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US FDA's Proposed ACNU OTC 'Failure' Reports Requirement: Asking Too Much, Or Too Little?

by Malcolm Spicer

Periodic summaries FDA is considering are "most effective method to track and report relevant concerns," but "failure" as outlined in proposed rule is too broad, says CHPA. Digital care delivery firm Amwell says FDA should ask ACNU OTC marketers for some individual adverse event reports in addition to summaries.

The views an industry trade group and a medical technology firm have on adverse event reporting requirements neeeded in the proposed "additional condition for nonprescription use" rule in the US track in some areas but diverge on an important point.

The Consumer Healthcare Products Association supports an alternative reporting mechanism the Food and Drug Administration is considering, which would require firm to submit a single, consolidated report to FDA Adverse Event Reporting System (FAERS) on all consumers affected by the same "failure" linked to a drug's approval with an additional condition for nonprescription use (ACNU) rather than a report for each person impacted by a failure as stated in the proposed rule.

A periodic summary suggested in an information collection notice "is the most effective method to track and report relevant concerns to the" FDA "without being overly burdensome," said Brigid Zeller, the CHPA's projects and policy director, in *comments* submitted on 27 July.

However, Zeller says CHPA members "believe the definition of a 'failure' as outlined in the proposed rule is too broad and poses challenges with collecting relevant data from consumers."

American Well Corp., on the other hand, said in 28 July *comments* that the FDA

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should ask OTC drug marketers to submit information on some individual adverse event reported for a product approved under the ACNU process in addition to summary reports for all consumers affected by the same failure reported for an ACNU OTC.

John Jesser, clinical solutions president for the digital care delivery product and services provider operating as Amwell, says in the comments that "we believe that the nature of the failure should determine the proper reporting response."

The deadline for comments on the *proposed rule* published in June, which particularly targets facilitating "novel" OTC switches for chronic conditions, to docket *FDA–2021–N-0862*, is 26 October.

Agency officials in 2012 launched the initiative which lead to the proposal rule expecting labeling for novel switches to be subject to the same limits as other OTCs, with all necessary information available on a Drug Facts label. However, in a 2018 *draft guidance* the FDA indicated switch sponsors could tap into digital media and other extra-label tools to help demonstrate that consumers can assess whether an OTC drug is appropriate for them and they can use the product safely. (Also see "*Proposed OTC Switch Rule Anticipates Digital World*" - HBW Insight, 29 Jun, 2022.)

Acknowledging that some consumers won't or can't use digital channels necessary for self-selection and for point-of-sale clearance to buy an OTC drug, the proposed rule allows a formulation of a drug – same ingredient at the same dose and in the same delivery format – labeled with same indication to remain available Rx after it's switch as an ACNU OTC. (Also see "*Dual Rx/OTC Status In US 'Additional Condition' Switch Proposal: Necessary Or Questionable?*" -

'Failure In Implementation' Of An ACNU

The proposed rule's post-market monitoring requirement is for ACNU sponsors to "submit a report when a failure in the implementation" of an ACNU OTC occurs. (Also see "*Proposed Rule Making More OTC Switches Likely In US Makes More Tools Necessary For Sponsors*" - HBW Insight, 28 Jun, 2022.)

An implementation failure "includes any event that results from a deviation in an applicant's implementation of the ACNU that may cause or lead to inappropriate medication use or consumer harm."

Description of an implementation failure associated with a prior adverse event can be reported to FAERS in a single individual case safety report (ICSR).

If a report previously submitted to FAERS describes only an implementation failure or an ICSR reports only an adverse event, and an associated adverse event or implementation failure becomes known, a firm must supplement its original FAERS report with additional information.

HBW Insight, 29 Jun, 2022.)

Information From 'Sharable Record Of The Consumer'

Digital communications infrastructure is available to "collect and record data along the consumer journey, from the point of initial interaction with the ACNU through fulfillment and ongoing use" creating a digital history with "a sharable record of the consumer," Jesser wrote for Boston-based Amwell, which owns the Converge, SilverCloud, Conversa and Carepoint brands.

The history, including purchase receipts and use of products over time, "enables the aggregation of meaningful, reportable, de-identified consumer data to capture Real World Evidence at a population level," according to the Amwell comment.

Interoperable data and system-connected processes can support drug firms' ACNU adverse event reporting requirements, Amwell says.

"The recording of data is intrinsic to the digital process and the reporting can be engineered to automatically generate according to ACNU determinations. The information collection, storage, and transfer should not unduly introduce a burden as many of these processes are part of health IT operations today and can be a reference, and in some cases a resource, for ACNU programs," Jesser wrote.

'Scale Of Failure Spans Potential For Harm'

While necessary digital infrastructure is available, Jesser stated concern about "the feasibility or practicality of producing the proposed reports and parameters that might be applied to determine the appropriate timing of reports" under the proposed rule's requirements.

'Don't Disregard Pharmacists'

Among additional comments submitted on the proposed rule, one states that pharmacists "MUST be involved in the delivery" of ACNU OTCs.

The commenter, identifying as a pharmacist, notes pharmacists helped consumers during the COVID-19 pandemic and "can do so again to reduce overall health care spend."

"Do not overlook, carve-out, or otherwise dismiss the immediately accessible and on-site healthcare professional right in front of the patient! (As proposed by this rule). Kiosks, videos on the phone or questionnaires pale in comparison to the knowledgeable and compassionate pharmacist," the commenter states.

He also suggests a step the FDA would need authorization from Congress to make. "Create a class of pharmacist prescribed medications available for the asking."

As drug firms could be overwhelmed providing reports on each separate ACNU failure they receive, the "nature of the failure should determine the proper reporting response," Jesser said.

Amwell suggests modeling ACNU adverse event reporting on the FDA's requirements for Rx drugs and medical devices, with "a scale of failure [which] spans the potential for harm."

"Those failures determined to be lower risk might be reported on a consolidated basis, while failures determined to introduce high risk might be reported for each individual affected," according to Amwell's comments.

'Define Types Of Information To Be Reported'

While supporting individual reports for some ACNU adverse events is at odds with the CHPA's preferences, Amwell's suggestion also tracks with the trade group's on defining events which must e reported.

The agency "might also consider establishing classes of failure with specific criteria and ascribing reporting requirements specific to each class of failure," Jesser wrote.

The CHPA, in addition to recommending requiring summary failure reports, asked the FDA not to expand the adverse event information needed for ACNU OTCs beyond other nonprescription drugs available through applications.

Zeller asked the FDA to "define the types of information to be reported in summary data so that it is also consistent with existing adverse event requirements and tracking systems currently in place for OTC medicines marketed under an approved application."

"While we agree that reporting of adverse events associated with potential failures due to an ACNU may be necessary, CHPA members believe the definition of a 'failure' as outlined in the proposed rule is too broad and poses challenges with collecting relevant data from consumers," she added.

The CHPA will include more details on how ACNU failures should be defined, captured and reported to the FDA in additional, more substantive comments it will submit on the proposed rule.