

# Amended and Restated Operating Procedures of the Industry Pharmacogenomics Working Group

## 08 February, 2023

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### INTRODUCTION

The Industry Pharmacogenomics Working Group (“**I-PWG**” or the “**Group**”) is open to all companies engaged in the marketing of pharmaceutical products, provided that they are also actively engaged in pharmacogenomic research, and further provided that they make timely payment of Member fees due hereunder and undertake to participate actively in its functions.

These Operating Procedures (“**Rules**”) have been adopted by the Group for its internal organization and management and each Member Company, by virtue of joining the Group, agrees to these Rules.

### NATURE OF THE GROUP

1a. The Group is a voluntary and informal association of companies, and does not constitute a partnership, joint venture, or legal entity of any nature or kind. No agency relationship exists either between the Group and the Member Companies or among the Member Companies, and neither the Group nor any Member Company is authorized to represent, act for, or bind any other Member Company without its express prior consent.

1b. It is acknowledged that a non-profit, non-stock corporation, Industry Pharmacogenomics Working Group, Inc. (“**I-PWG, Inc.**”), was incorporated in the State of Delaware, United States on April 16, 2018 to act as the secretariat for the Group. For the avoidance of doubt, the Member Companies of the Group shall not be deemed to be members or other legal constituents, managers or equity holders of I-PWG, Inc. nor shall any Member Company have any right to vote upon, approve or reject any action taken by I-PWG, Inc., nor to attend or receive notice of any meeting of I-PWG, Inc.

### MEMBERSHIP

2a. As conditions of membership, the Group shall be limited to companies (a) that are actively engaged in (i) the development, manufacture, marketing, and sale of pharmaceutical products and (ii) research in the science of pharmacogenomics; (b) that make timely payment of periodic Member fees invoiced pursuant to Rules 26 and 27; and (c) that comply with these Rules.

2b. Each Member Company shall have the right to participate in the Group’s meetings, discussions, activities, and programs.

3. By amendment to these Rules adopted pursuant to Rule 40 below, the Group may elect to limit the number of Member Companies if this becomes necessary or appropriate to ensure the Group’s efficient operation. By similar amendment, the Group may establish categories or levels of membership, or take other steps to facilitate its activities.

4. Applicant companies satisfying all of the conditions of membership set forth in Rule 2a, as well as any relevant limitations adopted pursuant to Rule 3, shall be admitted as members of the Group upon the approval of a majority of the Member Companies. No applicant company may be denied membership for any reason other than its failure to satisfy a condition of membership set forth in Rule 2a or any relevant limitation adopted pursuant to Rule 3.

5. Any Member Company that no longer satisfies any condition or obligation of membership set forth in Rule 2a shall no longer be eligible to be a Member Company and shall, upon receipt of written notification from the Chair(s), cease to be a Member Company in the Group.

6. Any Member Company may resign from the Group at any time and for any reason by submitting its resignation in writing to either or both Chairs.

## **VOTING**

7. A quorum for any meeting or teleconference of the Group shall consist of fifty percent of the Member Companies, plus one. In the event of dispute or uncertainty, the Chair(s) shall determine whether a quorum exists.

8. Voting shall be by company, with each Member Company entitled to one vote. Except as otherwise provided in these Rules, all elections, approvals, and decisions by the Group shall require the supporting votes of a majority of the Member Companies.

9. Each Member Company shall designate a single person authorized to exercise its right to vote (referred to as its "primary contact"), and may alter such designation as and when it elects. Alternative primary contacts may be designated in the same manner. Each Member Company shall give timely and unequivocal notice by email to the Chair(s) of such designations. In the event of dispute or uncertainty, the Chair(s) shall determine who is authorized to vote on behalf of a particular Member Company.

10. Voting may be conducted orally, in writing, in person, in teleconferences, or by email, as the Group may decide. In the absence of such a decision, the Chair(s) shall designate the applicable manner of voting.

11. Proxy votes are permitted if prior and unequivocal notice by e-mail is given to the Chair(s) by the Member Company for which the proxy will be exercised. For purposes of these Rules, a "proxy vote" is an official authorization by a Member Company that another Member Company may cast a specified vote or votes on behalf of the authorizing Member Company. Proxy votes may be revoked in writing by the authorizing Member Company at any time prior to the casting of the relevant vote.

