GSK Comment Letter
Response to Information Collection Request for Negotiation Data Elements

July 31, 2023

Via electronic submission: Regulations.gov

Office of Management and Budget (OMB)
725 17th St NW
Washington, DC 20503
Attn: OMB Desk Officer

RE: Information Collection Request for Negotiations Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB 0938-NEW)

Dear OMB Desk Officer:

GSK appreciates the opportunity to comment in response to the Centers for Medicare & Medicaid Services (CMS or the Agency) Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (ICR or the ICR), including the Federal Register Notice, Supporting Statement – Part A ICR Form (CMS-10847, Office of Management and Budget (OMB), 0938-NEW), and the Comment Summary Responses submitted to the OMB.

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. Our global specialist HIV company, ViiV Healthcare, is fully dedicated to delivering advances in prevention, treatment, and care for people with HIV.

GSK supports policy solutions that transform our U.S. healthcare system to one that rewards innovation, improves patient outcomes, and achieves higher value care. GSK is a member of and endorses the comments of the Pharmaceutical Research & Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) on this ICR.

Under the Paperwork Reduction Act (PRA), OMB must ensure that CMS "has taken every reasonable step to ensure that the proposed collection of information" is: 1) least burdensome necessary to satisfy legal requirements; 2) "not duplicative of information otherwise accessible to the agency"; and 3) maintains practical utility.[1] CMS' information request throughout the ICR, particularly for commercial unit prices and research and development (R&D) costs, fails to acknowledge the substantial and unreasonable burden placed on manufacturers and provides limited practical utility to the Agency.

Much of the information requested in the ICR is "new" -- that is to say, it does not currently exist in the form requested by CMS within commercial organizations such as GSK. CMS is asking for a respondent to **generate** new data, solely in response to the ICR inquiry. This is burdensome on numerous levels including, but not limited to, the fact that an organization must allocate resources just to respond to the inquiry and is disruptive of other internal functions to complete the task. Moreover, it raises questions about the appropriateness or "fitness" of the data. Here, commercial organizations with hundreds (perhaps thousands) of years of combined financial and economic experience do not currently use or create this type of data, perhaps as a signal of its value. Yet, because it does not cost the Agency

[1] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

anything to request information in **any** form, they have shifted the burden onto the respondent. To limit the burden on respondents, the Agency should limit its request to data in existence, perform its own data manipulations on submitted data or provide a justification for the new data categories that it seeks to compel.[2]

The ICR contains multiple information requests that is not collected in the least burdensome manner, is duplicative of information CMS may access, and provides limited utility. The federal government maintains some of the requested information (e.g., patent exclusivity data from the U.S. Patent and Trademark Office) or can access it from publicly available resources. Certain data requests may exist with manufacturers but not in the form requested by the Agency, creating additional burdens by demanding manufacturers generate new data. In certain circumstances, manufacturers may no longer have access to, or never had access to, the requested data. Regardless, the data requests place a heavy burden on manufacturers, made worse by CMS's arbitrary and rigid character counts, page limits, and inability to provide reasonable assumptions. OMB should require CMS to reverse its positions and allow manufacturers to provide responses with no limits on character counts or page limits and should allow the use of reasonable assumptions when providing data for this ICR.

To provide the requested data, manufacturers must pull data from multiple and varied aspects of operations, including global, regulatory, R&D, distribution, other business units, and possibly other manufacturers. The Agency erroneously estimates the cost to a manufacturer of a selected drug to range from $25,794.25 to $103,177.00 with a base estimate of $51,585.00. This incredibly low estimate disregards the complexity and operations size of the manufacturers with drugs most likely to be selected for the Medicare drug price negotiations program. In addition, the vast difference in the range highlights the high variability in investment necessary for manufacturers to collect and provide the requested information. GSK recommends OMB work with CMS to reduce burden, remove duplicative requirements, and ensure utility of requested information by adopting the following changes: 1) revise Questions 24 and 25 related to commercial average net unit prices; and 2) streamline and provide manufacturers the requisite flexibility with providing R&D costs for Questions 1-6.

We respectfully submit the additional comments below to highlight issues of paramount interest to GSK and the patients we serve.

1) **OMB Should Work with CMS to Remove or Revise Questions 24 and 25 Related to Reporting Commercial Average Net Unit Prices**

CMS requests in Questions 24 and 25 that Primary manufacturers provide, on behalf of themselves and any Secondary Manufacturers, the values and rationale for the U.S. commercial average net unit price with and without spending on patient assistance programs (e.g., coupons, co-payment assistance) and the lowest price offered in the commercial market. These questions exceed CMS's authority under both the IRA and the PRA and should be omitted from the ICR Form.

[2] This is especially important here where the entire inquiry focuses on what constitutes a "maximum fair price" and the vague and nebulous directives as to how to achieve it. Not tied to a clear statutory mandate, as found for example in the Tax Code, this request is ripe for abuse. Given the discretionary nature of materials in support of the "negotiation" and "MFP", all at the expense of the respondent, we believe restraint is required to limit overbroad and specious data requests.

