Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Urogynaecological Devices Working Group

Ratified Minutes

Meeting 1

27 August 2013

Teleconference

TGA Health Safety Regulation

Contents

The first meeting of the Urogynaecological Working Group (UDWG) was held on 27 August 2013 by teleconference, commencing at 6.30pm AEST.

Participants

Members: [redacted]

TGA officers:

Dr Jane Cook (Chair) – Head, Office of Product Review

Dr Jorge Garcia, Principal Science and Engineering Adviser, Office of Product Review

Ms Pamela Carter, Director, Device Monitoring and Vigilance, Office of Product Review

Dr Pamela Whalan, Medical Officer, Device Monitoring and Vigilance, Office of Product Review, Monitoring and Compliance Group

Dr Rhianna Thompson, Medical Officer, Device Monitoring and Vigilance, Office of Product Review, Monitoring and Compliance Group

Secretariat: Mr Craig Davies, Secretary, Advisory Committee on the Safety of Medical Devices, Office of Product Review

Item 1 Administrative arrangements

1. 1 Welcome and apologies

The Chair welcomed members to Meeting 1 of the UDWG.

1.2 Apologies

There were no apologies recorded for the meeting.

1.3 Disclosure of interest declaration forms

Members submitted disclosure of interest forms for the item under consideration prior to the teleconference. There were no declarations of interest made for this meeting.

1.4 Overview of the TGA and Office of Product Review (OPR)

The Chair provided a brief overview of the roles and responsibilities of the Therapeutic Goods Administration (TGA) and the Office of Product Review (OPR).

Members noted that the role of the TGA is to regulate therapeutic goods and this is done by applying scientific and clinical expertise to an assessment of the evidence of the risks compared to the benefits of use of therapeutic goods. The TGA applies this risk-based regulatory process to therapeutic goods before they are marketed and monitors products once they are on the market. Additionally, it assesses the suitability of medicines and medical devices for export from Australia.

The TGA also regulates manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality. It has a team of inspectors that audit manufacturing facilities around the world to ensure that products supplied in Australia are of high quality.

More specifically, OPR is responsible for ensuring all therapeutic goods maintain an appropriate level of quality, safety, efficacy and performance following entry into the Australian marketplace. OPR's mission is to protect public health and safety and support the therapeutic goods industry through effective post market monitoring of therapeutic goods, including the advertising of those products to consumers and when required take appropriate action, which may include regulatory action.

1.5 Purpose of Working Group

The Chair also advised members that the UDWG is a new working group which has been established to provide independent expert advice to the TGA on matters related to the safety and performance of urogynaecological mesh devices. This includes whether the adverse events associated with these devices have occurred due to the design and/or the materials used; or whether other factors, such as devices being supplied and/or used inappropriately, patient characteristics or training experience, are contributing to these adverse events.

The UDWG will consider post market safety information and provide advice to assist the TGA to develop strategies to ensure the safe use of the devices. This would include consideration of regulatory actions as well as the provision of information to health care professionals and consumers about urogynaecological devices.

The Chair advised that the UDWG may need to meet 3-4 times to consider all issues relating to the devices. However, discussions during this first meeting will further inform this, including the need for, and frequency of future meetings.

Members sought advice as to the TGA's classification system for medical devices and were advised that devices are classified as either Class I, IIa, IIb, III or as 'active implantable devices'. This is a risk based classification system which is consistent with international practice and determines the level of regulatory scrutiny applied to different types and groups of medical devices. The meeting was also advised that urogynaecological mesh devices are classified as either Class IIb devices (in the case of meshes manufactured from synthetic materials) or Class III (in the case of biological, resorbable meshes).

This was followed by a general discussion about adverse event reporting, the Australian regulatory framework and an acknowledgement that Australian clinicians often have greater familiarity with the United States Food and Drug Administration's (FDA) framework. Members also noted that the TGA considers post market monitoring to be important for medical devices due to the more limited amount of pre-market data available for evaluation during the market authorisation process.

Item 2 Minutes of the previous meetings

2.1 UDWG Meeting minutes

As this is the inaugural meeting of the UDWG, there are no previous Minutes to ratify.