## **REPRESENTATION**

12. Each Member Company shall be entitled to be represented at each of the Group's meetings and teleconferences by the designated primary contact appointed pursuant to Rule 9 above, and in addition other company colleagues that have been pre-identified by the primary contact may also be able to join the Group's meetings as observers. It is the responsibility of the primary contacts to provide the I-PWG administrator with the names, and contact details, of all additional meeting attendees prior to the Group's meetings. Attendance as observers is also open to any additional Member Company employees, provided that advance notice of their intention to attend is provided to the Chair and that, for in-person meetings, the available meeting space allows it.

## THE CHAIR(S)

13. The Group shall elect at least one Chair or may instead, in its discretion, elect not more than two Chairs, in each case, with the powers set forth in Rule 14 below. The Group may, in its discretion, also elect a single Chair-Elect or two Chairs-Elect. Elections shall be held at such times and in such manner as the Group may decide.

14. Except as the Group may otherwise decide, the Chair(s) shall conduct the Group's meetings and teleconferences, establish agendas, conduct or supervise the conduct of communications on behalf of the Group with third parties, designate committees, designate Invited Participants in accordance with Rule 34b below, and otherwise organize and oversee the activity of the Group. If there are two Chairs, then such Chairs shall act unanimously except in any case described in Rule 20a below in which one Chair is expressly authorized to act alone.

15. Individuals are eligible for election as Chair(s) or Chair(s)-Elect only if they are, at the time of election, designated representatives of a Member Company. In the event there are two Chairs, each must be the designated representative of a different Member Company and, in the event of two Chairs-Elect, the same shall apply. Individuals are eligible to serve as Chair(s) or Chair(s)-Elect only if and so long as they remain such representatives. The Member Company represented by a Chair may in its discretion designate either such Chair or another employee as its voting representative.

16. Except for interim periods provided for below by Rules 19 and 20a, the same or different representatives of the same Member Company may not serve as Chair for more than a single term or portion thereof, whether or not consecutively, until every other Member Company has been afforded the opportunity of providing a Chair. Any Member Company may at any time and for purposes of any election or series of elections waive its opportunity to provide a Chair. Whether or not this occurs, this Rule 16 may be waived for purposes of any election with the approval of two-thirds of the Member Companies.

17. A Chair shall serve in such position for a term ending when his or her successor is duly elected and shall qualify or until his or her earlier (a) resignation, submitted in writing to the other Chair (if any) and to the President of I-PWG, Inc., (b) removal by a duly conducted vote of the Group, (c) ceasing to be the designated representative of a Member Company, or (d) death. The Chair(s)-Elect, if any, shall succeed as Chair(s) at the end of such term. If there are two Chairs-Elect, they may themselves decide which of them shall first fill any such vacancy and, if they cannot agree, the Member Companies shall decide, in each case subject to the requirement of Rule 15 that when there are two Chairs, each must represent a different Member Company.

18. In the event of a vacancy in either or both Chair positions, a special election to fill the vacancy shall be held as soon thereafter as practicable.

19. If the positions of Chair and Chair-Elect are both vacant, the most recent Past-Chair(s) then eligible and available, without regard to his or her Member Company, shall serve as Chair(s) pro tem until an election is held.

20a. If there are two Chairs, and only one is absent from any meeting or teleconference or is otherwise temporarily unable to perform the duties of Chair during any period, the other Chair shall serve as Chair alone for purposes of that meeting or teleconference or during that period. If, however, there is only a single Chair and that person is absent or temporarily unable to perform, or if there are two Chairs both of whom

are absent or temporarily unable to perform, then the most recent Past-Chair(s) then eligible and available, without regard to their Member Company, shall serve as Chair(s) pro term for purposes of that meeting or teleconference or during the applicable period.

20b. Each Chair shall, during the term of his or her chairmanship, also serve as a director of I-PWG, Inc. and shall, upon the end of such term as Chair, promptly resign from the position of director of I-PWG, Inc. Each Chair agrees to take all actions and sign all documents as necessary or advisable in connection with his or her appointment and service as a director of I-PWG, Inc.

## **ACTIVITIES**

21. The Group's purposes are educational and informational. Its discussions and activities shall be restricted to non-competitive educational, informational, ethical, legal, and regulatory matters. The Group shall comply fully and faithfully with all applicable legal requirements, including all antitrust and competition law obligations. Accordingly, any matters that have any competitive significance or consequences shall not be referred to or discussed at or in connection with the Group's meetings and teleconferences. The Chair(s) may in their discretion engage, and the taskforce leaders may at any time request the Chair(s) to engage, legal counsel to participate in any meeting or teleconference at any time.

