



«Innovation for Patients»

Quarterly Bulletin of the Association of Pharmaceutical Research and Development

January – March 2010

JANUARY

In January, the Association's representatives continued lobbying amendments to Resolution No. 902 "On Approval of the Procedure for Exercising State Control over the Quality of Medicines Imported into Ukraine", and Resolution No. 610 "The Procedure for Medicine Sampling for State Control over Medicine Quality", adopted by the Cabinet of Ministers of Ukraine, which were developed in the last ten days in 2009 by the Working Group at the State Committee for Regulatory Policy and Entrepreneurship (SCRPE). In spite of the strong resistance from certain officials, the representatives of the pharmaceutical community managed to convey the necessary information about the urgent need to reform the quality control system to the key functionaries of the Cabinet of Ministers. The Healthcare System Reform Council, whose member is *Yuriy Savko*, the Association's Executive Director, evolved into a very effective tool for such communication. In view of the specific nature of the activities of the Cabinet of Ministers during the pre-election period, we managed to capture the attention of *Mr. Pavlo Kondyk*, Deputy Minister of the Cabinet of Ministers, inform him about the most pressing issues associated with regulating the circulation of pharmaceuticals, and describe our perspective on possible ways to solve such problems. APraD's application and vigorous assistance provided by *Ms. Oleksandra Kuzhel*, Chairperson of the SCRPE, were instrumental in organizing focused discussions of amendments to Resolutions No. 902 and 610 with the participation of the

management of the State Inspection for Medicine Quality Control (SIMQC). In this connection, it is necessary to point out that in the last 6 months of the past year all attempts by pharmaceutical associations to initiate any open dialogue directly with the SIMQC were doomed to failure because of the unconstructive attitude adopted by this agency's management.

A member of the Association, Bayer Schering Pharma, faced a flagrant violation of the company's intellectual property rights during a procurement tender after the enactment of the Law of Ukraine No. 1758-VI "On the Introduction of Amendments to the Law of Ukraine 'On the National Budget of Ukraine for 2009' with Regard to Financing Actions Aimed at Combating the Influenza Epidemic". On December 25, 2009, the company filed its bid with the tender committee in compliance with the required form and established deadlines. In view of the then-current epidemiological situation in the country, the company offered special prices on Avelox[®]. As early as on December 26, 2009, it was announced that based on the results of the tender, the winning bid was awarded to a copy of the bidder's *moxifloxacin* manufactured by AllMed International Inc., packaged in bulk by Alcon Parenterals (India) Ltd., India, Pharmaceutical Company Zdorovya LLC.

Immediately after the Association was informed by Bayer Schering Pharma about this gross violation of Ukrainian intellectual property protection laws, APraD sent a letter to the Delegation of the European Commission in Ukraine. In its letter, the Association informed the Delegation about the above-mentioned event and requested its assistance in addressing this issue of concern. In addition, the Association's Executive Director requested an urgent meeting with the Delegation's Section for Trade and Economy (headed by *Ms. Ulrike Hauer*, principal economist: *Ms. Oksana Popruga*), where he gave detailed information about the violation.

On January 15, APraD's Strategic Group on intellectual property rights protection held an extraordinary meeting to discuss the situation with Avelox, as well as to debate possible joint actions to be undertaken by the Association's members. It was resolved to create the APraD's database of violations of its members' intellectual property rights. In addition, persons in charge of the Strategic Group's activities were elected at the meeting: *Ms.*

Maryna Buchma (GlaxoSmithKlein) and *Mr. Viitaliy Hordiyenko* (Abbott) were appointed Co-Chairpersons.

To solve the problem posed by *Resolution No. 1335 of the Cabinet of Ministers of Ukraine, dated December 8, 2009, "On the Introduction of Amendments to Certain Resolutions of the Cabinet of Ministers of Ukraine"*, which introduced amendments to the process of purchasing goods, works and services at the expense of state funds, Yuriy Savko, the Association's Executive Director, addressed the Minister of Economic Affairs, *Mr. Bohdan Danylyshyn*, at the public session of the Cabinet of Ministers on January 13, 2010. The Executive Director of APRaD highlighted the pressing nature of the issue and reminded the Minister of the relevant letter addressed by the Association to the Prime-Minister, *Ms. Tymoshenko*, in late December. According to Minister Danylyshyn, his Ministry was at the time preparing proposals pertaining to amendments to the above-mentioned resolution, which were eventually put forward within the next few days.

FEBRUARY

In February, APRaD proceeded with its active informational and expert work related to amendments to Resolutions No. 902 and 610 of the Cabinet of Ministers of Ukraine in the context of the activities of the Working Group at the SCRPE and the Healthcare System Reform Council at the Cabinet of Ministers of Ukraine. APRaD's representatives participated in more than 10 meetings and sessions at the Ministry of Healthcare of Ukraine, the Ministry of Economic Affairs and the Cabinet of Ministers; new revisions of updated draft documents were sent for consideration by the senior officials of the Ministry of Healthcare and the SIMQC. *More than six-month-long efforts of the activists of APRaD and other professional associations culminated in the enactment by the Cabinet of Ministers of amendments to Resolutions No. 902 and 610 of the Cabinet of Ministers of Ukraine* (revised versions issued under No. 261 and 260 respectively) in February 2010.

