July 31, 2023

William N. Parham, III, Director
Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

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

Dear Mr. Parham:

AstraZeneca appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed information collection request (ICR) for the Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA).[1]

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas – Oncology, Cardiovascular, Renal & Metabolism (CVRM) and Respiratory & Immunology. We are also working to solve the challenges for rare disease patients through Alexion, AstraZeneca Rare Disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

I. AstraZeneca Supports the Revisions CMS Made in Response to Our Prior Comments.

The IRA directs CMS, for purposes of negotiating the maximum fair price (MFP) for a selected drug, to consider certain "manufacturer-specific factors" as well as "evidence about therapeutic alternatives," including comparative effectiveness research, and the extent to which a selected drug represents a therapeutic advance or addresses unmet medical needs. As a manufacturer of therapies that may be selected for negotiation, AstraZeneca has a vested interest in ensuring that the data collected by CMS through the ICR Form are clear, useful, and high-quality, and that CMS takes steps—including through the use of information technology—to reduce the burden on reporting entities.

Along these lines, we appreciate the revisions CMS made to the ICR Form based on the comments we submitted in response to the Agency's 60-day *Federal Register* Notice. In particular, for purposes of assessing therapeutic impact and comparative effectiveness, CMS has clarified the scope of the clinical and non-clinical outcomes the agency is collecting for purposes of negotiating the MFP. This additional clarity will increase the clarity and utility of the data CMS collects with respect to the therapeutic alternative factors by making clear that the agency

[1] 88 Fed. Reg. 42,722 (July 3, 2023).

will consider a broad set of factors most relevant to patients. In particular, we strongly support CMS's clarification that:

> Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients, and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered, including patient-centered outcomes when available, to the extent that these outcomes correspond with a direct impact on individuals taking the drug. The caregiver perspective will be considered when there is a direct impact on the individuals taking the selected drug or therapeutic alternatives.

We further support CMS's clarification that it is seeking data on patient-centered outcomes, which the agency defines as "[a]n outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves."

In addition, AstraZeneca strongly supports CMS's decision to pre-populate certain information specific to the manufacturer-specific information—including NDC-11 data—in the revised ICR Form. The prepopulating of data will reduce burden on manufacturers subject to the IRA's reporting requirements. As outlined below, we recommend that CMS go further by prepopulating additional data fields, and by taking other steps to reduce the burden on manufacturers and others submitting information through the ICR Form.

II. Additional Changes Are Needed to Improve the Quality and Utility of the Information Collected, and to Reduce Burden on Reporting Entities.

While there were some positive changes, AstraZeneca is concerned CMS has not addressed many of our other comments regarding the ICR Form. We therefore remain concerned that, without further revision, the ICR Form will impose unnecessary burden on respondents and/or result in the collection of data that are unnecessary, unclear, or unrelated to the purposes outlined in the IRA. Accordingly, we continue to recommend that CMS make the following additional changes to the ICR Form.

Research and Development (R&D) Costs and Recoupment: AstraZeneca remains concerned the level of granularity required for reporting R&D costs and recoupment is inconsistent with how life sciences companies and investors perceive and approach risk and risk-adjusted returns. For instance: CMS' reporting methodology is not consistent with how manufacturers track cost information; the focus on cash outlays by the Primary Manufacturer is too rigid for co-commercialized products; and CMS's definition of research failures does not consider the full costs of failures associated with drug development. To address these concerns, we recommend amending the ICR Form to allow a single global response for R&D costs, similar to Form 10K filings with the SEC. In addition, CMS should introduce a simple "YES/NO" attestation for cost recoupment, requiring additional information only if the respondent answers "NO." The statute merely contemplates the collection of information regarding "the extent to which the

manufacturer has recouped research and development costs."[2] Reporting extremely detailed cost recoupment data is not only extremely burdensome, it has no utility to CMS for purposes of implementing the Negotiation Program.

Current Unit Costs of Production and Distribution: We similarly remain concerned the ICR Form, as currently drafted, would collect information on current unit costs of production and distribution that is both burdensome for manufacturers to report, and not useful to CMS. We therefore urge CMS to update the form in order to improve the utility of the information collected while reducing burden on manufacturers. For instance, in Sections C and D, we recommend CMS compare U.S. costs of production and distribution with U.S. (rather than global) revenue figures and ensure that manufacturers can report all costs (e.g., royalties). In addition, given that per-unit cost of goods and services (COGS) are highly variable and thus not generally reported, CMS should permit the submission of a range of COGS. CMS should also provide manufacturers with discretion to describe production and distribution costs— if CMS moves forward with a specified methodology for production cost submissions without permitting such discretion, it will be difficult for companies to comply with the mandate without making costly changes to existing accounting systems.