2.2 Matters arising from previous meetings

Not applicable.

Item 3 Post market review of urogynaecological mesh devices

Background

Pelvic organ prolapse (POP) is a common condition, and up to 50% of parous women will have some degree of prolapse present. A degree of incontinence is reported by between 17 - 45% of adult women with some degree of stress urinary incontinence (SUI) affecting about one third of women of childbearing age.

There are a number of techniques for surgical repair of POP or stress urinary incontinence, including the use of surgical mesh. Following increasing reports of adverse events associated with the use of surgical mesh, the FDA issued a *Safety Communication* on 20 October 2008.

The TGA has conducted two formal reviews of these devices, in 2009 and 2012-2013. As part of the 2012-2013 review the UDWG has been established to provide advice by experts in this particular field to the TGA.

Although the TGA had not seen a similar rise in reported adverse events associated with these types of devices, in 2008 a joint TGA-Medsafe request for advice was submitted to a TGA expert committee, formerly known as the Medical Device Incident Review Committee (MDIRC).

At that time, MDIRC concluded that the recurrences of symptoms or erosion (into the vagina or rectum) were common adverse events with these types of devices. The committee advice emphasised the need for informed patient consent and that training of surgeons was important to the success of this type of surgery.

A formal, limited, post market investigation was instigated by the TGA in October 2009 in response to specific presentation (colour and radiopacity) and labelling concerns raised by the then Prostheses and Devices Committee (PDC) of the Department of Health and Ageing (DoHA). The TGA investigation was completed in September 2010 and concluded that information supplied with the devices available at that time was sufficient.

Following an FDA communication on 13 July 2011 (see Section 3.3*: International Regulatory Agencies* of the TGA evaluation report, *Post Market Review of Urogynaecological Graft Devices, Version 1.0, August 2013* ("evaluation report") and a letter from DoHA's Prosthesis List Advisory Committee (PLAC), the TGA commenced the current, wider post market investigation. The TGA has received a number of Device Incident Reports (DIR) related to the use of urogynaecological mesh. The number of DIRs received is small, considering the number of mesh devices supplied to the Australian market.

The review included analysis of the available literature, the information supplied with the device and training associated with these devices provided by sponsors and manufacturers. The TGA has found that the evidence in the literature is variable and the data does not provide sufficient information about long term safety, reoccurrence of the underlying conditions and adverse events, potentially reflecting under-reporting of adverse events.

The potential adverse effects of surgery and mesh exposure on the bowel, bladder and sexual function are considerable and serious, with possible long term implications for patients. The TGA literature review concluded that mesh complication rates were poorly and variably reported. The average mesh complication rate over one to two years was approximately 11.2%. Most studies reported a rate of between 5 - 15%.

Surgery for mesh-related complications over the same time frame is reported as ranging from 0.7 - 50%, with an average rate of 7.9%. There was a statistically significant increase in mesh exposure with smoking, or with a BMI ≥ 30 and or with age ≥ 60 years. Surgeon training and experience are additional factors increasing the risk of adverse outcomes with the use of urogynaecological mesh.

The evaluation report concluded that –

> *"In the context of the Australian regulatory framework, including the guidance provided in the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations, the risk-benefit for mesh surgery for POP and SUI is yet to be adequately established. While of low quality, the literature does not support a conclusion that the use of meshes leads to better clinical outcomes, yet there is evidence to suggest that the use of synthetic meshes introduces not insignificant risks that are not present with native tissue (NT) repair surgical interventions".*

The meeting was advised that since the last TGA review was undertaken in 2010, adverse event reports have continued to be received and the level of ongoing, international concern with regard to the safety and performance of these devices has remained. This concern has lead to the current review being undertaken (with a focus on the published literature) and the UDWG being established. From an international perspective, Members noted that the FDA is enhancing its post market monitoring of these devices by mandating that sponsors (or manufacturers) undertake two (2) year post market follow up studies. This requirement was further discussed later in the meeting.

Members also noted that there appeared to be limited premarket evaluation performed prior to the supply of medical devices and whilst noting the TGA advice that the reporting of adverse events is mandated for sponsors and manufacturers, advised of their awareness that company representatives aren't reporting all complications to the TGA.