22. The Group's discussions and activities shall be open and transparent. Information about them shall be available on request to all interested authorities, companies, and persons. The Group may, as and when it finds appropriate, establish or contribute to websites and other means of public communication.

23. The Group may organize, conduct, or sponsor meetings, workshops, or seminars, provide or arrange for speakers or lecturers, prepare publications or papers, submit statements or materials to regulatory authorities or others, or engage in any other form of non-competitive informational or educational activity to promote the public understanding of pharmacogenomic research and its development.

24. All activities to be conducted or sponsored in the name of the Group require the Group's express prior authorization.

25. Any Member Company may, in its discretion and for any reason, elect not to participate in any activity authorized pursuant to Rule 24. Any such Member Company may request that its non-participation be made clear in the conduct and promotion of the activity. Such requests must be communicated in a timely and unequivocal manner to the Chair(s). All such timely requests shall be implemented in a form and manner to be agreed upon between the non-participating Member Company and a majority of the other Member Companies. For the avoidance of doubt, no such election not to participate shall relieve a Member Company from its obligation to pay Member fees in the amount assessed pursuant to Rule 26.

## **FINANCIAL CONTRIBUTION**

26. Each Member Company shall pay periodic, non-refundable Member fees in order to participate in the Group at the levels determined by the Group. Member fees are set at \$4,000 per year. Any changes to the fees will require a vote by the IPWG membership to amend this Rule 26 accordingly, with approval of two-thirds of the Member Companies required, and with such approval to be effective as of the next fee cycle. New Member Companies who join the Group partway through any given annual fee cycle may be required to make payment of such year's fees either in full or on a pro-rated basis, as may be determined by the Chair(s) in their discretion.

27. Member fees shall be invoiced by and paid to I-PWG, Inc., which shall hold and disburse such funds in support of the Group's activities and operations.

## **PUBLIC AND REGULATORY STATEMENTS AND PUBLICATIONS**

28a. All statements to be made publicly or to any regulatory authority in the name of the Group, including all publications, white papers and other written statements ("Publications"), shall be made only after (a) the Group's express prior approval has been obtained by a majority of Member Companies pursuant to Rule 8, and (b) each individual listed as an author of such Publication has confirmed to the Chairs that he or she has obtained all necessary approvals and permissions from his or her employer to be so listed. Each such Publication shall list its individual authors, their Member Company affiliations (or, if such authors are Invited Participants or consultants to the Group, their employers), whereby such list shall conclude with a statement in the following form or such other form as is approved by a majority of the Member Companies that approved such Publication: "*on behalf of the Industry Pharmacogenomics Working Group*", No individual employed by a Member Company that voted against the approval of a Publication shall be listed as an author of that Publication. Notwithstanding the foregoing, nothing herein shall prevent any Member Company or its employees from releasing or publishing any statement or publication in its or their own names and not in the name of the Group.

28b. Each Publication approved in accordance with Rule 28a shall bear a notification in the following form or such other form as is approved by a majority of the Member Companies that voted to approve such Publication: "*This [publication] presents the views of the Industry Pharmacogenomics Working Group (I-PWG), a voluntary association of organizations in the biopharmaceutical sector.*"

29. Any Member Company that has voted against the approval of a Publication may, in its discretion and for any reason, elect to have a disclaimer in the following form or such other form as is approved by a majority of the Member Companies that approved such Publication and each of the Member companies making an election under this Rule 29: "*The following I-PWG Member Companies have not participated in the preparation of this [Publication] and this [Publication] does not necessarily reflect their views: \_\_\_\_\_.*" Such requests must be communicated in a timely and unequivocal manner to the Chair(s). In the event that three or more Member Companies elect not to join in any such Publication, such Publication shall not be released or published until fewer than three Member Companies have elected not to join.

## **NOTICES OF VOTES AND DECISIONS**

30. All proposals to amend these Rules or to conduct or sponsor any activity, or to release any Publication may be voted upon by the Group only if reasonable prior notice of the intended vote has first been given.

31. Notices shall be reasonable and adequate for purposes of Rule 30 if given in writing, whether in the form of a proposed agenda item or otherwise, at least seven (7) business days before the meeting or teleconference in which the vote is to be taken. Whenever reasonably possible, such notice shall also be given in the meeting or teleconference that immediately precedes the meeting or teleconference in which the vote is to be taken.

