Croatia's July Deadline for Removing Drug Batches from Market Too Short

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Croatia is debating how to deal with a legislative requirement to remove certain batches of medicines from the market by 1 July, after finding that the deadline may be too short.

The deadline is a transitional measure that came into effect when Croatia acceded to the EU on 1 July 2013. It applies to batches of medicines that are authorized at EU level under the centralized procedure but which had already been manufactured under a Croatian national approval prior to the country's EU accession. On the accession date, all European Commission decisions for centrally-authorized drugs became valid in Croatia and any previous national authorizations for these products were revoked. However, batches made before the accession were allowed to stay on the market for a year.

As the deadline nears, it has become clear that it "may not be long enough for the stocks to be exhausted," said Viola Macolić Šarinić, who is the head of Croatia's healthcare products regulatory agency, HALMED.

Sticking to the deadline would not only be financially detrimental for market authorization holders (MAHs), it would also remove from the market medicines that "should be there for the patients," Dr. Macolić Šarinić warned. The HALMED chief suggested that one option could be to allow the medicines to stay on the market "at least until their expiry date." Dr. Macolić Šarinić was speaking at the *26th Annual DIA EuroMeeting* in Vienna on 26 March during a presentation on HALMED's experiences following Croatia's EU accession.

Discussions are now under way by Croatia's Ministry of Health to see what can be done about the deadline. At "the initiative of the concerned marketing authorisation holders further steps are currently being discussed by the Ministry of Health with the assistance and co-ordination performed by HALMED," a spokesperson for the agency told *Scrip Regulatory Affairs*. "With the discussion still in process, we cannot predict the outcome at this moment, and are waiting for the Ministry of Health to reach its decision."

Drug availability problem

Since joining the EU, Croatia is also experiencing a problem common to other small EU member states relating to the availability of centrally-authorized drugs that are used by only a small group of patients and/or where the marketing authorization holder is not present in Croatia.

Prior to its accession, Croatia imported centrally-authorized products that had not been authorized nationally "based on HALMED’s approval if there was a medically justified need to protect human health," the agency's spokesperson said. After the accession, "MAHs were offered a possibility to receive an exemption from labelling in the Croatian language when placing the [centrally-authorized product] on the market." However, it appears that this exemption has not been enough of an incentive for companies, especially because of the resources they would need to meet EU pharmacovigilance obligations on a national level, for example, naming and approving the local qualified person for pharmacovigilance (QPPV) and providing the required educational materials.

A positive experience overall

Aside from this particular drug availability problem and the looming July deadline, HALMED's experience of Croatia's EU accession has overall been positive. The agency, which has nearly 200 employees, began preparing for the accession early on and this has paid off from the scientific, regulatory and technical points of view, says Dr Macolić Šarinić: "We are very proud of how we've dealt with transition, everything has gone very smoothly."
The EU legislation was fully transposed in Croatian drug law and bylaws on time, the HALMED chief said. In addition, HALMED's efforts to prepare Croatian MAHs and MAH representatives for the legislative and procedural changes by proving educational material on the agency's website and during conferences has resulted in a "significant decline" in regulatory questions the agency receives from companies, she noted.

The Croatian agency is actively involved in the EU regulatory and scientific network and participates in the committees and working groups of both the European Medicines Agency and the Heads of Medicines Agencies. Coordination teams relating to HALMED's involvement in the mutual

recognition procedure (MRP) and the decentralized procedure (DCP) were "fully prepared from the date of accession," Dr. Macolić Šarinić said. At the moment, HALMED is accepting applications for Croatia to act as the reference member state in MRPs/DCPs of generic drugs only. The agency also participates in the EU activities relating to the centralized procedure.