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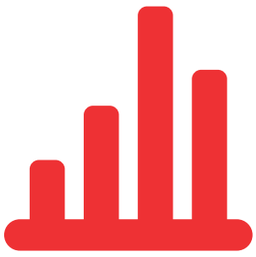
PROCESS & PURPOSE

The unrealized value of a combination drug product strategy

Fixed-dose combination drugs (FDCs) are increasing in popularity due to their benefits over monotherapy alternatives. While FDCs are typically indicated for the treatment of infections and cardiovascular, metabolic, and neurologic conditions, their potential to expand into other therapeutic areas is increasing. Currently, more than 400 FDCs are approved in the United States and approximately 200 are on the market in India and Europe.* In addition to the clinical benefits these therapies bring to waiting patients, there are several business advantages drug sponsors can derive from a combination drug strategy.



Enhanced therapeutic effect

Certain combinations of drugs can enhance each other's efficacy, creating a synergistic effect. This occurs when the drugs utilize different mechanisms of action, allowing each drug to fully express its therapeutic potential, thereby creating an enhanced effect in which the benefit of the combination is greater than the additive benefit of each drug individually. This increased effectiveness makes FDCs appealing to prescribers and patients.

Improved patient compliance

The simplified drug regimen that is characteristic of FDCs improves medication compliance among patients. In addition, replacing single-dose drugs with a fixed-dose combination minimizes the number of pills the patient must take, ensures appropriate dosing, and improves clinical outcomes.

Cost-effective development

Combination drugs consisting of APIs that have already received approval can have lower development costs since the safety and efficacy of the drug have already been established. Existing knowledge of the API's formulation and stability can be heavily leveraged in experimental design and provide a rationale to minimize the number of new studies needed, fast-tracking development and reducing costs.

*PharmaCircle: *Fixed dose combination (FDC) products overview.* Available at https://www.pharmacircle.com/presentations/Fixed_Dose.pdf.

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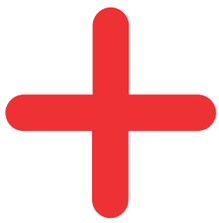
Potential for faster approval via ANDA

Combination drugs containing at least one approved drug product with a known pharmacokinetic profile may receive faster approval than new drugs by taking advantage of the FDA's 505(b)(2) abbreviated approval pathway.



Extended patent life

Patent protection can be extended for a proprietary product by incorporating the drug product into a new formulation. Utilizing FDCs helps patent holders maximize the value of branded products and defend against generics entering the market.

Expanded market penetration

Proprietary drugs, when repurposed as part of a combination therapy for new indications, have the potential to provide new market segments for specialized pharma companies to expand into.

Thermo Fisher Scientific supports clients in developing scalable, stable, and marketable fixed-dose combination therapeutics. Contact us to learn more.

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