32. Such notices shall be communicated to each Member Company's primary contact.

33. The notice requirement in Rule 30 may be waived with respect to any proposed decision with the approval of two-thirds of the Member Companies. If this occurs, the Chair(s) shall nonetheless make every reasonable effort to ensure that all Member Companies are informed of the proposed decision and vote and, so far as the situation permits, are given fair and reasonable opportunities to exercise their rights to participate in discussions and to vote.

## MEETINGS AND TELECONFERENCES

34a. It is the present intention of the Group to meet face to face as often as practical and to hold teleconferences at intervals of approximately one month. The frequency, scheduling, and location of meetings and teleconferences may be established or altered as and when the Group finds appropriate and, in addition, the Chair(s) may call meetings/teleconferences in their discretion and shall do so upon the written request of any three (3) Member Companies; provided, however, that whenever reasonably possible no less than thirty days' notice shall be given of all meetings and teleconferences.

34b. Either the Chair(s) or the Member Companies may designate one or more individuals as "**Invited Participants**." Invited Participants shall consist of advisors, experts, or other attendees the Chair(s) or Member Companies, as applicable, deem necessary or advisable to be present to attend meetings or teleconferences of the Group, in which case such individuals, for so long as they are designated as Invited Participants, shall receive notice of such meetings or teleconferences and shall be permitted to participate in deliberations of the Member Companies on a non-voting basis; provided, however, that at any time, by determination of the Chair(s) or the Member Companies, the Group may opt to meet in "executive session" with only the following individuals present: the Chair(s), those individuals who have been designated as primary contacts or observers of the Member Companies in accordance with Rule 9 or 12, and any of such Invited Participants as the Chair(s) or Member Companies deem necessary. As such, if requested by the Chair(s), any non-essential Invited Participants who are present at the meeting or on the teleconference shall exit during any such executive session.

## ADMINISTRATIVE AND LEGAL COSTS

35. The administrative and legal costs of the Group (which shall be deemed to include the administrative and legal costs of I-PWG, Inc.) shall be paid by I-PWG, Inc. from Member fees collected from the Member Companies. The Chairs shall have the authority, acting by decision of all then-sitting Chairs, to disburse the Group's funds to cover the Group's administrative and legal costs as they deem reasonable, provided that any such expenditure or group of related expenditures that exceeds Twenty Thousand U.S. Dollars (US\$10,000) shall require the prior approval of the Member Companies pursuant to Rule 8.

36. I-PWG, Inc. shall provide to the Group a full accounting of all transactions involving the Group at least once annually, at such times and in such manner as the Group finds appropriate.

## AFFILIATIONS

37. The Group may affiliate itself with, or enter into a cooperative relationship with, one or more industry or trade associations or groups, in such manner and to such degree as the Group finds appropriate. Each such affiliation or cooperative relationship shall require the approval of two-thirds of the Member Companies.

38. Any affiliation entered into pursuant to Rule 37 may be modified or terminated by the Group at any time and for any reason with the approval of two-thirds of the Member Companies.

#### **EFFECTIVENESS, AMENDMENTS, AND TERMINATION**

39. These Rules shall be adopted and take effect only with the approval of two-thirds of the Member Companies either at a meeting duly convened or by written action by the required two-thirds majority of the Member Companies.

40. These Rules may be amended by the approval of two-thirds of the Member Companies either at a meeting duly convened or by written action by the required two-thirds majority of the Member Companies. Proposed amendments shall be subject to prior review by legal counsel. No amendments shall be adopted that have any competitive significance, content, or consequences.

41. The Group may be terminated by the approval of two-thirds of the Member Companies. In so doing, the Group shall adopt reasonable and appropriate arrangements to ensure the proper satisfaction of any liabilities and the equitable disposition of any assets.

42. These Rules, and any claim or dispute arising under or relating to these Rules, shall be governed by the laws of the State of Delaware without regard to principles of conflicts of law.

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## CERTIFICATION OF ADOPTION

Each of the undersigned certifies that he or she is a Chair of the Industry Pharmacogenomics Working Group and that the foregoing Rules, which are an amendment and restatement of the original Rules adopted on June 3, 2003, were adopted by written consent of the requisite majority of the Member Companies of the Industry Pharmacogenomics Working Group as of the 1<sup>st</sup> Day of March 2019.

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Chair

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Chair