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

16-May-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/WD(2014)43
Unclassified

GENERIC PHARMACEUTICALS

-- Note by Bulgaria --

18-19 June 2014

This note is submitted by Bulgaria to the Competition Committee FOR DISCUSSION under Item VI of the agenda at its forthcoming meeting to be held on 18-19 June 2014.

JT03357407

English - Or. English

1. Pharmaceutical market in Bulgaria

1. In terms of statistical data, based on the information, received by the Bulgarian Commission on Protection of competition /CPC/ during its investigations of the sector, the economic background of the pharmaceutical sector in Bulgaria shows the following:

2. 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, Estonia and Malta being behind it[1]. 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 GDP[2]. 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 persons[3]. 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 States[4].

3. 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.

4. 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.

2. Reasons for the higher market share of generic pharmaceuticals in BG

5. As it was already mentioned the generic pharmaceuticals have higher market share than the original medicines in respect of number of units and volume of sales. Taking into account the conclusions, made by the CPC in its practice, this situation is due to the following reasons:

- The existing medicine manufacturing facilities in Bulgaria produce only generics;
- The national legislation establishes higher requirements for entering the market of original pharmaceuticals in comparison to the generic medicines;
- The low income of the population;
- 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.

---

1 See http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

2 See CPC Sector Inquiry of Pharmaceutical Sector.

3 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

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

3. Barriers to entry the pharmaceutical market

6. The Bulgarian legal framework on the use and trade with medicines for human use is to a significant extent 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.

7. 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. In general the original pharmaceuticals are authorized by EMA, while the generic drugs are usually authorized through the national procedure.

4. The CPC case law

8. In its practice the CPC has found that the national legislation establishes higher administrative barriers to entering the market of the original drugs in comparison to the generic pharmaceuticals. In particular, the CPC considered that the procedure for inclusion in the Positive Medicine List /PML/ and the terms for start of the effective reimbursement in Bulgaria is simplified and shorter for the generic pharmaceuticals in comparison to the procedure for original medicines.

9. In this respect 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 PML and the effective start of reimbursement of those medicines by the National Health Insurance Fund /NHIF/.

10. 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 PML the medicine should be reimbursed in 5 out of 17 EU Member States[5]. The claims from the applicant stated, that this provision unjustifiably restrict and delay the entrance of original/innovative drugs to the Bulgarian reimbursement market. 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.

11. 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. According to the Ministry of Health 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.

4.1 Reference as condition for inclusion in the PML

12. The CPC determined that the requirement for 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

[5] 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.

year[6]. 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.

13. 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.

14. In practice this requirement for referencing is not applicable as regards the generic pharmaceuticals, which facilitates their entering to the Bulgarian market. The referencing as a condition for inclusion in the PML is done by the international non-proprietary name (INN) recommended by the WHO. As the generic pharmaceuticals have the same INN as the original products, referencing is not required for drugs, whose INN already exists in the PML.

4.2 Start of the effective reimbursement by NHIF

15. 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.

16. Within one calendar year NHIF updates 2 times a month or 24 times per year, the information of the included in the PML generic drugs and their effective reimbursement begins with the same frequency. In respect of the original medicines within one calendar year NHIF updates 2 times per year the information in the PML and the effective reimbursement of original medicines begins twice a year. Thus the national legislation provides competitive advantage to the generic drugs.

4.3 Effects on competition

17. 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.

---

6 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 Gesuntheitswesen (ÖBIG), commissioned by the European Commission.

18. Further to this, the CPC considered that 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.

4.4 Prescription and sale of medicines

19. 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. Conclusion

20. By establishing higher barriers to entering the national reimbursement market the Bulgarian legal framework is directly favoring the potential competition to the originator companies from the generic companies, which already have higher market share. This situation in combination with other factors like the low income of the population and the small volume of sales in the pharmaceutical market in Bulgaria discourage originators/ innovative companies to enter the national market. This could negatively affect the interests of the patients, whose access to original medicinal products may be restricted.