~1 Euro) per prescription instead of legally set surcharges (22%, 20% or 18% of the manufacturers' price for each dispensed medicine depending on its price) for all other, including reimbursable, drugs. Each prescription for 100% reimbursable drugs could contain up to three different medicines. NHIF pays the pharmacies 30 days after they send their report, which is made twice monthly.

54. 100% reimbursed medicines in Bulgaria are the drugs for treatment of HIV, of infectious diseases, for the mandatory vaccines, special serums and immunoglobulins, as well as the medicines for very serious chronic diseases, leading to strong worsening of the quality of life or to disability. As a rule, those medicines are very expensive and/or often there are few, if any, generics.

55. The motives for the introduction of this provision are: to balance and spent effectively the NHIF budget and for the patients not to co-pay certain percentage for the medicines, which would restrict their access to those drugs.

56. In its decision the CPC took into consideration those legitimate objectives of the provision in question. On the other hand, the Commission reached a conclusion that the negative effects of the provision on competition in fact lead to restriction of access to 100% reimbursable drugs for the patients. In particular, the CPC took the view that with this provision the state imposes on the pharmacies the social function of dispensing the medicines to patients only for payment of small tax, which contradicts the nature of the drug retailers as undertakings, working for profit. At the same time, the other distribution levels of those drugs (manufacturers and wholesalers) receive their normative surcharge (profit). Thus, the pharmacies, which take the economic risk as undertakings of buying and paying those drugs from the

wholesalers, are deprived of their legitimate expectation to earn profit in their private interest from this activity for the benefit of other (patients). In addition, the time period between the purchases of those drugs from the wholesalers and the reimbursement of the 1 Euro tax per prescription by NHIF may reach 51 days, while the payment of VAT to tax administration should be made by the pharmacies on average 29 days after the purchase. For the pharmacies this means they have to attract additional financial resources in order to “sell” those drugs, because, in difference with the 25%, 50% or 75% reimbursable drugs, the retailers don’t receive any partial payment by the patients, which could be used for further purchases of medicines and other expenses until the payment by NHIF much later. The CPC noted, that the pharmacies could receive rebates and discounts and/or delayed payment terms for those drugs from the retailers, but such a possibility depends on the will and the commercial policy of the distributors.

57. Therefore, in the CPC opinion, this provision strongly discourages the pharmacies to sell 100% reimbursable drugs, which conclusion was proven by the fact that only 25% of all registered pharmacies sell those drugs and in ~15% of Bulgarian municipalities there is not a single pharmacy, selling those drugs. Accordingly, the patients from those areas are forced to travel and to incur the corresponding costs in order to get their medicines, which have to be 100% reimbursed. The CPC considered that in this case the price regulation for 100% reimbursable drugs deprives the pharmacies from incentives to sell those drugs, drives them out of this market, which, in the final analysis limits the access of the patients to 100% reimbursable drugs. The Commission recommended to the competent authorities to discuss and find a solution, which will not restrict competition and will balance the interests of all stakeholders (NHIF, the distribution chain and the patients).

5. Conclusion

58. As it could be seen from the CPC cases described above, the Commission has adopted very proactive approach to competition problems arising from the legal framework, governing pharmaceutical sector in Bulgaria. In few cases the CPC opinions were taken into account.

59. Still, in the CPC view, several other problems remain, that require intensive public debate, especially as regards the reimbursement policy for medicines. As the reimbursement of medicines is an area that focuses several public policies – protection of citizens health, effective spending of public resources and competition policy, such a debate should reach a decision on what areas should remain reserved for regulation and to what extent the free competition should be left to create benefits for the society. The Bulgarian Commission on Protection of Competition considers that widening the scope for competition in the pharmaceutical sector may well facilitate the achievement of the other legitimate public policies and more scope for application of competition law rules.