



REPUBLIC OF BULGARIA

NATIONAL COUNCIL FOR PRICING AND REIMBURSEMENT OF THE MEDICINAL PRODUCTS

Sofia 1431, "Ivan Geshov" №15
tel.: (+359 2) 8953 102, fax:(+359 2) 8953 157

office@ncpr.bg
www.ncpr.bg

Registration № 75-00-173/12.-6.2014

OPINION OF THE NATIONAL COUNCIL ON THE TWO REPORTAGES ON BNT "PO SVETA I U NAS" (WORLD AND DOMESTIC NEWS)

In connection with the two reportages of the healthcare journalist Mrs. Maria Cherneva in the "Po Sveta i u Nas" (World and Domestic news) emission on the Bulgarian National Television on 8 and 10 June 2014 entitled "Absurd in Drug Policy" with the participation of a representative of a pharmaceutical company, we hereby express the following opinion of ours:

The National Council on Prices and Reimbursement of Medicinal Products categorically refutes the data reported in the central news of the Bulgarian National Television on 8 June 2014, 20:18, by the healthcare journalist Maria Cherneva in the "Po sveta i u nas" (World and Domestic News) entitled "An Absurd in Drug Policy".

The used qualification "a next absurd in drug policy" discredit the regulatory authority National Council on Prices and Reimbursement of Medicinal Products and its administration.

The broadcasted reportage creates intimations and misleads the public with unproven facts that the National Council "at present has no opinion on the case". This statement is incorrect in view of the fact that no opinion of the National Council has been sought prior to the broadcast of the reportage on 8 June 2014. The question of Mrs. Cherneva was received in NCPMP by a letter 61-00-57/09.06.2014, just only on 09.06.2014.

On 09.06.2014, the National Council filed its opinion in the Ministry of Health under incoming № 61-00-57/10.06.2014 where the comments on the opinion were not included in the content of the second reportage (10.06.2014, 20 hrs).

In the annexes to the said opinion, we also provided a letter of the National Council № 04-00-388/29.05.2014 to MH and NHIF relating to the price decrease of nine oncology medicines applied for, where we appealed in advance to set up a meeting with the applicant "Accord Healthcare" Dr. Iva Hristova, in view of the experience with other generic medicinal products where the prices have been decreased and, in certain cases, the necessary quantities have not been provided.

In connection with its full transparency policy in the conducting administrative procedures, the National Council has established an organisation for access to the latest information relating to the procedures applied for which is publically available on the web-site of the Council, so the National Council has implemented a policy of full transparency and publicity in the fulfilment of the administrative procedures. In so far as it concerns the procedures received in the Council on 22.04.2014, no demand for information in any of the ways provided on the NCPMP web-site has been received. Instead, the Council was directly attacked via a national medium, the BNT, and had been exceptionally adversely covered.

The reference performed in the Council's registers shows that all applications

submitted in the month of April have been duly reviewed in the legal timelines which is obvious from the information under heading “Sessions” on the Council’s web-site. Under this heading, an excerpt of the decisions taken on 29.05.2014 has been loaded on 30.05.2014, point 4. Apparent from the above, the Council has pronounced within the legal timelines (30 days), i.e. 8 days prior to the reportage broadcast on BTV), whereas it should be taken into consideration that in the course of the procedure under Regulation additional information has been requested from the applicant and in such case the time stops to run.

The person taking part in the reportage does not possess the capacity of “applicant” in the sense of the Regulation and has not prided the Council of a letter of attorney as to the effect of been able to represent any pharmaceutical company whatsoever which has applied for procedures on 22.04.2014. The reference made in the Council’s registers show that all applications submitted in April have been duly processed in the legal timelines.

The claim that the Council creates obstacles for the participation of pharmaceutical companies in tenders for oncology medicinal products in health establishments is unreasonable since the Council regulates the ceiling prices of medicinal products and the sale, participation in tenders respectively, with prices under the ceiling prices is allowable and not subject to sanctions. In other words, no obstacle exists as to medicinal products being sold under the ceiling prices on the territory of the Republic of Bulgaria.

In connection with the position expressed and concern from the part of MH and CITUB (Confederation of Independent Trade Unions in Bulgaria), NCPRMP allowed preliminary implementation of the decisions after coordination with NHIF for the decrease of the prices of the 9 oncology medicines applied for on 22.04.2014, which shall be reflected in the Positive Drug List at its update on 16.06.2014.

Sincerely,
PROF. TATYANA BENISHEVA, DSC
PRESIDENT
(Signed – signature illegible)