Prior Federal Financial Support: CMS has selected an overly broad definition of federal funding or collaboration. The burden of obtaining and reporting data in the specific manner CMS requests would significantly outweigh the utility of this information to CMS. We therefore continue to recommend that CMS consider only prior federal financial support resulting in a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government Agency for an invention directly related to the development of the selected drug (e.g., excluding basic science, research tools, or similar general concepts). In addition, to reduce burden on manufacturers while enhancing the quality of the information collected, CMS should obtain information regarding such prior financial support from existing sources, such that manufacturers need only report the total federal financial support figure with an explanation (and no longer need to separately report funds received from each of the identified sources).

Market Data, Revenue, and Sales Volume Data: There is no legitimate reason for CMS to request the pricing data as outlined in the ICR Form, and we fail to see how this data collection will meaningfully assist with MFP negotiation. Specifically, CMS would require that manufacturers provide the 340B Ceiling Price and 340B Prime Vendor Program Price Medicaid Best Price, Federal Supply Schedule (FSS) Price, and the Big Four Price. Of the pricing data listed, the IRA specifies only that non-FAMP pricing must be reported to CMS. Using the broad term "market data, and revenue, and sales volume data" to request proprietary pricing information across all markets not only exceeds CMS's authority but is unnecessary for the Negotiation Program. Additionally, CMS has not stated a non-arbitrary reason to seek 20 quarters of revenue and sales volume data; reporting data over this period would burden manufacturers, especially regarding average commercial and Medicare Part D prices. To the extent CMS considers these data at all for the Negotiation Program, which it should not, CMS should prepopulate this information into the ICF Form (as it will for NDC-11 data), and any related data reporting should align with the units already required by other federal entities.

[2] SSA § 1194(e)(1)(A).

Selection of Therapeutic Alternatives: AstraZeneca also remains concerned with CMS' proposed approach to selecting therapeutic alternatives. As a threshold matter, we are deeply concerned with the new definition of "therapeutic alternative,"[3] which indicates CMS will consider off-label uses as therapeutic alternatives. There is generally very little data regarding the use of therapies for off-label indications, so we question CMS's ability to collect high-quality information on this topic. We also remain concerned that CMS has not established a process to provide manufacturers with advanced insight and understanding into how CMS intends to select therapeutic alternatives, as well as notice of those alternatives once chosen by the Agency. While we appreciate the addition of a manufacturer meeting and patient-focused listening sessions in the Revised Guidance, AstraZeneca continues to urge CMS to provide manufacturers with an opportunity to engage with Agency and review CMS's methodology for the selection of therapeutic alternatives *before* CMS makes such a determination. Misalignment on the appropriateness of therapeutic alternatives during negotiation will introduce significant risks to the process and could create delays in data submissions— leading to additional work for CMS and increasing uncertainty in the negotiation process.

In addition, while somewhat outside the scope of this particular ICR, we note that additional transparency regarding the nature and source of therapeutic alternative data under consideration by CMS will improve the utility of information CMS receives through, for example, the Counteroffer ICR Form. As noted in the revised ICR Form, any organization or member of the public may submit data on therapeutic alternatives to drugs selected for negotiation. We appreciate the need for broad stakeholder input on this issue. However, the source of these data may have a bearing on the weight CMS should place on the information submitted. So, while we appreciate CMS's efforts to collect information regarding the entities reporting information related to therapeutic alternatives,[4] to enable manufacturers of selected drugs to make an informed counteroffer as part of the negotiation process, CMS should publicly identify the therapeutic alternative(s), as well as any evidence-based resources (e.g., clinical guidelines) it relied upon to identify the therapeutic alternative.

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AstraZeneca thanks you for the opportunity to submit comments and looks forward to continuing to engage with CMS as it implements the Negotiation Program for IPAY2026 and beyond. We can be reached at sarah.arbes@astrazeneca.com and lisa.feng@alexion.com with any questions.

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[3] In the revised ICR Form, CMS proposes the following definition: "A therapeutic alternative must be a pharmaceutical product that is clinically comparable to the selected drug. CMS will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar ***and may be on-label or off-label to treat a given indication***. CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are most clinically comparable to the selected drug." (emphasis added).

[4] *See* Question 26.

Sincerely,

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