

Article by Larry Butler, Principal Deputy High Representative: “Parliamentarians Can Make Safe Medicine Universally Available”

The BiH pharmaceutical market is fragmented. The Federation and the RS have different laws and rules governing the manufacture and wholesale of pharmaceuticals and medical devices, while Brcko District has none. This means that safeguards related to the pharmaceuticals market in BiH are inadequate.

The result is that medicine in Bosnia and Herzegovina costs more than it should, and this year has been a major factor in your higher cost of living; some medicines commonly prescribed elsewhere in Europe are unavailable in this country; and inspections of the drugs that *are* available are inadequate.

In short, medicines that people need they can't get, and medicines that people *can* get are often overpriced and of suspect quality.

To address these problems, pharmaceutical and legal experts delegated by the State, Entities and Brcko District and fully supported by the International Community have agreed on the text of a single Law on Pharmaceuticals and Medical Devices for the entire country. This Law is the result of several years of intensive work and political negotiations, and it is also the result of active participation by domestic and international manufacturers, and regional experts in EU

pharmaceutical practices.

The law, which was adopted by the Council of Ministers last week and is now awaiting parliamentary debate, is aimed at creating a single pharmaceutical market in BiH. It will establish uniform conditions for the manufacture, testing and wholesale of pharmaceuticals and medical devices in BiH. It also prescribes conditions and foresees measures for ensuring their quality, safety and efficacy. Finally, it introduces supervision over the single market and establishes a State Pharmaceutical Agency as its regulator.

The law, it should also be noted, is fully in accordance with EU standards and directives (which is a must for BiH in the process of EU accession).

The fact that BiH pharmaceutical companies have played an active role in drafting this law is as it should be. Companies that create and sustain employment should rightly be partners in policy-making. In fact the law itself foresees the participation of BiH experts in further regulating the areas that it covers.

However, there has also been a good deal of misunderstanding as to what the law will actually do. Indeed, I have even seen some editorials whose authors comment on the Law and at the same time claim that they have never read it!

The new Law will establish a single market for pharmaceuticals and medical devices. That means that the same painkillers can be made available at the same price throughout the country. Currently, different medications are available in each of the Entities and in Brcko and prices are generally reckoned to be above market levels because some companies enjoy monopoly status in one part of the country or another.

Moreover, under the present system, a drug that is judged to be safe in the RS can be deemed *unsafe* in the Federation and vice versa – and unscrupulous importers make use of the

existence of a fractured inspection system to import cut-price and low grade drugs from abroad (check the bottles you have in your medicine cabinet – if the indications are not in local language, chances are the medicine has not been inspected by any authority).

This outrageous system should change when the Law on Pharmaceuticals and Medical Devices is enacted and the BiH Agency is established to control the market. When the new law is in place and the Agency is up and running, citizens in BiH will be able to have confidence that any medication they are obliged to take has been properly inspected.

And the law can be enacted in the next few weeks.

As far as the industry is concerned, by prescribing uniform conditions for the production, testing and sale of pharmaceuticals and medical devices, the law will put companies on a level playing field inside BiH and will put BiH companies on a level playing field internationally.

By providing for the proper control of medicines imported into BiH it will help ensure more safety, greater choice and better prices. But it will *also* allow BiH companies to move into the international market, as they will have access to internationally recognised certification facilities. It will then be up to these companies to compete effectively and by doing so to increase the number of jobs they are able to create.

And the enactment of the law will have a positive economic impact too.

Every single prospective investor in BiH – anyone thinking about starting a company here and creating desperately needed jobs – has to be persuaded that the country has a functioning modern economy. A fractured internal pharmaceutical market suggests a *dysfunctional* economy. So, even if there weren't overpowering ethical and commercial arguments for the

enactment of the BiH Law on Pharmaceuticals and Medical Devices, the economic argument alone would win the day.

Will the representatives of the BiH Parliament vote to make affordable and safe medicine universally available in this country?

Let us watch very closely in order to make sure they do the right thing.

Larry Butler is the Principal Deputy High Representative for Bosnia and Herzegovina