

# OHR's Statement at the International Agencies' Joint Press Conference in Banja Luka

## BiH Citizens' Safety Must Come First

The BiH Law on Pharmaceuticals and Medical Devices will be considered by the Constitutional-Legal Committee of the House of Representatives tomorrow. This law will regulate the sale and manufacture of drugs throughout the country: one of its principal objects is to make medicine safer and cheaper.

At present, the Entities have different laws and rules governing the manufacture and sale of medicine and medical devices, and Brcko has none. The result of this fractured pharmaceutical market is that medicines in BiH are not as safe as they should be, and investment in developing new medicines is not as high as it could be. This is jeopardizing the health of the people of BiH – and it need not be so.

The new law, which will be considered tomorrow, was drafted by pharmaceutical and legal experts delegated by the State, the Entities and Brcko and is fully supported by the responsible authorities and the International Community (its passage was urged by the Peace Implementation Council in its 23 June Communiqué). It is fully in accordance with EU standards and directives – and will bring BiH into line with the European Union's *acquis communautaire*. BiH and international manufacturers, as well as EU pharmaceuticals experts actively participated in preparing the draft.

The law will create a single pharmaceutical market in BiH, establish uniform conditions for manufacturing, testing and wholesale of pharmaceuticals and medical devices and prescribe conditions and foresees measures for ensuring their quality, safety and efficacy. It will also introduce supervision over the single market and establish a State Pharmaceutical Agency as its regulator.

I would also draw your attention to the fact that this law is crucial for the implementation of the BiH Law on Prevention and Suppression of the Abuse of Narcotic Drugs – which is at the

heart of everything now being done to tackle drug addiction in BiH.

OHR notes with great concern that proposed amendments to the law, which will be discussed tomorrow, would – if adopted – undermine its basic principles. Provision for the location of the State Pharmaceutical Agency headquarters in Banja Luka and the Control Laboratory in Sarajevo will ensure that these agencies can be launched quickly and will also ensure an optimal division of labour. In addition, measures have been agreed that will protect domestic manufacturers while ensuring that citizens get the benefits of a free market – safer medicines at fairer prices.

Any deviation from these key issues would cast doubt not only on BiH's SAA compliance, but the well-being of BiH citizens and their access to high quality domestically produced medicines.

The BiH Law on Pharmaceuticals is about making cheap and safe medicine available to citizens – parliamentarians are honour bound to enact this crucial piece of legislation before the summer recess.

### **RS Higher Education Law a Blow to University Students**

The RSNA on Wednesday enacted a Higher Education Law. This law deals with issues that are dealt with in the BiH Higher Education Law, which will be discussed at tomorrow's session of the Constitutional and Legal Committee and by the House of Representatives next week.

The passage of an Entity Higher Education Law at this point will simply plunge the BiH education sector into confusion – thus further damaging the interests of students. It does nothing to help BiH's integration in the European Higher Education Area.

RS Prime Minister Dodik has given assurances that his government will prioritise the enactment of a BiH Higher Education Law – which will regulate university standards throughout the country and complete the implementation of the Bologna Process. The RSNA has chosen to ignore the prime minister.

OHR continues to believe that there is a possibility of compromise if the BiH Higher Education Law is adopted as early as next week. The new RS law could then be harmonized with the state law. The OHR therefore urges the BiH parliamentarians to enact this law without delay.