July 31, 2023

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

Re: ICR Reference Number: 202306-0938-013. Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847).

To The OMB Desk Officer:

Boehringer Ingelheim Pharmaceuticals, Inc. (BI) welcomes the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS or the Agency) *Information Collection Request for Negotiation Data Elements under Section 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, OMB, 0938-NEW), and the Comment Summary Responses submitted to the Office of Management and Budget.[1] BI adopts and incorporates by reference the comments submitted on these documents by the Pharmaceutical Research and Manufacturers of America (PhRMA). We offer the following comments to elaborate and expand on certain issues raised.

BI is a leading research-driven biopharmaceutical company committed to innovation in areas of high unmet medical need. Accordingly, BI has a significant interest in CMS's implementation of the Inflation Reduction Act (IRA). While BI supports the goal of ensuring patient access to affordable, life-enhancing medicines, it has significant concerns relating to aspects of the ICR, including concerns that it includes unlawful and impracticable—even impossible—data reporting elements, processes, and deadlines.

Under federal regulations, "an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:

(i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;

(ii) Is not duplicative of information otherwise accessible to the agency; and

[1] 88 Fed. Reg. 42,722 (July 3, 2023); CMS, Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act; Supporting Statement – Part A (June 30, 2023), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847; CMS, Information Collection Request for Negotiation Data Elements under Section 11001 and 11002 of the Inflation Reduction Act, ICR Form (June 30, 2023) https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847; CMS, Responses to Public Comments Received for CMS-10847, Final clean 60-Day Data Elements Comment Summary Responses (Uploaded June 29, 2023), https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202306-0938-013.

(iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."[2]

In multiple instances, CMS's ICR fails to meet this standard. The following sections detail the extraordinary burdens BI will face in reporting R&D costs and recoupment in the manner and at the level of detail CMS has proposed, especially given the accelerated timeline for submission, and other data proposed for collection that is of questionable utility to CMS. CMS has also failed to guarantee that the sensitive commercial information that manufacturers must submit will be transmitted securely and remain confidential, despite its statutory directive otherwise. In addition, BI emphasizes the need for CMS to specify formulary coverage terms to ensure continued, broad patient access to drugs selected for the "Drug Price Negotiation Program" (Program).

I. The ICR's Questions on R&D Costs and Recoupment are Overly Burdensome and Not Adequately Supported by Legal Requirements and Articulated Program Objectives.

Both BI and PhRMA have already commented extensively on how the data elements included in the ICR go far beyond the data reporting requirements mandated or allowed in the statute and are inconsistent with how manufacturers organize, report, and retain such data. CMS's proposed approach to collecting R&D cost and recoupment information is both exceedingly granular and exceedingly broad. To cite just one example, it is extraordinarily burdensome for manufacturers to disaggregate direct expenses and identify those that are "specifically attributed" to the selected drug, particularly for costs incurred early in the development process and potentially many years in the past.[3] Here, as in other places, CMS creates terminology that is not used in the ordinary course of business (e.g., "specifically attributed"). In the current state of science, researchers are looking at multiple candidate molecules and conducting multiple work streams in parallel. The requirement to list all "activities" that the Primary Manufacturer included in the direct research expenses and the indirect research expenses categories compounds the ICR's burdens, particularly since CMS provides limited guidance as to how relevant "activities" should be broken down and reported.[4] Moreover, reporting on how "shared expenses" were allocated among the Primary Manufacturer and other entities would require disclosing sensitive commercial arrangements.[5]

As a private company based in Germany, BI in particular faces unique and significant challenges with providing the information CMS requires, especially on an accelerated timeline. R&D cost information is held abroad and is not organized according to the categories and definitions CMS proposes. Obtaining, compiling,

[2] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).
[3] ICR Form at 10 (Question 2) (defining "direct research costs"). *See, also id.* at 12-13 (Questions 3-5) (limiting reporting to direct costs only). Additionally, CMS's "proportional" allocation approach for reporting indirect research costs in Question 2, *see id.* at 10-11, would not accurately capture costs for all products. The proportion of direct costs for preclinical testing owing to one drug is not necessarily equal to the proportion of indirect costs attributable to that selected drug.
[4] *Id.* at 11 (Question 2).
[5] *Id.* at 9 (applicable to Questions 1 through 5).

and breaking down this data in the way CMS requests is a time-intensive process that — if it is even possible — would require far more resources from the manufacturer than the unreasonably low estimates provided in CMS's supporting statement. As a privately held company, BI has never reported R&D cost information at this level of detail.

CMS provides no sufficient explanation as to how manufacturer responses to the seven questions, including the calculations or assumptions in free text response fields, will ultimately be used to determine the initial offer. CMS's revised guidance states that CMS "*may* consider adjusting the preliminary price upward" if the manufacturer has not recouped its R&D costs and "*may* consider adjusting the preliminary price downward or apply[ing] no adjustment" if a manufacturer has recouped its R&D costs.[6] And CMS also asserts it may "adjust the preliminary price" based on "the R&D costs reported by the Primary Manufacturer and the calculated recouped costs, including the assumptions and calculations in the accompanying narrative text, and/or other factors as described in the Negotiation Data elements ICR and in Appendix C of this revised guidance."[7] Yet, CMS does not explain why the volume and granularity of information it is requesting is required and how answers to each question and sub-question will affect the initial offer.

II. Other Aspects of the ICR Impose Significant Burdens on Manufacturers and Otherwise Deviate from Requirements Under the Paperwork Reduction Act.

