

SCHEDULE D – Distribution Protocol

1. All capitalized terms used in this schedule have the same meaning as in the *Settlement Agreement*.

Process to Advance a Claim

2. A Class Member who wishes to receive benefits pursuant to the settlement of this Class Proceeding must provide the Claims Administrator with a *Claim Form* (Appendix 1) before the Claims Deadline.

3. Mailed or couriered *Claim Forms* received after the Claims Deadline but post marked or deposited with the courier on or before the Claims Deadline will be deemed received on the post marked date or the date deposited with the courier.

4. E-mailed or faxed *Claim Forms* will be deemed received on the date received by the Claims Administrator

Determination of Eligibility

5. To receive a Compensatory Payment, a Claimant must satisfy the Claims Administrator that he or she is an Eligible Claimant by the completion and submission of a valid *Claim Form* with related medical and pharmacy records.

6. To be eligible for compensation, the Claimant Mother, Claimant Child, or their legal or estate representative must satisfy the Claims Officer that:

- (a) Neither the Claimant Mother or Claimant Child:
 - i. had a cardiovascular birth defect with no other Qualifying Congenital Malformation(s); and
 - ii. was a resident of the Province of British Columbia prior to February 3, 2006 when they were prescribed Paxil® or Paxil CR™;
- (b) The records described below confirm that the Claimant Mother of the Claimant Child was prescribed branded (and not generic) Paxil® or Paxil CR™ (**Paxil**) in Canada.
- (c) Paxil was dispensed to the Claimant Mother during the First Trimester of pregnancy.
- (d) The prescription for Paxil referred to in paragraph 6(b) was dispensed:
 - i. prior to February 3, 2006, in which case no percentage reduction will be applied to any Compensatory Payment;
 - ii. between February 3, 2006 and February 3, 2007, in which case a reduction of 50% will be applied to any Compensatory Payment; or
 - iii. February 3, 2007 or later, in which case, the Claimant will not be eligible for compensation.
- (e) The Claimant Child was born alive and subsequently diagnosed with a birth defect that constitutes a Qualifying Congenital Malformation.

Qualifying Congenital Malformations

7. Qualifying Congenital Malformations are limited to the following exhaustive list:

- (a) Anencephaly;
- (b) Spina bifida;
- (c) Encephalocele;
- (d) Craniosynostosis;
- (e) Cleft lip;
- (f) Cleft palate;
- (g) Structural cardiovascular defects;
- (h) Diaphragmatic hernia;
- (i) Gastroschisis;
- (j) Omphalocele;
- (k) Hypospadias;
- (l) Undescended testes; and
- (m) Club foot.

8. To establish a diagnosis of a Qualifying Congenital Malformation, and the severity and/or necessary medical intervention to treat or resolve same, the Class Member must provide supporting medical documentation, which may include medical records, clinical records, hospital records, pathology records, laboratory records, and similar records. The records may be supplemented by a sworn affidavit of the Class Member's health care provider that confirms the diagnosis, treatment, and nature of the injury.

Reduction in Compensation for Confounding Factors

9. The Claims Officer will have the discretion to reduce the points value assigned to Claims of eligible Class Members on a percentage basis up to a maximum of 50% where there are confounding factors from the list below that, in the opinion of the Claims Officer based on his or her review of the available medical records, may have caused or contributed to the Qualifying Congenital Malformation(s) or other underlying health issues that impacted the Class Member's health, care, and/or quality of life, being:

- (a) genetic diagnoses of the kind associated with one or more of the Qualifying Congenital Malformations;
- (b) smoking, alcohol and/or illicit drug use of the mother during pregnancy;
- (c) maternal age;
- (d) pre-gestational diabetes;
- (e) metabolic disorders during pregnancy;
- (f) body mass index outside of the normal range (18.5 to 25);

- (g) significant physical trauma experienced during pregnancy; and/or
- (h) exposures to medications or chemicals during pregnancy that are associated with birth defects, as determined by the Claims Officer.