Discussion of current TGA Evaluation Report

Prior to discussing the questions presented for consideration, members sought to clarify the manner in which certain issues were analysed and presented in the evaluation report.

Whilst noting the extensive amount of work and commenting on the high quality of the evaluation report, members advised, that from the literature papers reviewed, the report did not provide sufficient distinction between the usage of mesh for the treatment of SUI and POP, nor was it clear that not all meshes are the same eg polypropylene mesh comes in different types which were not distinguished.

The TGA noted that the difficulty in separating mesh types to be assessed individually was both beyond the scope of the report submitted and would have resulted in one or two poor quality studies available for assessment of each type of mesh product.

Based on the literature, the Working Group advised it needs to consider the questions raised by the TGA from a clinical perspective ie consider the data for meshes used for the treatment of POP and then consider the data for the treatment of SUI, for both primary and secondary repair. It is also important to consider the different types of sling meshes for the treatment of SUI separately.

Committee members suggested use in primary procedures was probably very low and most of the use was for recurrence. The TGA stated that from information in the adverse event reports received, it appeared that mesh is being used widely for primary procedures. Members noted that the current Medicare item number descriptor doesn't differentiate between NT and mesh repairs, or between primary and subsequent repairs. Due to this, there is no way to determine the total number of devices which have been utilised to then make comparisons with the rates of adverse event reports.

The TGA advised that product use cannot be determined, but supply figures have been requested of sponsors and have been provided in the information presented to the UDWG (Appendix C). The nature of the TGA reporting system was discussed and it was noted that with mandatory reporting by sponsors and spontaneous reporting from other sources, it is not possible to determine an incidence rate from adverse event reports. It was noted that there was recognition of significant under-reporting across DIRs for all products, with the TGA estimating it only receives 10-20% of all events.

Members discussed the development of different Medicare item number descriptors as this would provide a starting point as to how many devices are being utilised in the health care system. The TGA advised that this was not within the TGA brief, however the TGA would discuss with DoHA's Medical Benefits Division the issues associated with establishing separate Medicare item numbers for NT and mesh repairs and primary repair, or surgery for recurrent symptoms.

> Action – TGA to discuss with DoHA's Medical Benefits Division the issues associated with establishing separate Medicare item numbers for NT and mesh repairs and for primary repair, or surgery for recurrent symptoms.

The meeting was also advised of two further international reviews recently concluded in March and April 2013 which were completed after the TGA literature search. Members who were aware of the publications provided a discussion of the findings of these reports and it was noted that the evidence for anatomical improvement with mesh repair in the anterior compartment appeared to have an advantage over native tissue (NT) repair.

> Action – [redacted] to provide copies of the papers to Members and the Secretariat.

The committee concurred with the advice provided by the TGA, adding that although there was evidence for possible improved anatomic outcome in the anterior compartment, this was at a cost of potential harm including increased adverse events, re-operation (three times higher with anterior compartment mesh use than with NT repair) and no demonstration of a functional improvement for patients. The committee stated that the current evidence was that there was no benefit with the use of mesh in the posterior compartment. They also advised that there was no clear evidence to support the use of mesh in the apical compartment.

The committee also provided advice regarding the paucity of evidence for use in recurrent prolapse. They noted that although there was an historical, accepted practice for the use of mesh in the management of recurrent prolapse, there was no evidence in the literature to support the use of these devices in this type of surgery.

Advice

The committee's advice on a number of specific questions asked by the TGA is detailed below.

From the information sourced for the review of urogynaecological mesh, there does not appear to be evidence of benefit, but there is evidence of harm. Does the Working Group agree with the conclusion? Why and/or why not?

Having regard for the need to consider different types of procedures for the treatment of different conditions (as detailed above), the Working Group did not agree with the generalised, overarching statement that *"there does not appear to be evidence of benefit, but there is evidence of harm"* resulting from the use of mesh as it is inaccurate to apply such a statement to both POP and SUI mesh repairs.

