Jödicke *et al.: Intrinsic Activity*, 2016; **4**(Suppl.3):A5.2
http://www.intrinsicactivity.org/2016/4/S3/A5.2
published online: 5 September 2016

22nd Scientific Symposium of the Austrian Pharmacological Society: Joint Meeting with the Hungarian Society for Experimental and Clinical Pharmacology

Vienna, 8–10 September 2016

MEETING ABSTRACT

A5.2

A retrospective study of international pharmacovigilance safety reports on irreversible injection-site reactions after subcutaneous administration of Sayana®

Annika JÖDICKE[1,#], Hendrike DAHMKE[1,#], Beat DAMKE[2], Martina SCHÄUBLIN[2], Gerd A. KULLAK-UBLICK[1] and Stefan WEILER[1,*]

[1]Regional Pharmacovigilance Centre Zurich, Department of Clinical Pharmacology and Toxicology, University Hospital Zurich and University of Zurich, Switzerland; [2]Swissmedic, Schweizerisches Heilmittelinstitut, Bern, Switzerland
([#]contributed equally)

Background: Sayana® was introduced as the first depot medroxy-progesteron acetate (DMPA)-containing contraceptive, administered via subcutaneous injection. In 2014 and 2015 the regional pharmaco-vigilance centre of Zurich (RPVC Zurich) received 11 anonymised reports of severe and persistent local reactions after Sayana® administration, which were classified as lipodystrophies, atrophies or persisting indurations. In this retrospective study, we analysed global individual case safety reports (ICSRs) of this adverse drug reaction (ADR).
Methods: International, national and regional ICSRs associated with Sayana® administration were analysed. Data on ADRs were retrieved from the WHO Global Database VigiBase™ and were analysed statistically. For the local reports additional demographic data, drug administration information, duration of Sayana® treatment, latency time of the ADR, its course, severity and outcome were collected.
Results: Worldwide, 398 ICSRs associated with Sayana® were registered in the database until 2016-01-01. After selecting all cases possibly related to a severe or persistent local reaction, 355 reported corresponding terms, corresponding 323 (81.4%) international ICSRs remained for analysis. Of these, 91.6% ($n = 296$) were categorized as serious. The majority of the reactions ($n = 193$; 54.4%) did not recover (*e.g.* atrophy, fat necrosis or lipoatrophy). In the 67 Swiss ICSRs, 77 ADRs were reported using 10 different terms including severe or persistent local reactions like lipodystrophy, atrophy or fat necrosis. Of these, 32 patients (47.8%) did not recover. All 11 regional cases reported to the RPVC Zurich were categorized as serious ADRs. For the majority of the patients ($n = 7$; 63.6%) the interval between the application of Sayana® and the development of the lipodystrophy was 2–4 months. Most of the reactions were irreversible ($n = 9$; 81.8%). One patient even required plastic surgery.
Discussion: Administration-site reactions during Sayana® treatment do occur frequently. Persistent local injection site reactions such as lipodystrophy, fat tissue necrosis or atrophy do occur under subcutaneous Sayana® use. These reactions were recently integrated in the Swiss product information. Patients should be informed and advised about these potentially irreversible effects at the injection site.

*Corresponding author e-mail: *stefan.weiler@usz.ch*