10. Additionally, and to account for the resolution of class action litigation commenced in British Columbia concerning the use of Paxil during pregnancy, and the resulting compensation received by class members diagnosed with a cardiac defect, a percentage reduction may be applied where the Class Member resided in British Columbia and the Claimant Child was diagnosed with a cardiovascular defect in addition to at least one other Qualifying Congenital Malformation to reflect that any claim by these Class Members for a cardiovascular defect was previously settled.

Evidence of Prescription and Use

11. To establish the prescription and ingestion of Paxil necessary to being an Eligible Claimant, the Class Member must provide either prescription records, medical records, hospital records, clinical records, pharmacy records, receipts and/or insurance records (the **Records**) that show that brand name Paxil distributed by GSK was prescribed or dispensed to the Class Member in Canada during their First Trimester of pregnancy.

12. Where the records described in Item #11 are unavailable, and there is therefore no Record confirming that the Class Member was prescribed and/or ingested branded Paxil during the First Trimester, then the following may be considered by the Claims Administrator as acceptable evidence of the Class Member's prescription and use of branded Paxil:

- (a) A signed letter from the Class Member's physician who treated the Class Member at the material time, which includes current contact information, confirming that, to the best of his or her recollection, branded Paxil was prescribed to the Class Member, or that the treating physician was otherwise aware that the Class Member was ingesting branded Paxil, during the First Trimester of the pregnancy; and
- (b) An affidavit sworn by the Class Member's physician who treated the Class Member at the material time explaining that:
 - i. a search of the treating physician's records was undertaken and no Record confirming proof of ingestion or use of branded Paxil could be located;
 - ii. the physician treated the Class Member at the material time;
 - iii. based on the review of the treating physician, there is no Record that contradicts the treating physician's recollection with respect to the timing of use and branded Paxil being prescribed or ingested;
 - iv. to the best of the treating physician's knowledge, there is no reason to doubt the accuracy of his or her recollection with respect to the Class Member's prescription or use of Paxil during the First Trimester;
 - v. his or her memory should be considered sufficient in the absence of Records; and
 - vi. the treating physician agrees to comply with any further questions or audits conducted by the Claims Administrator with respect to statements that the Class Member was prescribed or ingested branded Paxil during the First Trimester.

13. A statement by the Class Member that Paxil was ingested during the First Trimester of pregnancy is not sufficient unless the physician described in Item #12 is deceased or has ceased to practice and if medical records, including hospital records or physician notes, state that no medications were taken during pregnancy, the Class Member will not be eligible for compensation.

14. Evidence of prescription or purchase of Paxil will also be considered evidence of ingestion of the drug.

15. Where, after the first date of generic entry of paroxetine occurred, supporting medical documents reference only “paroxetine” and there is no indication in the evidence provided that Paxil, as opposed to generic paroxetine, was prescribed, then the Class Member will not be eligible for compensation.

16. For greater certainty, this settlement is designed to compensate for the use of branded Paxil distributed by GSK only, and not generic paroxetine.

Eligibility and Compensation to the Discretion of the Claims Administrator and Claims Officer

17. Whether eligibility can be accurately determined through the *Claim Form* and the Records provided will be to the sole discretion of the Claims Administrator and Claims Officer.

18. It is the responsibility of the Class Member, or his/her legal or estate representative, to provide sufficient evidence to support his/her Claim. Any fees or charges incurred by the Class Member with respect to filing his/her Claim are the responsibility of the Class Member.

19. The determination of the validity of the Claims submitted by Class Members shall be made by the Claims Administrator and may be appealed to the Court of King’s Bench within 30 days of the Claims Administrator’s decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. The appeal decision shall be final and binding, and shall not be subject to any further appeal.

20. The Claims Officer shall review each *Claim Form* and determine whether the individual is an Eligible Claimant.

21. If a person is acting on behalf of the Claimant Mother or Claimant Child, the Claims Administrator shall require verification that the person has the legal authority to do so, and if the person is a lawyer in any jurisdiction, that he or she is licensed to practice law in a Canadian province or territory.