The Working Group noted that the use of full-length synthetic slings for SUI had adequate support in the literature – including long term data. The Working Group noted that there was a lack of long term clinical evidence for the use of short or mini-slings.

With regard to the use of mesh for POP repair the Working Group stated that the data indicated there is some evidence of benefit in using mesh via an abdominal approach for apical compartment repairs.

The Working Group also advised there is very minimal data available to draw any clear conclusions regarding the use of transvaginal polypropylene mesh in the anterior compartment. Anterior compartment repairs are usually performed trans-vaginally, although there may be some cases where the abdominal approach could be considered. However, the Working Group agreed that with insufficient evidence of benefit and with some suggestion of increased harm, there was no current evidence to support the use of mesh in the anterior compartment when inserted trans-vaginally, unless determined to be appropriate on a case-by-case basis.

It was also noted there is a three-fold increased rate of reoperation rates to treat complications such as pain, and erosion when compared with complications and reoperations for NT repair. The Working Group also agreed that while there is some evidence of potential harm following the use of mesh in the posterior and apical compartments, the current evidence was that there was also no benefit in using mesh in the posterior compartment. The Working Group also advised that there was insufficient evidence to determine the role of mesh in the apical compartment when inserted transvaginally.

Can the Working Group provide additional comments on the review, including about the robustness of the evidence considered?

The Working Group agreed there is a lack of good evidence to demonstrate a clear benefit in the overall use of mesh compared to non-mesh procedures. In relation to whether there is sufficient evidence that the use of mesh causes clear patient harm, members pointed to conflicting advice in the literature.

Against this background, the Working Group agreed that there is some long term data in the literature which supports the use of full length sling meshes for the treatment SUI and in these cases the devices have demonstrated satisfactory safety and performance. Members noted that the use of mesh for transvaginal repairs is the main problem area. The committee therefore agreed that consideration of the remaining questions would be in the context of meshes used for transvaginal repair and there was no need for further consideration of meshes used in the treatment of SUI.

From the evidence considered, can the Working Group identify any patient groups where the use of urogynaecological mesh would be particularly advantageous?

Members noted the statement from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) that "very little robust information is available on the efficacy and long term safety of polypropylene mesh kits marketed for use in the surgical management of pelvic organ prolapse".

Members also noted the RANZCOG advice that it is not easy to identify who would benefit from a transvaginal mesh implant "since clear evidence is lacking and no guidance can be given regarding which specific mesh implant should be used since there is simply no robust comparative data available".

A recent useful consensus statement has been published in the International Urogynaecology Journal and a broad summary of the recommendations are:

> *"Exercise caution in using transvaginal mesh implants in:*
> *1. Primary prolapse cases;*
> *2. Patients younger than 50;*
> *3. Lesser grades of prolapse (POP-Q ordinal grade 2 or less);*
> *4. Posterior compartment prolapse without significant apical descent;*
> *5. Patients with chronic pelvic pain; and*
> *6. Postmenopausal patients who are unable to use vaginal oestrogen therapy since this will be first line therapy for erosion".*

It was also noted that "these suggestions on patient selection are not intended to be exclusive or all encompassing and do not preclude the necessity of a broad based wide ranging discussion with the patient regarding her specific situation".

The Working Group agreed that the evidence of benefit in higher risk groups (eg obese patients, smokers, the elderly, those with failed primary repairs) is limited and the overall body of evidence shows no clear benefit for any patient group. They noted that although there was no evidence available, there may however, be a theoretical benefit in some cases, for example –

- where there has been a failed previous repair in the anterior compartment (which is traditionally performed by the vaginal approach); or
- in groups where there is a potential for higher rates of recurrence eg patients with higher grades of prolapse, or poor connective tissue, failed previous surgery in any compartment, obese patients and patients with raised intra-abdominal pressure (such as a chronic cough in smokers).

It was noted that the identified risk groups are those who experience higher rates of prolapse as well as a higher comparative rate of complications. Members emphasised that it is not possible to set parameters which would adequately define an appropriate patient population for the use of these devices. The role of clinicians in determining patient suitability on a case by case basis will continue to be very important.

From the evidence considered, can the Working Group identify any patient groups where the use of urogynaecological mesh would be particularly disadvantageous?

