The drug approval process deviates slightly when it comes to generic drugs. Once a brand drug patent expires, generics can enter the process by submission of an abbreviated new drug application (ANDA) (1). ANDA reports must show proof that the generic product is similar to the innovator product based on the generic’s pharmacokinetics, bioavailability, and clinical activity.

Expedited programs
The drug approval process allows the FDA to regulate safety and efficacy of drugs before medications can be marketed. The drawback to this process is that it can take several years to reach
approval. To speed up the availability of drugs, especially for serious diseases, the FDA has developed four approaches, priority review, breakthrough therapy, accelerated approval, and fast track (2). This summary will cover the latter two.

The following definitions assist in understanding the accelerated programs.

**Fast Track**
Fast track is a method to expedite drug approval. The justification for fast track is for serious conditions and can fill an unmet medical need (6). Fast track hosts its own conditions that must be followed. FDA will require more frequent meetings to discuss the drug’s development plan to ensure appropriate collection of data to support drug approval (6). This applies to written communication over design of clinical trials as well. Should criteria be met, the fast track drug may become eligible for accelerated approval and priority review.

**Accelerated approval**
The accelerated approval regulations pathway was established in 1992 (5). This allowed drugs for serious conditions that would qualify for an unmet medical need to be approved (5). In 2012, Congress passed an amendment called the Food and Drug Administration Safety Innovations Act (FDASIA), allowing the FDA to accelerate approval of drugs for serious conditions that fill an unmet medical need and have an effect on a surrogate or an intermediate clinical endpoint (5).

A surrogate endpoint is a marker that predicts clinical benefit, but in of itself is not a measure of clinical benefit. Surrogate markers may include a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit. Similarly, an intermediate clinical endpoint is a measure of therapeutic effect that is likely to predict clinical benefit. By utilizing a surrogate endpoint or intermediate endpoint, the accelerated drug approval process saves important and valuable time towards providing benefit towards serious diseases.

**Emergency Use Authorization (EUA)**
Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA may authorize unapproved products or use of approved products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases caused by chemical, biological, radiological, or nuclear (CBRN) threat agents (7). However, this process can only be approved when the Secretary of HHS declares that an EUA is appropriate. An example of this occurred on February 4, 2020 when Secretary of HHS identified COVID-19 as a public emergency that has significant potential to affect national security or the health and security of the US citizens (7). The same rigorous approval process applies to EUA as standard approval process. Data is reviewed and analyzed by independent experts and not scientist employed by the drug manufacturer (8-9).
The P&T Committee met for its quarterly business meeting on August 11, 2022.

Highlights of this meeting include:

Tlando, Vtamo, Camzyos, Voquezna, Ztalmy, and Radicava will be limited to indication. Tlando, Quiviviq, Vtamo, Mounjaro, and Voquezna were referred to the Department of Health for cost analysis and PDL placement.

Lyvispah will require prior authorization.

The prior authorization requirement for Paxlovid will be removed to provide pharmacies easier access to the associated dispensing fee.

Proposed criteria is open for public comment. Comments can be sent by email to alewis13@uwyo.edu. All comments should be received by October 1, 2022. The next P&T Committee meeting will be held November 10, 2022 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.
Summary of drug approval process: Accelerated, fast track, and emergency use authorization
P&T Committee Meeting Update

Please contact WY-DUR at 307-766-6750 to have your name added or removed from our mailing list, or if you need to update your address. The WY-DUR newsletter is also available online at www.uwyo.edu/DUR/newsletters.