In view of the interpretation letter issued by the Deputy Chairman of the SIMQC, *Mr. Andriy Zaharash*, with regard to the companies' obligation to submit **standard samples** for analysis of pharmaceuticals, the Association requested Mr Pavlo Kondyk, Deputy Minister of the Cabinet of Ministers, to facilitate the settlement of the issue. The crux of the matter is that there is no legal framework in Ukraine to regulate the import of standard samples for laboratory analysis. This results in a conflict: pharmaceutical companies raise no objections to submitting such samples to the SIMQC for laboratory analysis; however, the State Customs Service of Ukraine does not allow the samples to enter Ukraine due to the absence of the relevant regulatory document. Under instructions from the Deputy Minister of the Cabinet of Ministers, a Working Group headed by *Mr. Kostiantyn Kuryshchuk*, Deputy Minister of the Ministry of Healthcare of Ukraine, was established to develop the relevant regulatory document. **Anna Pogodaeva (Delta Medical)** joined this working group on behalf of the Association.

The 3rd Meeting of Ukrainian Pharmaceutical Associations was held on February 8. Among other things, its participants reviewed the most recent drafts of legislative documents related to the regulation of prices on pharmaceuticals, developed by the SIMQC. In addition, the participants engaged in an extensive discussion concerning the draft Law on Medicines, submitted to the relevant committee of the Verkhovna Rada by *Mr. Zhebrivskyi, People's Deputy*. The participants of the meeting resolved: a) to resume work on the redraft of the Law which commenced in July 2009 but was later suspended owing to the situation with the Moratorium on pharmaceutical price hikes; and b) to request People's Deputy Zhebrivskyi to postpone the consideration of his draft law until it has been analyzed by the professional pharmaceutical community in more detail.

MARCH

The most significant event in early March was **the official publication of Resolutions No. 260 and 261 of the Cabinet of Ministers of Ukraine (former Resolutions No. 610 and 902 as amended)**. This represented the enactment of new transparent procedures for medicine quality control

during the importation of pharmaceuticals into Ukraine. Moreover, this marked the first significant joint victory of the pharmaceutical community in the present year. It is important to highlight the fact that the eight-month-long work on the amendments to the above-mentioned resolutions represented yet another step towards the consolidation of Ukrainian professional and business associations. It should also be noted that it was the Association's representatives, Anna Pogodaeva and Arkadiy Lytvak, who initiated these regulatory changes and became perhaps the most important driving force behind them.

Another challenge for pharmaceutical associations was the enactment of **Order No. 130 of the State Customs Service of Ukraine on the establishment of the "Excise" customs station**. Thus, paragraph 2 of the above-mentioned Order was used to supplement clause 3.1 of Order No. 991 of the State Customs Service of Ukraine dated September 10, 2008, also supplementing the list of goods subject to customs control and customs clearance to be exercised by the Kyiv Central Specialized Customs, namely: alcoholic beverages, tobacco goods and pharmaceutical products. Order No. 130 was to have taken effect on March 30, 2010.

The implementation of the provisions of this Order gave rise to considerable concern among the Association's members, as it could cause significant problems associated with its further implementation due to: a) the absence at the "Excise" customs station of special facilities for the handling and storage of pharmaceuticals which require temperature control; b) increased duration of customs clearance and inconsistency of customs procedures; c) increased financial expenses incurred by entities engaged in foreign economic activities. APRaD sent a letter to the *management of the State Customs Service of Ukraine* and the Chairman of the SCRPE, *Mr. Brodskiy*, requesting them to cancel the Order in view of the fact that it failed to comply with the current legislation and obstructed foreign economic activities.

It ought to be noted that the *Association of Distributors PharmUkraine* and the *American Chamber of Commerce in Ukraine* became APRaD's main allies and partners in their attempts to tackle the problems posed by Order

No. 130. Due to joint actions undertaken together with the Association PharmUkraine we managed to secure the establishment of a working group at the State Customs Service to examine the issues associated with the new procedures for the customs clearance of pharmaceuticals. Only three representatives from market participants (distributors) and two representatives from professional associations: *Denys Shevchenko*, Executive Director of PharmUkraine, and *Yuriy Savko*, Executive Director of APRaD, became members of the working group.

In addition, APRaD sent an urgent request to the Delegation of the European Commission in Ukraine (the Section for Trade and Economy), seeking its assistance in solving the new problem encountered by pharmaceutical importers. In our request we used the legal analysis of the Order and its potential consequences, conducted by the American Chamber of Commerce in Ukraine (by courtesy of the Chamber's representatives). The Delegation of the EC responded promptly to our request: two days later *Ms. Ulrike Hauer*, head of the Section for Trade and Economy of the Delegation, requested a meeting with the then-new management of the State Customs Service of Ukraine. The European Commission's prompt response to our request and its timely intervention supplemented the efforts exerted by APRaD and the Association PharmUkraine and aimed at abolishing this regulatory document: it was cancelled by the Order of the State Customs Service of Ukraine dated March 14, 2010, together with the liquidation of the newly established "Excise" customs station.

Another positive outcome of this joint campaign undertaken by APRaD and the Association of Distributors PharmUkraine was the establishment at the State Customs Service of a working group of logistics specialists aimed at examining customs clearance procedures applicable to pharmaceutical products and developing recommendations concerning their simplification. *Mr. Andriy Yudin (Delta Medical)* joined this working group as a representative from APRaD.

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