March 15, 2024

SUBMITTED ELECTRONICALLY
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Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services (CMS)
Health and Human Services (HHS)
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Attention: Room C4–26–05
7500 Security Boulevard,
Baltimore, Maryland 21244–1850

Re: Comments on CMS Proposed Rebate Reduction Requests; Document Identifiers: CMS-10858, CMS-10215 and CMS-10394

Dear Ms. Brooks-LaSure:

Teva hereby provides comments on the CMS–10858 Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (IRA). Teva is pleased to submit these comments prior to the March 29, 2024 deadline in support of the CMS Information Collection Request (ICR) and to implement the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program codified in Section 1847A(i) and Section 1860D–14B of the Social Security Act ("the Act"), respectively.

Teva is pleased to see your interest in this critical topic and we look forward to serving as a resource as you develop solutions to what former director of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) called a "silent crisis" facing the U.S. healthcare system *in 2018.*[1] Teva is a market leader in the U.S. and Europe, and we are highly concerned about the issue of drug shortages and the outlook of the generics industry in general. This inflation rebate reduction proposal is a positive step toward addressing the problem of drug shortages by working with manufacturers to help get products back on-line and to providers and their patients. An initiative to achieve this purpose is a mutual benefit.

Drug Shortages Are a Shared Responsibility in the Marketplace

Today, hundreds of manufacturers are trying to capture one of three contracts for any given molecule. These dynamics have created a hyper-deflationary market that has led not just to a "race to the bottom," but an absolute free fall in certain generic drug prices. As prices have fallen, manufacturers like Teva have taken reasonable steps to manage production costs: manufacturing has been consolidated from several facilities to

[1] "Generic drug makers face 'a silent crisis,' FDA official says, and raising prices could help." STAT News. September 21, 2018.https://www.statnews.com/2018/09/21/generic-drug-makers-fda-prices/

one, eliminating excess supply capacity; production and supply chains have moved overseas to countries such as India and China which benefit from large volume facilities, low energy prices, reduced work standards and wages, and lax environmental laws. In order to save costs, other manufacturers have delayed maintenance or forgone necessary upgrades. Yet others have reduced quality systems to a minimum. Meanwhile, raw materials and production costs continue to rise due to inflation and other factors. Buyer consolidation and contracting practices coupled with state and federal laws that restrict the ability to increase a medicine's sales price limit manufacturers' ability to respond to an increase in the cost of raw materials. Especially over the last two years with hyperinflation, manufacturers were banned from passing on manufacturing cost increases to their customers due to these regulations, thus pushing many product categories further into the red. Often, manufacturers are left with few options: they can sell the drug at a loss to keep their manufacturing going until all raw materials are consumed, or they can discontinue the product entirely. This business reality results in drugs that have fewer than three companies as suppliers, and often, these companies rely on a single drug substance supplier themselves (often from China). The industry is unable to respond quickly due to year-over-year efforts to cut costs to preserve margins when a drug goes into shortage. It needs to be understood that drugs cannot be manufactured overnight when another competitor goes out of stock: the supply chains have lead times of 6 to 12 months, and no manufacturer knows if the prices in the market will cover the costs. FDA Commissioner Dr. Robert Califf recently underscored this reality when he testified before Congress saying, "If I offered you the chance to produce a drug and guaranteed you would lose money on every pill you made, it is unlikely you would go into that business."[2] CMS should adopt FDA's drug shortage list as reference to its inflation rebate reduction initiative.

CMS Needs to Collaborate with Manufacturers on Information Collection

Teva welcomes the collaboration between CMS and manufacturers to proactively anticipate when and where a drug shortage is to occur, and also to determine the type of information collected and the severity of the causation for the disruption in the supply chain. This inflation rebate reduction provision is based on Sections 1847A(i)(3)(G)(ii) and 1860D–14B(b)(1)(C)(ii) of the Act requiring "CMS to reduce or waive the inflation rebate amount owed (if any) for a Part B rebatable biosimilar biological product and generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during a calendar quarter or applicable period, respectively, such as that caused by a natural disaster or other unique or unexpected event." It further states that "CMS must also reduce or waive the inflation rebate amount owed (if any) for a generic Part D rebatable drug if CMS determines that without such reduction or waiver, the drug is likely to be in shortage in a subsequent applicable period."[3]

Conclusion

Thus, while individual drug shortages may have complex origins, the cause of all drug shortages can be condensed down to two simple factors: unsustainable economics and a bad policy environment.

[2] Oversight and Investigations Subcommittee Hearing: "Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains". Energy and Commerce Oversight and Investigations Subcommittee Hearing. https://energycommerce.house.gov/events/oversight-and-investigations-subcommittee-hearing-examining-the-root-causes-of-drug-shortages-challenges-in-pharmaceutical-drug-supply-chains. Accessed June 29, 2023

[3] Required by section 1860D–14B(b)(1)(C)(iii) of the Inflation Reduction Act (IRA)

Teva and other generic drug manufacturers must often decide how to reallocate resources to meet new or changed regulatory requirements, which may require manufacturers to abandon certain low- or no-profit drugs. This can happen even when the scientific and technical standards for a drug remain unchanged but there are new administrative burdens like reporting on supply and demand or taking steps to attain a high-quality management maturity (QMM) rating. While these programs often have merit, it is a simple fact of business that if increased costs cannot be offset by increased revenue or profit, the product becomes commercially unsustainable. Close collaboration between CMS and the industry can immensely improve the successful implementation and positive outcomes of this inflation reduction rebate initiative.

Thank you for your consideration of these comments. We believe this Inflation Rebate Reduction initiative is a step in the right direction. Therefore, we are in support of this initiative by CMS to provide rebate relief under its Inflation penalty during any interruptions or FDA-recognized shortages in the drug supply. Please do not hesitate to contact Teva directly if you have any questions.

Sincerely,

DocuSigned by:
Patrick Mcintosh
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Patrick Mcintosh
SVP US Commercial Generics & Biosimilars
Teva Pharmaceuticals USA, Inc.