



December 18, 2024

VIA ELECTRONIC SUBMISSION —

William N. Parham, III
Director
Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10849/OMB Control Number **0938-1452**
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 (IRA) (CMS-10849; OMB 0938-1452)

Dear Director Parham,

GSK appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Information Collection Request (ICR) for the Negotiation Data Elements (NDE) included in the Drug Price Negotiation Process for Initial Price Applicability Year (IPAY) 2027 (CMS-10849, OMB 0938-1452). GSK reasonably believes that one or more GSK product(s) may be directly impacted and subject to price setting under the IRA, giving GSK an interest in the development, interpretation, and application of the procedures set out by CMS for IPAY 2027. As CMS finalizes this ICR, GSK appreciates the agency's willingness to solicit comments to understand stakeholder impacts and concerns related to implementation. While GSK is a member of both BIO and PhRMA and supports each organization's respective comments on this issue, we respectfully submit these more targeted comments in response to CMS's revised ICR forms.

GSK is a global biopharmaceutical company with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. We seek to prevent and treat disease with vaccines, specialty, and general medicines. GSK supports policy solutions that transform our U.S. healthcare system to one that rewards innovation, improves patient outcomes, and achieves higher value care.

To summarize GSK's comments on the ICR:

- GSK appreciates clarifications and reductions in data reporting periods relative to the 60-day notice for this ICR.
- GSK remains concerned about Primary Manufacturers' obligation to submit information on behalf of Secondary Manufacturers, which is operationally unviable and creates liability for Primary Manufacturers for data creation and submission outside of the Primary Manufacturers' control.
- GSK is concerned about CMS's inconsistent inclusion of inflation adjustments for various metrics and encourages the agency to adopt a consistent policy regarding inflation adjustment across all required metrics (e.g., revenue, expense numbers that must be reported).

Support for Burden Reduction and Clarification

Recommendation: GSK thanks CMS for adjusting the reporting period for all pricing metrics to three years of data, and for clarifying the inclusion of Puerto Rico in reporting.

In Section G, regarding market data reporting, GSK appreciates that CMS has adjusted the reporting period required to three years of pricing data across all pricing metrics, both reducing the burden for manufacturer reporting and aligning the time period across all pricing metrics. GSK also appreciates the clarification of the appropriate geographic area for reporting under U.S. commercial markets, Medicare markets, and Medicaid markets, to rely on the definition at 42 C.F.R § 400.200, which includes Puerto Rico and other US Territories.

Primary/Secondary Manufacturer Submissions

Recommendation: GSK reiterates its recommendation that CMS ease the burden on Primary Manufacturers associated with collecting data on behalf of Secondary Manufacturers.

GSK continues to emphasize that CMS's burden estimate for manufacturers is woefully understated, and that CMS must give further credence to industry recommendations to address this issue. In particular, GSK remains concerned about the burden and uncertainty associated with CMS's expectation that Primary Manufacturers collect and submit data on behalf of Secondary Manufacturers. This expectation of accountability significantly increases the burden for Primary Manufacturers and creates possible problematic implications that Primary Manufacturers are responsible for the accuracy of data being reported by Secondary Manufacturers. Specifically, this accountability requirement on Primary Manufacturers is unreasonable and unrealistic given Primary Manufacturers' lack of visibility into or control over Secondary Manufacturers' reported data, calculations, and methodologies. GSK has raised these concerns to CMS and has yet to see CMS make any significant changes to its expectations around reporting by Primary Manufacturers on behalf of Secondary Manufacturers. Specifically, under the current framework proposed by CMS, GSK may only be able to certify receipt of Secondary Manufacturer information.¹ GSK strongly believes that Primary Manufacturers should not be held accountable for reporting on behalf of Secondary Manufacturers.

Consistency of Inflation Adjustment

Recommendation: GSK supports the use of inflation-adjusted amounts but recommends that CMS take a consistent approach to collecting inflation-adjusted data across costs, revenue, and federal support received.

In Sections C and E, CMS provides inconsistent instructions regarding inflation adjustment to various monetary amounts, which raises significant concerns.

¹ GSK's key concerns focus on GSK's potential liability for submitting fraudulent or simply incorrect information provided by the Secondary Manufacturer. As stated above, GSK does not believe Primary Manufacturers should be responsible for the accuracy of Secondary Manufacturer data as Primary Manufacturers have no visibility to Secondary Manufacturer Government Price Reporting methodologies, calculations, and financial assumptions. Further, to the extent a Secondary Manufacturer is considered a competitor to the Primary Manufacturer, it is unclear of the risks associated with Primary Manufacturers having visibility into product pricing and sales data – without clarity, raising antitrust violation concerns.

Specifically, in Question 6a (Global Total Lifetime Net Revenue for the Selected Drug) and 6b (U.S. Lifetime Net Revenue for the Selected Drug), as well as Questions 9 and 10 (Federal Funding Support), CMS asks both for inflation-adjusted and non-inflation adjusted amounts (as well as an explanation of the methodology used to adjust for inflation). However, in Questions 1 through 5, there is no discussion of inflation adjustment with respect to research and development (R&D) and other manufacturer costs.²

These amounts, like lifetime revenue and federal funding support, cover long-term periods, potentially dating back almost a decade or more, during which inflation can have a very large impact on the value of the amounts reported. This is especially concerning because the costs that manufacturers are required to report in Questions 1 through 5, which would not include any inflation adjustment, will be directly compared to the revenue data from Question 6, which does include inflation adjustment. CMS has explicitly stated that it will compare the R&D costs with the global and U.S. total lifetime net revenue, but this would be an inaccurate comparison without consistency across metrics. For example, an inflation adjustment from 2015 to 2024 represents a more than 30 percent increase and, as such, would represent a significant difference between inflation and non-inflation-adjusted amounts.³

GSK recommends that CMS adopt a consistent approach to whether it includes an inflation adjustment across costs, revenue, and federal support received. A workable approach to address this issue would be for CMS to request non-inflation-adjusted amounts, inflation-adjusted amounts for all metrics, and a manufacturer's methodology for inflation adjustment across all metrics. Whatever approach it chooses, CMS needs to be consistent across all relevant financial metrics (R&D costs, revenue, and federal support received).

GSK appreciates the opportunity to comment on this IPAY 2027 ICR. Please contact me at harmeet.s.dhillon@gsk.com if you have any questions about the topics discussed in our comments or if GSK can provide any further information.

Sincerely,



Harmeet Dhillon

² In addition, the general instructions CMS provides for the ICR state that manufacturers should “not make any adjustments for inflation to any dollar amounts reported unless the additional specific instructions for that question instruct you to do so.”

³ [Top Picks : Consumer Price Index for All Urban Consumers \(CPI-U\)](#) Example based on 2015 and 2024 numbers (to date).