# The Focal Point: Advocacy & Legislative Update
# July 30, 2019

## Altaire Expands OTC Ophthalmic Product Recall

Altaire Pharmaceuticals is recalling prescription and over-the-counter drugs sold by OCuSOFT, as well as OTC products sold by Accutome, Focus Laboratories, Grandall Distributing Co. Inc. Prestige Brands Inc., Natural Ophthalmics and TRP Company, Inc., the company announced in press releases. Earlier this month, Altaire recalled products sold at CVS, Walgreens and Walmart and manufactured and labeled for Perrigo Company PLC for the same reason.

Quality assurance control concerns, including a lack of sterility assurance, were raised by the FDA, prompting the recall to the Retail Level. Altaire has received no reports of adverse reactions and to date, have not obtained any out of specifications results, including in-house and third-party sterility testing for these products.

EBAA worked with the 28 eye banks affected by the recall to identify alternative products and coordinate their CAPA response and FDA reporting.

Following discussions with EBAA, the FDA will require eye banks to submit a single deviation report for tissue affected by this recall. For more information, please refer to our July 25 alert.

## WHO Declares Ebola Outbreak an International Health Emergency

The World Health Organization (WHO) has declared the worsening Ebola outbreak in the Democratic Republic of the Congo (DRC) a public-health emergency of international concern (PHEIC). The declaration is the WHO's highest level of alarm.

This is the fifth time that the agency has declared a global emergency—a step it reserves for events that pose a risk to multiple countries and that require a coordinated international response. The declaration is meant to induce further international aid for fighting the Ebola outbreak. The agency based its decision in part on the first confirmed case of Ebola in Goma, a DRC city of nearly two million people on the country's eastern border with Rwanda.

The EVD outbreak has not yet been classified by the CDC as widespread transmission that would trigger blood donor screening in the U.S. The DRC outbreak has infected 2,518 people and killed 1,756 since it began 11 months ago.

## FDA Finalizes Combo Product Postmarket Safety Reporting Guidance

The FDA finalized guidance explaining postmarket safety reporting (PMSR) requirements for combination products and their constituent parts. The guidance explains how combination product makers can comply with a rule issued on December 20, 2016, that established new requirements for submitting safety reports based on all the constituent parts of the product in addition to application-type reporting.

The final rule also established that the makers of constituent parts must share certain postmarket safety information with one another.
The final guidance is broken up into sections providing background information about the guidance and how combination products are regulated; general and specific considerations for postmarket safety reporting for combination products; details on how and where to submit postmarket safety information to FDA and what data should be included in those reports. The guidance also includes hypothetical scenarios that illustrate how to comply with certain PMSR requirements.

## FDA Explains What Submissions Warrant Exemptions or Waivers From eCTD Requirements

FDA has revised its guidance on the electronic common technical document (eCTD) format to note specific cases where the agency believes a submission should be exempted or granted a waiver.

This revision modifies previous versions by including exemptions for Type III drug master files (DMFs), which provide information on packaging or packaging materials in support of drug, generic drug or biologic applications.

In addition, this guidance has been updated to include the criteria identifying those types of submissions that may qualify for a long-term waiver (see section III.D) or a short-term waiver (see section III.E) from the eCTD submission requirement and instructions on how to submit a waiver request.

## WHO Revises Guidance on QMS Requirements for National Inspectorates

The World Health Organization (WHO) has revised its guidance on quality system requirements for national good manufacturing practice (GMP) inspectorates to align with international standards and the latest quality management system (QMS) principles and to expand the document's scope. Comments are requested by September 20th.

The adoption of a common standard for QMS requirements is an essential element in achieving consistency in inspection practices and facilitating structured communication with other units of the national regulatory authorities (NRA), as well as enabling mutual confidence and permitting recognition between pharmaceutical inspectorates.

The guidance outlines what a QMS is, what it should do for an inspectorate and how it should help senior management better achieve their targets and quality objectives. The guidance also discusses management, management system planning, resources including personnel and infrastructure, documentation, operational planning and performance evaluation.

## Stay Up to Date with ISBT 128

Version 7.27.0 of the ISBT 128 Product Description Code Database is now available and can be downloaded as a Microsoft Access database. All database updates are listed in the version control sheet. The new codes can also be found using the online Product Lookup Program.

The Standard Terminology for Medical Products of Human Origin v7.27 document provides definitions to all ISBT 128 terminology and should be used in conjunction with the ISBT 128 Product Description Code Database.

## CDC Releases Interim Measles Guidance for Healthcare Facilities

The CDC has rolled out their interim infection prevention and control (IPC) recommendations for healthcare facilities during the ongoing measles outbreak. The CDC reaffirmed the most important

measure to prevent measles transmission is ensuring community immunization. However, core measles prevention in healthcare settings requires a multifaceted approach including:

- Ensuring healthcare personnel (HCP) have presumptive evidence of immunity to measles
- Rapidly identifying and isolating patients with known or suspected measles;
- Adhering to Standard and Airborne Precautions for patients with known or suspected measles;
- Routinely promoting and facilitating respiratory hygiene and cough etiquette;
- Appropriately managing exposed and ill HCP;

CDC defines healthcare personnel (HCP) as all paid and unpaid persons working in healthcare setting including contractual staff not employed by the healthcare facility (such as eye bank recovery technicians) and persons not directly involved in patient care.

### France to Reduce MSM Deferral Period to 4 Months

The French Minister of Solidarity and Health Agnès Buzyn announced that France will reduce the deferral period for blood donations from MSM from 12 months to 4 months.This decision is a first step in the process of aligning eligibility criteria for all donors in favor of individual behavior rather than sexual orientation. The decision will take effect Feb. 1, 2020.

### Winning TRaM Team Innovation to Advance Corneal Transplant Surgery

CorGel, a team comprised of researchers from the University of Melbourne and the Centre for Eye Research Australia (CERA) is making corneal transplants easier for surgeons and improving their rate of success via the development of a specialized gel that prevents donated corneas from rolling up during the procedure.

The team had won a $20,000 funding grant in 2018 from Translating Research at Melbourne (TRaM) for the invention of the hydrogel film CorGel, which helps the tissue unfold without the need for excessive handling from the surgeon.

The team are now looking to translate their research into a commercial product, and they have secured an industry partner, Eversight, to help them make the leap.

### Climate Change May Have Aided *Candida auris* Emergence

Researchers hypothesize that climate change played a role in the emergence of the multidrug-resistant fungus *Candida auris*, according to a paper published in *mBio*.

*Candida auris* is a new drug-resistant fungal species that was first isolated in 2009 from a human ear and has been associated with human disease in many countries. The clinical isolates are remarkable for exhibiting nonsusceptibility to antifungal agents.

The sudden, independent emergence of *C auris* as a human pathogen on three continents simultaneously cannot be explained solely by widespread use of antifungal drugs or recent acquisition of virulence traits. Fungal pathogens are rare in mammals because they can't grow at human body temperature. The researchers suggest that *C auris* was until recently an environmental fungus that adapted to warmer ambient temperatures caused by climate change and was able to break the mammalian thermal barrier.