

An Example of a Rapid Response to Adverse Event shared through Social Media

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Executive summary

- Social media presence in daily life has significantly increased during the last years. Information shared through Social Media is quickly spread, reaching a high number of users and gaining relevant proportions.
- An Adverse Event (AE) to a IL-17A antagonist was tweeted by the patient's husband and it spread on Social Media and top-tier online journals and TVs.
- Novartis managed to appropriately and timely respond to the AE potentially caused by a IL-17A antagonist by providing scientific and medical evidence about the drug reversing the initially established causal relationship.



Myriad of Social Media platforms

SOCIAL MEDIA AND ADVERSE EVENTS

- The wide spread of the internet and rapid adoption of smartphones and tablets has transformed the usage pattern of the internet from static to mobile.
- With the offspring of all kind of Social Media, new possibilities have arisen for the sharing of information of all types and from different users.
- Patients are posting Adverse Event information with the intent to gather further information but also to raise awareness to other patients.
- Once out in the public domain, it can be extremely difficult to make patients regain trust in a drug which has been associated with a particular adverse event.

Table 1. PATIENT DETAILS

Female patient, 65 years old, with severe chronic psoriasis
Travelled from Egypt to Switzerland to receive a IL-17A antagonist (▼ drug) in March 2015
Patient received 6 injections of the product in a Swiss hospital

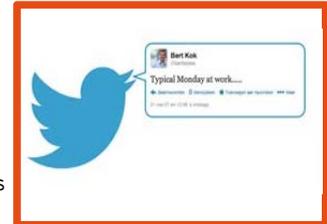
Table 2. CHRONOLOGY OF THE EVENTS

18 AUG 2015	20 AUG 2015	21 AUG 2015	22 AUG 2015	24 AUG 2015
<ul style="list-style-type: none"> • Patient's husband tweeted in his personal account that his wife was not feeling well and was suffering from 'hepatitis' as a side effect of a biologic drug treatment • IL-17A antagonist treatment stopped mainly due to hepatitis • Patient remained in Switzerland for hepatitis testing and deciding whether treatment can be restarted 	<ul style="list-style-type: none"> • Global Project & Rapid Response Team from Novartis produced a stand-by statement with medical evaluation of cumulative hepatic safety data • Medical information was provided to the journalist 	<ul style="list-style-type: none"> • Patient's liver dysfunction resolved and the patient intended to continue the IL-17A antagonist treatment, subject to medical advice 	<p>Balanced and scientifically based article was published in a daily newspaper</p> <ul style="list-style-type: none"> • Article included Novartis statement and assured readers that here was no causal relationship between the IL-17A antagonist and the liver injury • Author confirmed that patient's condition was not hepatitis but an elevation in liver enzymes due to concomitant medication • Author mentioned the IL-17A antagonist by name and included clinical efficacy rates • Some online journals featured a message sent by the patient to her father stating her liver condition could be caused by any medicine and that her skin had dramatically improved 	<ul style="list-style-type: none"> • A correction was issued by the journalist (patient's husband), clarifying it was not hepatitis as previously written but a minor elevation in liver enzymes • Based on new evidence it was determined the report of increased liver enzymes (at peak 10 times upper limit of normal) already existed. The newly created case was deactivated and associated reports nullified, with all new information included in the original record (master ICSR) • There was a symptomatic improvement of the patient's psoriasis • Patient has been diagnosed with latent tuberculosis confirmed via positive QuantiFERON test and treated isoniazid and pyridoxine for 4 months prior to the event • Checklist for drug induced liver injury was sent to the reporter in order to obtain more complete information and to request confirmation of the outcome

19 AUG 2015
Inquiry from medical journalist "Is hepatitis a side effect of the drug?"

MEDIA COVERAGE OF THE ADVERSE EVENT

- The patient is a famous actress in Egypt and the Middle East.
- The patient's husband is a prominent journalist and television anchor in Egypt, considered one of the top two medical journalists in the country. The daily newspaper which published his column has the second highest circulation in Egypt.
- Immediately after the husband's tweet, the news was spread out on social media (Facebook, Twitter, top-tier online journals and talk shows on television)



Twitter as the sharing platform

OPERATIONAL ASPECTS

- Additional efforts to determine the country incidence (Switzerland vs Egypt) for Individual Case Safety Report (ICSR) and for follow-up attempts initially in Switzerland but at longer term in Egypt; several checks to identify the duplicates being entered by the 2 Affiliates
- Rapid communication between Swiss & Egyptian affiliates and Global Safety
- Scientific assessment of the ICSR with prompt assessment of confounding by anti-TB meds (isoniazid, pyridoxine) and use of knowledge of the safety profile of the drug
- Close monitoring of mass media

CONCLUSION AND NEXT STEPS

- There will be instances where unconfirmed AEs will be made available to users through Social Media, gaining significant proportions in terms of reach.
- Novartis has demonstrated that if promptly responding with a medical and scientifically supported statement to the media inquirer, the situation can be reverted.
- Positive messages linked to health issues are also very quickly spread and 'listened to', contributing to a good perception of the drug.
- The patient and her husband are planning to establish a psoriasis patient organization in the country in order to provide affordable treatment to psoriasis patients in Egypt.