Patents, Exclusivities, Applications, and Approvals

In its response to initial ICR comments, CMS notes that it "revised questions 12 and 13 and their instructions to provide additional information about the types of patents and patent applications considered to be 'related to' the selected drug."[8] Instead of merely "providing additional information," the revised ICR significantly *expands* the patent information that manufacturers must submit. The revised ICR defines patents "related to" the selected drug as:

> *Patents and patent applications related to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book; utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug.*[9]

This purported "clarification"[10] extends to patents that are not actually *for* the "selected drug" (e.g., patents that claim the metabolites or intermediaries of the selected drug). Requiring submission of such patents is contrary to the statute, which authorizes CMS to collect only

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[6] CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* at 150-51 (June 30, 2023) (Revised Guidance), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[7] *Id.* at 151.

[8] CMS, Response to Public Comments Received for CMS-10847 at 12.

[9] ICR Form at 23-24.

[10] Revised Guidance at 7.

"[d]ata on pending and approved patent applications . . . *for* the drug"[11] and describes the "[m]anufacturer-specific data" that must be submitted as data "*with respect to* such selected drug."[12] Moreover, the original version of the ICR did not reference design patents in the definitions for the *Patents, Exclusivities, and Approvals* section. Explicitly requiring this information from manufacturers adds an additional burden to an already complex data submission.

Market Data, Revenue, and Sales Volume Data

CMS is requiring that manufacturers provide data for three new metrics: (1) U.S. commercial average net unit price; (2) U.S. commercial average net unit price – without patient assistance program; and (3) U.S. commercial average net unit price – best. The definitions for these pricing metrics are not clearly written, and CMS provides insufficient guidance on how exactly to perform the calculations needed to arrive at the required metrics. Since these metrics are not collected in the normal course of a manufacturer's business, companies will have to develop and launch a new transaction-level data collection and analysis infrastructure for these new measures on an expedited timeline. This endeavor is complicated by having to account for support provided to purchasers, potentially including patients, such as "coupons" and "goods in kind," which CMS views as "concessions" in the average net unit price calculations. OMB should instead require that CMS collect only *existing* metrics such as Average Manufacturer Price and Best Price, which manufacturers already collect and report to CMS and therefore would be far less burdensome while remaining informative.

Prior Federal Financial Support

The ICR's instructions for providing information related to prior federal financial support are unclear, making compliance difficult for manufacturers. For example, CMS defines prior federal financial support to include tax credits but fails to articulate any directions for a manufacturer to allocate tax credits to R&D for the selected drug specifically. Without this clarification, manufacturers of selected drugs may take a variety of methodological approaches to allocating a portion of broadly applicable tax credits to their selected drugs specifically, leading to varying reported values for prior federal financial support. Additionally, BI notes that record retention rules for tax information do not necessary align with record retention rules related to R&D expenditures.

III. CMS Fails to Guarantee a Secure Transfer of Highly Confidential Manufacturer Information

CMS's lack of a secure, alternative data submission mechanism to the Health Plan Management System (HPMS) could expose manufacturer data to unacceptable security risks. In the Supporting Statement, CMS notes that "[i]f CMS HPMS is not used for submission because the CMS HPMS tool is delayed, responses to this ICR should sent by email to IRARebateandNegotiation@cms.hhs.gov."[13] The data being transmitted to CMS is sensitive and highly confidential. By statute, CMS must protect proprietary information submitted by manufacturers and ensure that it is used only by CMS or disclosed to and used by the

[11] SSA § 1194(e)(1)(D).
[12] *Id.* § 1194(e)(1).
[13] Supporting statement at 4.

Comptroller General of the United States for purposes of carrying out the program.[14] If the HPMS system is not operational, submitting the information to an unencrypted email box poses unnecessary risks of compromising the proprietary nature of this information for manufacturers. At minimum, OMB should require that CMS prepare a secure, encrypted file-sharing alternative that can guarantee the confidentiality of manufacturer data. Until a secure system can be validated, OMB should remove any requirements to submit commercially sensitive information.

IV. Without Further Action by CMS, Prescription Drug Plan (PDP) Sponsors Will be Incentivized to Disadvantage Drugs Selected for the Program.

The fundamental purported purpose of the Program is to lower drug costs for patients and Medicare. Yet, Medicare beneficiaries and the Medicare program will fail to realize such cost savings if PDP sponsors are permitted to disadvantage selected drugs. The law requires PDP sponsors to "include each covered part D drug that is a selected drug under section 1192 for which a maximum fair price . . . is in effect with respect to the year."[15] In the revised guidance, CMS states that it will use "monitor Medicare Part D plans' compliance with all applicable formulary requirements" using its "formulary review process."[16]

Nevertheless, given CMS's regulatory authority over PDPs, mere *inclusion* and *monitoring* are insufficient to guarantee continued, broad patient access if PDP sponsors are allowed to unfairly disadvantage drugs selected for the Program by, for example, increasing patient cost sharing or imposing burdensome utilization management requirements. To ensure that prescription drug cost savings are realized, CMS should specify formulary coverage terms that ensure broad patient access to drugs selected for the IRA's Program, defined as covering a product (1) on the most favorable formulary tier afforded any brand name product in the therapeutic class, but at a minimum, on the formulary tier and level of cost sharing predating selection, and (2) without stricter utilization management requirements, unless related to clinical safety or product label limitations.

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Conclusion

Boehringer Ingelheim appreciates the opportunity to provide feedback on these proposals and looks forward to working with CMS and OMB to inform the development of meaningful policy solutions.

[14] SSA § 1193(c); *see also* Revised Guidance at 123-24.
[15] SSA § 1860D-4(b)(3).
[16] Revised Guidance at 176.

Thank you for considering these comments and those submitted by PhRMA. If you require any additional information or have questions, please contact Michael Penn, Head of Public Policy at (203) 791-6680 or michael.penn@boehringer-ingelheim.com.

Sincerely,

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