Medication Shortage Updates per FDA

1. **Amoxicillin**

On October 28, 2022, FDA posted the shortage of amoxicillin oral suspension. This information can be found here.

While alternative antibiotics are available, amoxicillin is a narrow-spectrum antibiotic (i.e., an antibiotic that acts against limited species of bacteria), and alternatives are often for broader-spectrum use. As you know, experts generally advise using as narrow a drug as possible given concerns about antibiotic resistance, patient safety, and side effects.

There are several manufacturers who make amoxicillin oral powder for suspension (Aurobindo, Hikma, Rising Pharma Holding, Inc, Sandoz, and Teva). FDA has contacted all five manufacturers and they continue to produce and release product. However, increased demand is currently exceeding available supply. FDA is working directly with manufacturers, and product continues to be manufactured. We understand that while some pharmacies do not have amoxicillin oral powder for suspension, others do. In many cases, it is proving challenging and time consuming for pharmacists and patients to track down supply. Occasionally, hospitals or pharmacies report local supply issues. In some cases, these are temporary and involve distribution issues and resolve when the pharmacy is able to reorder from their distributor. The five companies who make amoxicillin oral powder for suspension all report that they are producing product as quickly as possible and, as discussed below, the Agency has released compounding guidance to enable greater supply of beta-lactam oral suspension products until manufacturers are able to meet the full demand. FDA has also offered assistance to all of the manufacturers of approved products regarding anything they need to increase production, such as helping to identify additional raw material or component suppliers.

On November 18, 2022 FDA issued, *Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, to help alleviate the shortage of amoxicillin for oral suspension The guidance describes compounding of the oral suspension using FDA-approved amoxicillin tablets and capsules. With respect to the compounding of certain beta-lactam products in shortage by compounders under section 503A of the Federal Food, Drug, and Cosmetic Act, FDA recommends that health care providers monitor for reports of allergic reactions, including anaphylactic shock, that might be related to unintentional beta-lactam exposure from the use of non-beta-lactam drugs.

While FDA continues to work with manufacturers to increase supply of amoxicillin suspension, inappropriate prescribing may be contributing to current demand. The literature has documented overprescribing to pediatric patients (e.g., Hersh AL, Shapiro DJ, Pavia AT, et al., Antibiotic prescribing in ambulatory pediatrics in the United States. Pediatrics 2011; 128:1053–61. 10.1542/peds.2011-1337), and in 2019 NIH supported research found that telehealth may be associated with additional inappropriate prescribing compared to in-person visits (Ray, KN, et al., Antibiotic prescribing during pediatric direct-to-consumer telemedicine visits. Pediatrics. 2019. DOI: 10.1542/peds.2018-2491) FDA continues to raise awareness of antibiotic resistance through promotion of our webpages (Antibiotics and Antibiotic Resistance and Antimicrobial Resistance Information). In addition, multiple centers within FDA are part of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), and we recently highlighted World Antibiotic Awareness Week (Nov. 18 – Nov. 24) on social media, along with other HHS agencies.

For more information, including information on resolution projections, please see: *Drug Shortage List:* **Amoxicillin Oral powder for Suspension**

Medication Shortage Updates per FDA

1. **Pediatric Acetaminophen and Ibuprofen**

   FDA is actively monitoring the pediatric ibuprofen and acetaminophen supply and will take steps, as appropriate, to try and prevent or mitigate a shortage. Here, again, FDA is in close communication with the manufacturers of these products. To date, they have reported that they are able to supply the U.S. market. However, the Agency continues to monitor the conditions closely and is ready to act if necessary. Occasionally, hospitals or pharmacies report local supply issues, and we are working to understand these reports fully. We also understand that there is a shortage of these products across Canada, and we are ready to assist with that shortage if possible.

   FDA has multiple possible mitigation tools to help prevent shortages and selects specific tools depending on the severity of the potential shortage and the surrounding circumstances. One tool we use to mitigate shortages is to reach out to manufacturers to see if they have data from studies that may support a patient or provider's choice to use a drug after its labeled expiration date. If a manufacturer has such data, the Agency has, in certain circumstances, exercised temporary regulatory flexibility by reviewing and communicating the results of these studies. This has been a successful shortage mitigation tool. On the FDA Drug Shortage webpage, there is a list of products for which FDA has made such communications regarding extended expiration dates.

   We note that there are differences between the Canadian and U.S. marketplaces, including the requirement that drugs intended for use in Canada be labeled in two languages and different suppliers for the Canadian market versus the American market.

1. **Tamiflu (Oseltamivir)**

   Each year, FDA's Drug Shortage Staff provides and posts on our webpage antiviral product availability. The last update (from 11/4) can be found here. FDA closely monitors supplies for these products and manufacturers provide FDA with monthly updates. Manufacturers are aware of their historic forecasting and keep FDA up to date on changes.

   Manufacturers have seen some increases in demand for oseltamivir. However, there is not currently a shortage of oseltamivir, and FDA has been in contact with the manufacturers and continues to monitor supply closely. Occasionally, hospitals or pharmacies report local supply issues. This may be why there are scattered anecdotal reports of difficulty accessing antivirals and why American Society of Health-System Pharmacists (ASHP) lists some oseltamivir products in shortage. When the FDA receives reports from pharmacies, hospitals, or others, we confirm with the manufacturers that supplies continue to be adequate to meet demand at the national level.

   Some reports have indicated that generic oseltamivir supply is under more pressure than the Tamiflu brand product and individuals are having issues with their insurance covering the brand product, resulting in a lack of access. It may be worth engaging with Pharmacy Benefit Managers (PBMs) to discuss their formularies and ways of addressing this issue.