

# Annual Declaration for Purposes of California Health and Safety Code, §§ 119400-119402



July 1, 2021

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## ANNUAL DECLARATION FOR PURPOSES OF CALIFORNIA HEALTH & SAFETY CODE, §§ 119400-119402

Section 119402 of the California Health & Safety Code requires a pharmaceutical company to adopt a Comprehensive Compliance Program that is in accordance with the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Compliance Guidance"), and include policies for complying with the Pharmaceutical Research and Manufacturers of America Code ("PhRMA Code"). Further, the law requires that the Comprehensive Compliance Program include an annual limit for certain items and activities given to healthcare professionals covered by this California law. Finally, the law requires that each manufacturer make its Comprehensive Compliance Program and an annual declaration of compliance publicly available.

GlaxoSmithKline LLC (the "Company") has committed significant time and resources into the development of each of its policies, procedures and processes that make up its Comprehensive Compliance Program, which includes an annual limit for items and activities provided to healthcare professionals in California. In developing these policies, procedures and processes, the Company reviewed the OIG Compliance Guidance and PhRMA Code, although neither the OIG Compliance Guidance, nor the PhRMA Code is a compliance program in and of itself. Rather, these two documents set forth voluntary guidelines to be considered when developing a new compliance program or updating an existing one, and must be adapted and interpreted to meet each individual company's specific circumstances. The Company adapted the objectives and principles underlying these guidelines to its own unique circumstances. As such, the Company believes that its Comprehensive Compliance Program is consistent with a reasonable interpretation of the OIG Compliance Guidance and the PhRMA Code.

The Company has a Comprehensive Compliance Program with which it is in substantial compliance as of the date of this declaration. As the OIG recognizes in the OIG Compliance Guidance, "the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer." Accordingly, this declaration is not intended and should not be construed to imply that the Company has not identified individual instances in which an employee or agent of the Company has or may have violated one or more provisions of its Comprehensive Compliance Program. In those situations, the Company takes reasonable and appropriate remedial or corrective action with respect to any actual or potential non-compliance in a manner consistent with its Compliance Program. The Company's Comprehensive Compliance Program and this Annual Declaration are publicly available on our website, <http://www.gsk.com>.