The Working Group considered that this was a very difficult question and that it wasn't possible to categorically state that the use of mesh in any particular group would be "disadvantageous" and this is ultimately determined in the clinical setting and on a patient by patient basis. It was therefore suggested that reference to 'use with caution' would be more appropriate than referring to "disadvantageous".

The Working Group agreed that mesh should be used with caution in the following groups - patients who have undergone previous pelvic radiotherapy treatment, patients with pelvic pain, patients with any active pelvic infection, those with other non-pelvic chronic infections, smokers, immunosuppressed patients, those with a BMI ≥ 30, and those whose age is ≥ 60 years. The use of mesh in the posterior compartment should also be avoided. Prolapse repair in patients ≤ 40 require extra caution due to the greater risk of dyspareunia and of recurrence.

Given the associated harms with the use of urogynaecological mesh, can the Working Group provide advice on what risk mitigation strategies could be employed to minimise these harms. For example, the following strategies could be used:

- ***the addition of contraindications to the Instructions for Use;***
- ***the use of black box warnings;***
- ***additional training prior to supply; and/or***
- ***any other alternatives the Working Group considers may be effective in mitigating the risks of these devices.***

Could the Working Group comment on the likely effectiveness of each of these examples.

For new devices coming onto the market, the Working Group suggested the TGA looks at the adequacy of both manufacturing and clinical evidence provided as part of the pre-approval process and assess whether the current processes were adequate to determine the quality, safety and performance of these devices. To assist in this regard, members suggested reclassifying all urogynaecological mesh devices as Class III medical devices. (It was noted that this proposal would require broader consideration across the TGA, external consultation and legislative amendments).

> Action: TGA to discuss and respond regarding the feasibility/appropriateness of the re-classification of all urogynaecological mesh devices as Class III medical devices under the current legislation.

It was also suggested that post market monitoring could be enhanced by mandating that sponsors (or manufacturers) undertake two (2) year post market follow up studies, comparable to the requirement recently imposed by the FDA. Members also reaffirmed the suggestion that the TGA discuss with DoHA the issues around variation of the Medicare item numbers to clarify the profile of use of these devices (see above).

The Working Group advised that surgeons do not have a strong awareness of Australia's adverse event reporting systems (relative to the FDA) and questioned how the TGA could make the relevant forms more readily available. Members were advised of the existing

(and recently re-developed) Incident Report Investigation Scheme (IRIS) database and of the TGA's development of a strategy aimed at enhancing the rates of adverse event reporting in Australia.

Members were also advised that all information about adverse event reporting, including the ability to submit reports and search the recently launched Database of Adverse Event Notifications (DAEN) can be accessed from the TGA website.

> Action – Secretariat to send members the TGA website links to the DAEN, the medical device adverse event reporting form and other relevant information concerning the TGA's post market product safety program.

The provision to mandate surgeon reporting was discussed. Committee members were advised that the TGA only has the legislative power to mandate requirements for sponsors and manufacturers and in this regard, the TGA is planning to commence a new program of 'vigilance audits' which will aim to check whether sponsors are satisfying their reporting obligations under the legislation.

The UDWG was asked about the role of the British Society of Urogynaecology's (BSUG's) database, Australian surgeons' use of, and potential access to this database. Members advised that this database has the limitation of not including all patients who have undergone pelvic surgery since sign up is on a voluntary basis only. Further, this database will be subject to the further limitation of under-reporting since those clinicians who have signed up to use it, still exercise their own discretion as to which patient cases to enter.

The Working Group was also asked to consider these questions in terms of existing products which are currently entered on the Australian Register of Therapeutic Goods (ARTG). The TGA noted that the FDA has required all manufacturers to conduct extensive post market surveillance studies It is believed that this has led to manufacturers reconsidering their commercial position and deciding to withdraw certain devices from the market. The TGA also noted that the FDA process includes manufacturers submitting proposed study protocols to the FDA for approval prior to commencing any study. It is believed that the protocols for these studies are still being negotiated and are still to be finalised prior to the commencement of any post market study.