22. Upon the request of counsel to the Plaintiffs or Defendants, or the Claims Officer, or at the discretion of the Claims Administrator, the Parties agree that the Claims Administrator may conduct an audit or such other review to confirm the veracity of (a) the Records, (b) the treating physician’s letter and accompanying affidavit, and/or (c) the absence of the Records and explanation for that absence. The Claims Administrator and Claims Officer may revoke any findings with respect to eligibility and/or adequate evidence of the Class Member’s claim as a result of the Claims Administrator’s review or audit.

Distribution of Settlement Fund

23. The Claims Administrator shall distribute the Settlement Fund in accordance with the terms of the *Settlement Agreement* and based on the determinations of the Claims Officer.

Damages – Category Assessments

24. A Class Member’s entitlement to a Compensatory Payment under this Distribution Protocol shall be determined by the Claims Officer as outlined herein.

25. Compensatory Payments will be assessed by the Claims Officer through a review of the medical records and other documents submitted on behalf of the Claimant Mother, Claimant Child, or from the submissions of a physician applying the following grid:

Cardiac Malformations: atrial septal defect excluding patent foramen ovale; atrioventricular septal defect; coarctation of the aorta; transposition of the great vessels; hypoplastic left heart syndrome; pulmonary atresia; pulmonary stenosis; tetralogy of fallot; total anomalous pulmonary venous return; tricuspid atresia; truncus arteriosus; and ventricular septal defect.

A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 20
C.	One surgery to repair or treat the malformation(s)	20 to 60
D.	Multiple surgeries to repair or treat the malformation(s)	40 to 100

Neural Tube Defect Malformations: anencephaly; spina bifida; and encephalocele

A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 20
C.	One surgery to repair or treat the malformation(s)	20 to 50
D.	Multiple surgeries to repair or treat the malformation(s)	40 to 75

Skeletal Malformations: club foot

A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 15
C.	One surgery to repair or treat the malformation(s)	15 to 30
D.	Multiple surgeries to repair or treat the malformation(s)	30 to 50

Abdominal Malformations: gastroschisis; omphalocele; and diaphragmatic hernia

Urinary/Genital Malformations: undescended testes and hypospadias

A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 15
C.	One surgery to repair or treat the malformation(s)	15 to 20
D.	Multiple surgeries to repair or treat the malformation(s)	20 to 35

Craniofacial Malformations: cleft lip; cleft palate; and craniosynostosis.

A.	No procedure, only diagnosis and ongoing monitoring	1 to 5
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	5 to 10

C.	One surgery to repair or treat the malformation(s)	20 to 30
D.	Multiple surgeries to repair or treat the malformation(s)	30 to 60

26. The Claims Officer will identify the categories within which each Class Member's Claim falls and assign a points value within the range identified. Where a Class Member has more than one malformation, he or she will be awarded a points value respecting each category into which the Claim falls.

27. In determining the points value within the range, the Claims Officer will consider the following criteria in relation to the congenital malformations and the Claimant Child's medical condition:

- A. Severity of malformation(s);
- B. Duration and complexity of treatments;
- C. Likelihood of future complications;
- D. Likelihood of future medical interventions;
- E. Likelihood of future medical/non-medical care; and
- F. Likelihood of vocational impairment.

28. Each eligible Claimant Mother of a Class Member born alive with a Qualifying Congenital Malformation will be entitled to 25% of the points that the eligible Claimant Child is entitled to under this heading in full and complete satisfaction of her own Claim and the claims of any other Family Members.

General

29. The Claims Officer will seek to follow the processes outlined herein, but the Claims Officer may also establish further processes for the management or the determination of the Claims so as to ensure a fair, just, and timely determination of the Claims on the merits, and consistency in the application of this *Settlement Agreement*, and may implement such revisions upon approval by the Court, after providing 15 days' notice to the Parties.

