to Republic Ministry of health of Serbia. In next regulatory step, after getting demand of Ministry of health of Serbia, ALIMS experts have to re-evaluate all registration documentation and their own decision in order to issue final decision.
Disclosure of Interest: None declared.

PP249—BRINAVESS® – ARGUMENTS OF REGULATORY SUSPENSION IN SERBIA

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Introduction: BRINAVESS® /vernakalant/ is an antiarrhythmic medicine that acts preferentially in the atria to prolong atrial refractoriness and to rate dependently slow impulse. Anatomical Therapeutic Chemical Classification/ATC/ is: C01BG11.

Patients (or Materials) and Methods: According to Serbian Law on Medicinal Products and Medical Devices, regulatory procedural steps taken for getting Marketing Authorisation Approval in Serbia, started on 2011 year.

Results: After evaluation and reevaluation of submitted documentation/Module 1-5 Common Technical Documentation, Advising Working Group for medicinal products of Medicines and Medical Devices Agency of Serbia suggested refusal application. On June 2012,year ALIMS issued the final decision/No. 515-01-0020-11-003/ about refusal registration. The reasons are related to divergence of facts cited in Summary Product Characteristics and pre-registration clinical trials’ results devoted to efficacy, safety, statistical significance of total number of patients included in clinical phase of drug development, as well as suspicion about the drug quality. Although the applicant declared that specified impurity limits in active substance are in accordance with preclinical toxicological testing, these results did not exist in Drug Master File, so the ALIMS assessor concluded that this applicant’s statement is not true.

Conclusion: Impossibility to submit additional relevant regulatory data caused applicant’s claim on March 2013.year for withdrawing registration of BRINAVESS® in Serbia.
Disclosure of Interest: None declared.

PP252—ETHICS OF RELATIONSHIPS IN THE SPHERE OF PHARMACEUTICAL SERVICES

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Introduction: Study of ethical aspects of relationships of pharmacists and patients during rendering of pharmaceutical services for the purpose of improving effectiveness and safety of pharmacotherapy of patients.

Patients (or Materials) and Methods: A social poll using a method of selective anonymous survey of pharmacists and customers. The objects of research were the chemist’s shops of the city of Bishkek determined randomly. The analysis is based on the survey of 121 pharmacists and 207 patients. The pharmacists were 45 (37.2%) specialists with university education and 76 (62.8%) with college education, the average age was 31.4 and the work of experience in pharmacy was 7.2 years. The patients were respondents older 18 years old. The age distribution was 28.8% for 18–27; 34.6% for 28–37; 9.7% for 38–47; 22.7% for 48–57 and 4.2% for older 60. In terms of gender, the customers broke down into 133 (64.3%) female and 76 (35.7%) male. 43.3% of them had a university education, 32.7% had a college education, and 21.9% were students. The received data were processed with the help of specialized SPSS statistical software package.

Results: According to the processed data most pharmacists (72.7%) know about the Code of Ethics for pharmacy practice and its contents. All specialists (100%) admit that customers have the right to receive the information about the medicine they buy. As pharmacists note (64.5%), customers are most often interested in dosage and proper use of medicines. 63.6% of patients need professional assistance when they choose a medicine. However, 27.1% of patients say pharmacists give consultations reluctantly. In the course of the research, customers of the chemist’s shops were suggested to evaluate some indices reflecting the degree of their satisfaction by pharmacists’ work (10-point scale). The average evaluation of the indices, such as appearance, consideration, tactfulness, patience and the ability to turn medical notions into plain language was 7.5. According to 23.4% of pharmacists the most often reason of conflicts in chemist’s shops is patients’ dissatisfaction with a price of a medicine. This is confirmed by 67.7% patients thinking that most pharmacists are oriented for selling expensive and advertised medicines regardless of other affordable generics which do not concede in quality and effectiveness.

Conclusion: The research has revealed significant gaps in professional ethics of pharmacists. This allows us to make a conclusion that measures of interference in relationships of pharmacists and patients in the process of rendering pharmaceutical services need to be taken.
Disclosure of Interest: None declared.

PP255—IFN-GAMMA INTERFERE THE EFFECT OF BETA-2 AGONIST ON TNF-ALPHA INDUCED CXCL10 THROUGH CREB PHOSPHORYLATION IN HASM CELLS

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Introduction: CXCL10 is a potent mast cell chemotactant responsible for the mast cell eosinophilia characteristic of asthma. We have identified human airway smooth muscle (HASM) as a rich source of CXCL10 which is increased by TNF-alpha and IFN-gamma. We have previously shown that beta-agonists inhibit TNF-alpha induced CXCL10 release but the effect is lost when IFN-gamma is given concomitantly through poorly defined mechanisms. Here we defined the mechanism involved.

Patients (or Materials) and Methods: HASM cells taken from 3 normal donors were cultured using standard techniques. ELISA was used for quantitative measurement of CXCL10 release. Cyclic AMP assay was used to measure the cAMP level. Western Blot was used to indicate CREB phosphorylation.

Results: We found that salmeterol time dependently increased CAMP generation. TNF-alpha or IFN-gamma alone or in combination had similar effects on salmeterol time dependently induced CAMP generation suggesting that the inhibitory effect of IFN-gamma on beta-2 agonist signaling was not at the level of CAMP generation but rather was likely to be an effect on downstream signaling pathways. Next we looked at the phosphorylation of CREB by Western blot and found that salmeterol and caused phosphorylation of CREB but this was differentially affected by the cytokines. Whereas TNF-alpha