



Association of Bulgarian Pharmaceutical Manufacturers

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Position paper

New Bulgarian pharmaceutical legislation: Challenges for contributing to sustainability and free competition in an enlarged European Union

Introduction

The Bulgarian pharmaceutical legislation has recently gone through a period of major change regarding implementation of European pharmaceutical legislation and Directive 2004/27/EC amending Directive 2001/82/EC. As a consequence, the new Medicinal Products in Humane Medicine Act is to be welcomed as a follow-up process of the harmonization of the Medicinal Products and Pharmacies in Humane Medicine Act, adopted by the National Assembly in December 2002, which has successfully implemented Directive 2001/82/EC.

The new legislation greatly increases patients' accessibility to both innovative and generic medicines, and ensures a safe regulatory environment for all citizens. *However it fails to address certain provisions of EC treaty like freedom of establishment and free movement of capital and important European Commission recommendations regarding free competition and sustainability of the internal market.*

1. Pricing of medicinal products

The new medicines legislation is to impose a ban on free pricing of non-reimbursed prescription medicines in contradiction with Recommendation 6 of the G10 High Level Group on innovation and provision of medicines action report (07 May 2002), stating that *"Member States should secure the principle that a Member State's authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets."*

Regarding Recommendation 3 of the G10 High level Group, the new medicines legislation provide improvement of time taken between the granting of a marketing authorisation and pricing and reimbursement decisions in consistency with EU Transparency Directive and by merging the positive and the reimbursement lists existing in the country into a single formulary.

Also the new Bulgarian medicines legislation *implements the relevant intellectual property rights provisions for data exclusivity and Bolar* to ensure an appropriate balance between innovative and generic medicines, but still *fails to secure the development of a competitive generic market in Europe "by exploring ways of increasing generic penetration in individual markets, including generic prescribing and substitution"* as in Recommendation 2 and Recommendation 4 of the G10 report.

2. Pharmacies ownership structure

Although the new Bulgarian medicines legislation introduces more transparency in terms of pharmacists control and responsibility by implementing provisions for pharmacists to be registered as legal entities under the national Trade Law, the ownership of a pharmacy remains restricted only to the pharmacists themselves.

However the control and the ownership of a pharmacy are totally separate issues. There is no question that a pharmacy must be under the professional control of a pharmacist who is legally responsible to dispense medicines to patients irrespective of the owner.

The restriction of ownership constitutes an infringement of the Articles 43 and 56 of the EC Treaty concerning freedom of establishment and free movement of capital within the EU, as stated in the EU decision "Internal market: infringement proceedings concerning Italy, Austria and Spain with regard to pharmacies" from 28 June 2006 to take Italy to the Court of Justice on account of restrictions imposed by its national legislation on the acquisition of holdings in and ownership of retail pharmacies, and to make a formal request to Austria and Spain to amend their national rules relating to the setting-up of pharmacies.

As the EU Decision continues, "these three infringement procedures concern a series of existing national restrictions relating to the opening and running of pharmacies, such as: incompatibility between the distribution and the retail sale of pharmaceutical products; ownership of pharmacies reserved for pharmacists; ... ban on owning more than one pharmacy; mandatory legal forms for pharmacies", etc.

The EU commission also states that "prohibiting non-pharmacists or legal entities not consisting of pharmacists from having holdings in pharmacies also goes beyond what is necessary to achieve the objective of public health protection, since it would be sufficient to require the presence of a pharmacist to dispense medicines to patients or for stock management."

Changes under the new Bulgarian medicines legislation introduce discriminatory measures. The restriction of pharmacies ownership only to pharmacists on the bases of a single educational criterion, actively discriminates against all other individuals and legal entities based in the European community.

3. Implementation of the new medicines legislation regarding manufacturing licenses

The new medicines legislation implements the EU legislation regarding manufacturing and GMP requirements and provide for the process of gradually updating the manufacturing licenses granted under the current legislation being amended.

However a potential late amendment has been proposed which could lead to current manufacturing licences being terminated a year after the law comes into effect.

The proposed licence revocations are "unprecedented" among member states implementing the revised European Union pharmaceuticals legislation, and may lead to infringement of legally granted rights.

Therefore sufficient attention and monitoring on this issue should be carried out by the state in order to secure the proper implementation of the EU legislation regarding respecting local manufacturers' rights and manufacturing authorizations granted under the current legislation.

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