30. The Claims Officer may at any time request further information, via the Claims Administrator, from the Class Member if the Claims Officer believes such information is necessary and available to validate the Claim, including as it pertains to ambiguities or inconsistencies in the Claim.

31. If the Class Member has legal counsel, all inquiries or requests will be sent to his/her lawyer. If the Claims Administrator does not receive the additional information requested or responding answers within 90 days after advising the Class Member of the deficiency or request, the Claim shall be assessed on the basis of the material provided by the Class Member.

32. The Claims Officer may consider the materials provided whether or not such materials would be admissible in a court of law. The Claims Officer may grant extensions of the time to provide materials on the written request of a Claimant; provided that all documentation respecting Claims shall be submitted on or before the Claims Perfection Deadline, and the Claims administration process shall be completed within a further 60 days thereafter.

33. The Claims Officer shall make best efforts to adjudicate a Claim and render a decision as to eligibility and point allocation within 60 days of receiving a Claim.

34. The Claims Administrator shall provide the decision of the Claims Officer in writing by way of a letter or email to the Class Member. If the Class Member has legal counsel, the decision will be sent to counsel directly.

35. Confirmation of eligibility and entitlement shall be determined on a balance of probabilities and common law principles. The determination of the validity of the Claims submitted by Class Members shall

be made by the Claims Administrator and may be appealed as outlined in the *Settlement Agreement* to the Court of King's Bench within 30 days of the Claims Administrator's decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. The appeal decision shall be final and binding, and shall not be subject to any further appeal. Disputes, other than eligibility and assessment of Compensatory Payments, will be determined pursuant to the laws of Alberta and Canada, and where necessary will be adjudicated by the case management justice in the Court of King's Bench.

Distribution of Compensation Fund

36. Compensatory Payments to Class Members shall be paid from the Compensation Fund on a pro-rata basis based on the number of points. All Claims will be adjudicated and finally determined before any amounts for Compensatory Payments are paid pursuant to the *Settlement Agreement*.

37. Compensatory Payments will not be paid until the Claims Administrator has satisfied itself of the adequacy and veracity of the evidence and documents provided by all Class Members in support of their Claims. In the event that Compensatory Payments are paid and the Parties subsequently learn that the Records or other supporting evidence of a Class Member's Claim were misrepresented or fraudulent, the Defendants and Claims Officer reserve all rights and remedies to recover the entirety of the Compensatory Payment at issue.

38. Lawyers' Fees will be paid as and when Compensatory Payments are made to Eligible Claimants from the Compensation Fund. Subject to section 8.5 of the *Settlement Agreement*, the Claims Administrator shall pay to Class Counsel:

- (a) 35% of the Compensatory Payments made to Class Members they represent;
- (b) 10% of the Compensatory Payments made to Eligible Claimants who are represented by other lawyers who executed retainer agreements with Class Members before the *Notice of Settlement Approval Hearing* is given;
- (c) 25% of the Compensatory Payments made to any Eligible Claimants who are represented by other lawyers who executed retainer agreements with Class Members after the *Notice of Settlement Approval Hearing* is given; and
- (d) 15% of Compensatory Payments that are made to Eligible Claimants who are unrepresented.

The amount of the combined Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) will not exceed 33.33% of the Settlement Fund. Lawyers' Fees (but not the Class Counsel Fees) will be proportionately reduced if the amount of the combined Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) otherwise determined herein would exceed 35% of the Settlement Fund plus interest thereon.

39. Within 7 days of the Effective Date, the Claims Administrator shall pay Health Insurers CDN \$525,000 out of the Settlement Fund for healthcare costs recovery in full and final satisfaction of any and all claims they have respecting any and all Class Members, provided that each signs full and final releases in forms that are satisfactory to each Health Insurer. Health Insurers shall thereafter have no role in the Distribution Protocol

40. Distribution of payments to Class Members (other than the Honorarium), will not commence until after all Claims have been determined or adjudicated.