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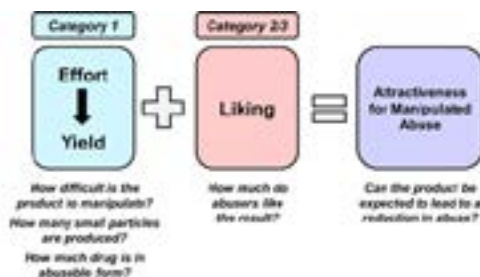
Importance of “level of effort” in the evaluation of abuse-deterrent drugs – the multi-faceted approach to the fight against opioid abuse – what can, and can’t we expect from ADFs

Statement of the Problem: The effort expended in attempts to manipulate a prescription opioid is an important element of Category 1, 2 and 3 studies of AD (abuse-deterrent) opioids, but it is challenging to assess this objectively. Epidemiologic data indicate that making the manipulation of opioid drugs more challenging (‘more effort’) creates new community dynamics, reducing the misuse/abuse of AD opioids. Pinney Associates (Bethesda, MD) has developed the ALERRT™ instrument for ‘level of effort’ evaluations. Egalet has worked with Pinney Associates on creating data on a morphine ER product developed with AD properties (ARYMO® ER; Egalet US Inc., Wayne, PA) was assessed with Egalet’s proprietary ADF technology using the ALERRT instrument as part of the evaluation of its abuse-deterrent formulations (ADFs) has shown that making the manipulation of the opioid drugs more challenging taking “more effort” to create an effective abusable form of the drug creates new dynamics in the abuser communities. The purpose of the study discussed herein was to describe the experience with the ALERRT tool in the evaluation of ARYMO® ER and how these data are important in the holistic evaluation of the abuse-deterrent properties of a drug.

Findings: A significantly higher level of effort was needed to manipulate ARYMO® ER tablets relative to the non-abuse deterrent comparator across the 10 tools that were tested. The expectation is that making opioid drug products more difficult to misuse/abuse will, in time, be a barrier to misuse/abuse for opioid naïve patients rather than preventing experienced opioid abusers from indulging in addictive behavior.

Conclusion & Significance: Tools are available for evaluation of ‘level of effort’ and can provide relevant and important data for characterization of abuse-deterrent properties. ARYMO® ER was shown to be very resistant to manipulation. It is believed that a multifaceted approach to combat the abuse is needed and AD opioids, in concert with several other critical initiatives.

Evaluating attractiveness of abuse in ADF testing:



Biography

Karsten Lindhardt has been the initiator of the CCALC Cat 1 focus group, which purpose has been to make meetings for professionals in the abuse deterrence space with a particular interest in the field of in vitro abuse deterrence studies. Dr Lindhardt is the CSO of Egalet Corp. and has 20 years of experience as a scientific manager in the pharmaceutical industry. Dr Lindhardt has earned a Diploma of Business Excellence (DBE) at Columbia University, Copenhagen Business School. Dr Lindhardt received an MSc in Pharmaceutics and a Ph.D. in pharmaceutical development and pharmacology, each from the Royal Danish School of Pharmacy, Copenhagen DK.

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