Annex 5: Declarations of interest

Of the 52 experts who participated in this work, 12 declared an interest related to contraception. Of the 12, two participants (Andy Gray and Chelsea Polis) declared an academic interest specific to the subject matter of this statement. The WHO Secretariat and the Guidelines Development Group reviewed all declarations and found no conflicts of interest sufficient to preclude anyone from participating in the deliberations or development of recommendations relevant to hormonal contraception and HIV. Although not all of the interests declared are specifically related to hormonal contraception and HIV, they are nonetheless all disclosed and summarized below.

Eliana Amaral received US$ 100 000 from WHO to conduct research on the pericoital use of a levonorgestrel-containing emergency contraceptive pill.

Jean-Jacques Amy received €2500 in 2013 from Merck Sharpe & Dohme (MSD) to present a paper at a scientific symposium and receives an annual stipend of €5000 from the European Society of Contraception and Reproductive Health to serve as the Editor-in-Chief for the Society’s journal.

Sharon Cameron works at a research unit that received funding from Pfizer Ltd (United Kingdom) to undertake a feasibility study of self-administration of an injectable method of contraception and to conduct another study that will be used to apply to the Medicines and Healthcare Products Regulatory Authority (MHRA, United Kingdom) for a license for self-administration of an injectable contraceptive. HRA Pharma (France) provided funding to Cameron’s research unit to conduct a trial on the effectiveness of ulipristal acetate. Cameron is a paid consultant on the European Advisory Board of Exelgy.

Alison Edelman is a co-investigator of research studies funded by the United States National Institutes of Health (NIH), the Bill & Melinda Gates Foundation and the Society of Family Planning (USA). The research unit that Edelman works with receives funding from MSD and Bayer HealthCare on an ongoing basis to undertake acceptability, efficacy and safety studies on contraceptive pills, transdermal patches and hormone-releasing intrauterine devices.

Anna Glasier is an expert consultant to HRA Pharma (France). Her husband also currently consults for HRA Pharma on an occasional basis (approximately once every two years), as a member of a scientific advisory board, and less frequently participates as a speaker or chairperson at international conferences on behalf of the company. Specifically, Glasier works with HRA Pharma on the development of new methods of emergency contraception (EC). She was the principal investigator of a large randomized controlled trial which resulted in the marketing of ulipristal acetate (UPA) for EC. Glasier was not personally remunerated; the clinic where she works and conducted the research received these funds. Since the publication of the study results in 2010, Glasier has been actively involved and has been paid a regular consultancy fee to advise the company in their attempts to obtain approval for over-the-counter use of UPA, and on the work HRA Pharma has undertaken relating to EC effectiveness according to the body weight of the user. She is also paid as a member of the company’s Scientific Advisory Board and participates as a speaker or chairperson at international conferences on behalf of the company (approximately twice a year). Glasier has provided expert opinion on UPA to regulatory authorities and has represented HRA Pharma at these meetings. In the light of this relationship with a company that manufactures EC, including UPA, Glasier did not chair or take part in the discussions on EC and weight at the March 2014 meeting and absented herself from the meeting room when inclusion of UPA in the Medical eligibility criteria for contraceptive use (MEC) and Selected practice recommendations for contraceptive use guidelines was discussed. Glasier has an independent research grant from Pfizer Ltd (United Kingdom) to conduct a study of
the feasibility of pharmacists dispensing and injecting a subcutaneously administered injectable contraceptive. In addition, Glasier has an independent research grant from HRA Pharma to pay a clinical research fellow for up to three years to undertake research in contraception.

Andy Gray works at CAPRISA, a research unit that receives donations of antiretroviral medications from the NIH Clinical Research Products Management Center (including products manufactured by Abbott; Boehringer Ingelheim; Bristol Myers Squibb; Gilead; GlaxoSmithKline; MSD; and Roche) for use in the clinical trials conducted through the AIDS Clinical Trials Group and International Maternal, Paediatric, Adolescent AIDS Clinical Trial network. The unit also received donated microbicide products from Gilead Sciences for a Phase IIb clinical trial.

Philip Hannaford works for an academic department that received fees from several manufacturers of oral contraceptives in the past for lectures on matters related to contraception, especially oral contraception.

Olav Meirik received US$ 5000 from WHO in 2013 to conduct a survey to estimate the patterns of combined oral contraceptive use among formulations containing “3rd and 4th generation” progestogens, and he serves as an unpaid senior research associate with the Instituto Chileno de Medicina Reproductiva (ICMER).

Chelsea Polis collaborated on a trial investigating the acceptability of a subcutaneous injectable contraceptive; data collection for this study ceased in 2013. Pfizer, Inc. donated the injectable units, which were not yet commercially available, to her research unit for the conduct of the trial, but did not provide any monetary support.

Regine Sitruk-Ware received €1500 twice in a four-year period from Bayer to provide lectures on the future targets for a non-hormonal contraceptive in the female reproductive tract, and €4500 in 2014 from MSD to advise the company on the development of a progestin, nomegestrol acetate.

Carolyn Westhoff receives an honorarium from Agile Therapeutics to serve on its Scientific Advisory board (approximately US$ 2500 per quarter). She receives honorariums as a member of the Data Safety and Monitoring Boards of both MSD and Bayer HealthCare to monitor contraceptive safety studies conducted by these companies (about US$ 3500 per year, and €2700 per year, respectively). Westhoff’s research unit receives funding to conduct studies on intrauterine devices (Bayer Healthcare and Medicine 360), a trial of the efficacy of self-administration of an injectable method of contraception (Pfizer, Inc.) and a trial on the safety and effectiveness of oral contraceptive pills (MSD).