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Postmarketing safety surveillance program results of the first Russian interferon beta-1b biosimilar

The first Russian interferon beta-1b biosimilar was registered by CJSC BIOCAD in September of 2009 in the territory of the Russian Federation, and by the end of 2015 the exposure was 14,789 patient-years. BIOCAD initiated an intensive monitoring program. By the April of 2016 there were 1903 ICSR processed. The bulk of notifications, 58.5% (n=1115) was received by the company specialists, 805 notifications (42.3%) were received from the patients, 300 notifications (15.7%)–from the patient support team members and 10 notifications (0.5%)–from the healthcare specialists. There were 788 notifications (41.1%) received from the national regulatory authority (Roszdravnadzor). Additionally, BIOCAD has initiated a non-interventional observational study. 650 patients were included, at this stage the study database was being prepared for the final analysis. Most often, the patients had injection site reactions (n=1256), general reactions (n=1189), as well as the nervous system reactions (n=383). There were 8 cases of injection site necrosis, that, taking into account exposure and intense monitoring, is a low value. 41 notifications on the lack of efficacy do not contradict the information about the drug product as about 25% of patients had no response. There were 8 reports of pregnancy. Four of them resulted in a birth of a healthy child, three were spontaneously interrupted (one in the stage of 5 weeks because of thrombocytopenia, two–in the stage of 14 weeks), one pregnancy still continues. Unexpected reactions have low levels of causality, new risks have not been identified. The received information confirms the known risk/benefit ratio.

Biography

Alexey Skripkin, MD, graduated from Rostov State Medical University (Rostov-on-Don, Russia) in 2005. He passed Residency in Neurology in 2007 and Postgraduate Training Program in 2010 at the Moscow State Medical Academy, I M Sechenov, Moscow, Russia. He continues his neurological practice. He has 6 years of experience in pharmacovigilance, has passed a number of comprehensive pharmacovigilance and pharmacoepidemiology trainings from 2010 to 2016. He was a Neurolology Medical Affairs Manager at BIOCAD from 2010 to 2012. He is BIOCAD's Qualified Person for Pharmacovigilance since 2010, and the Head of Drug Safety Department since 2013.

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