The IRA authorizes CMS to collect, "[m]arket data and revenue and sales volume data for the [selected] drug in the United States"[3] but the proposed requirement to provide these new, unverified drug pricing metrics exceeds CMS' statutory mandate, creates undue administrative burden, and lacks the specificity and clarity in definition and will result in reporting inconsistencies. Furthermore, patient assistance is not a price available to either commercial payers or federal programs. It is ambiguous why CMS would be collecting data in this manner and the underlying implication of patient assistance programs on price. Moreover, it is unclear what CMS means by "patient assistance" as the Agency refers to it in several different contexts. CMS should eliminate all mentions of "patient assistance" from its questions and from the negotiation process. ***GSK recommends OMB work with CMS to remove, or at the minimum, to revise the proposed definitions related to U.S. commercial average net unit price.***

CMS' requirement for Primary manufacturers to provide U.S. commercial average net unit prices with or without patient assistance, as well as the lowest prices offered in the commercial market will not provide the Agency with useful information that should be considered when establishing the Medicare "maximum fair price" (MFP) for selected drugs. The federal government is using its extraordinary power to gather market data using terms with unclear definitions for application in drug price negotiations. While CMS is generating these new pricing metrics in a remarkably short timeframe, other mandatory drug pricing metrics have evolved over time and taken years to define (e.g., Average Manufacturer Price, Best Price, and Average Sales Price). Commercial prices used for a younger patient population with different clinical needs should not be relevant to how CMS assesses a selected drug used by Medicare beneficiaries. In addition, the proposed data represent only a small portion of the overall market, making it difficult for CMS to use this information to understand the market, sales, and volume.

Further, the burden on primary manufacturers to collect and to report these data within 30 days of being announced as a selected drug is unreasonable. Manufacturers do not currently track or maintain on a quarterly basis for the past five years data on a "U.S. commercial average net unit price" with or without patient assistance programs as defined by CMS. The Agency has not provided any rationale for requiring five years of data or the need to do so on a quarterly basis. Clearly, these requirements are beyond the statutory mandates of the IRA and are not applied in the least burdensome method.

Moreover, the burden on Primary manufacturers is exacerbated by holding Primary manufacturers responsible for the reporting and data submissions of Secondary manufacturers. Primary manufacturers cannot verify or require a secondary manufacturer to provide complete and accurate information. A Primary manufacturer may be negatively impacted with a lowered MFP because of inaccurate or no reporting from Secondary manufacturer(s).

If OMB is unable to remove Questions 24 and 25, GSK recommends that CMS revise the definition of "U.S. commercial average net unit price" to ***exclude prices from the Federal Supply Schedule (FSS) and the Big Four (i.e., Veterans Affairs, Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard).*** The prices in these federal government markets are not reflective of drug prices in the commercial market. CMS notes their intent to "achieve the lowest MFP for each selected drug."[4] Use of these prices will artificially deflate the MFP, as they are recursive, manipulated prices that are, by definition, lower than any "commercial price."

[3] Inflation Reduction Act. Pub. L. No. 117-689, 136 STAT. 1847.
[4] Information Collection Request (ICR) for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act. (CMS-10847, OMB 0938-NEW). Supporting Statement – Part A. pg. 3.

The proposed definition and use of "U.S. commercial average net unit prices" with and without patient assistance programs, and the lowest price offered in commercial markets creates substantial burden and provides minimal practical utility for the Medicare drug price negotiations program. OMB should work with CMS to remove or to revise these terms.

2) OMB Should Work with CMS to Streamline the R&D Information Requested (Questions 1-6) and Provide Manufacturers Flexibility

CMS requires manufacturers to provide R&D costs across five categories: 1) acquisition costs; 2) basic pre-clinical research costs; 3) post-investigational new drug (IND) application costs; 4) abandoned and failed drug costs; 5) all other R&D direct costs. Manufacturers do not uniformly collect, report, or organize these data into the categories above, and in some instances, it may be impossible to allocate data into these categories. Moreover, manufacturer retention policies may not allow reporting of these data elements. The Agency places excessive burden on manufacturers to comply with reporting data elements that may no longer exist for a variety of reasons. Manufacturer may have changed internal accounting systems, or removed records in accordance with retention policies, or acquired the asset from another manufacturer that did not convey the requested records. Notably, other government agencies place less burdensome retention requirements. The Internal Revenue Service requires maintaining records for only three years while CMS is unreasonably mandating manufacturers provide data from decades ago.

Furthermore, it is not reasonable and excessively burdensome to require manufacturers to comply retroactively with data retention practices. Manufacturers could not have conceived of CMS implementing the Medicare drug price negotiations program with R&D reporting requirements. It is not feasible for a manufacturer to have anticipated passage of the IRA and CMS request for information it no longer maintains in accordance with its retention policies. ***GSK recommends OMB work with the Agency to streamline the R&D costs reporting requirements under Questions 1-6 and to provide manufacturers with the necessary flexibility to report such data.***

GSK appreciates the opportunity to provide comments on the ICR of the Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act. We stand ready to engage with CMS on this critical work to ensure the program is implemented without adverse impacts to Medicare beneficiaries. Please do not hesitate to contact me at Harmeet.S.Dhillon@gsk.com, should you have any questions or requests for additional information.

Respectfully,

Harmeet Dhillon
Head, Public Policy
GSK