The meeting also discussed whether the inclusion of a 'black box warning' on mesh devices would enhance product safety, noting that this would be a first ever for any medical device. The effectiveness of such a warning was raised since surgeons may not see the product packaging prior to use. It was also raised as to whether a warning of this nature could increase surgeons' liability.

Although the TGA is responsible for negotiating changes to the Instructions for Use (IFU) and labelling of products, it is the sponsor who has responsibility to ensure that users are aware of existing and updated information within it. Having a 'black box warning' would also differentiate the products from other devices.

The meeting then considered the likely content of any such warning and agreed that the following information would need to be included – the need to discuss the risks and different treatment options with patients, the likelihood of the need for re-operation, the need to obtain appropriate patient consent, that mesh must be used with caution, that surgeons should have undertaken appropriate training to use that particular type of mesh product, and that mesh grafts should not be used by infrequent users. Members advised that 'infrequent use' would need to be defined and pointed to overseas guidelines which advise that 25 SUI and 25 POP procedures constitute 'frequent use'.

Action – TGA to draft a proposed 'black box warning' statement for inclusion in the Instructions for Use of urogynaecological mesh devices for consideration at the next meeting.

The meeting was also advised that a lot of similar details are already included in information sheets about the use of mesh, its risks and evidence about complications. This information is already used as part of the patient consent process, although it was also suggested that offering a standardised, one page patient information leaflet could provide increased rigour to the patient consent process.

The meeting then discussed who or which organisation would be best positioned to develop any such leaflet, for example the Working Group, the TGA or the relevant professional associations. The meeting was advised the latter would be a lengthy process and subsequently agreed that the Working Group could prepare an appropriate leaflet in a much shorter time period.

Whilst it was noted the TGA doesn't provide clinical advice and cannot mandate any requirements upon health care professionals, members suggested the TGA could still disseminate the leaflet to the relevant professional colleges with the recommendation that it be on-forwarded to clinicians to discuss with their patients. At the same time, sponsors could be required to provide the leaflet to all users for on-forwarding to their patients, thus providing a different pathway of distribution.

Since the devices are supplied directly into hospitals and all packaging is discarded by theatre staff during the procedures, the meeting was advised that it may not be realistic to mandate that sponsors ensure patients receive the leaflet prior to surgery.

Action – TGA to review existing information sheets and draft a one page patient information leaflet on urogynaecological mesh devices for consideration at the next meeting.

If training were to be considered as an appropriate risk mitigation strategy, how could training prior to supply assist in mitigating the risk? If so, what form could the training take?

Members advised that there is no credentialing process before surgeons use these devices. Surgeons are able to earn points from credentialing towards their Continuing Medical Education (CME) in this area. Currently, if a surgeon is undertaking POP or SUI surgery, one third of the CME points have to be generated in this sub-speciality area and surgeons also need to be able to demonstrate competence in the procedures undertaken.

Notwithstanding CME activities, the meeting was also advised that ultimately decisions to use mesh devices are made individually by surgeons based on the needs of their particular patients. The amount of training completed prior to using any particular urogynaecological mesh device is an individual decision of the surgeon.

The Working Group discussed whether consideration should be given to developing a credentialing system, but noted this could not be implemented under the legislation and would need to occur via the relevant professional colleges. Any such system would have to include the need to conduct a minimum number of surgeries in a set period of time in order to maintain the credentials. The TGA was advised that a draft publication regarding credentialing has been prepared by the Urogynaecological sub-speciality group and forwarded to the College for further assessment.

The Working Group advised that a system of credentialing for mesh devices could be modelled upon the process which is already in place for the use of *Botox* in various

ophthalmological and urogynaecological procedures. This process is administered by the professional colleges / societies who oversight CME and it is linked to Medicare reimbursement. If surgeons are not credentialed, they will not receive reimbursement for the procedures undertaken.

Members discussed the current credentialing for certain *Botox* procedures, and raised the question as to whether a similar process may be viable for urogynaecological mesh devices.

For current surgeons, it was suggested that credentialing could occur via one of two pathways –

- surgeons' credentials could be 'grandfathered' based on a set of criteria which would need to be developed; or
- surgeons demonstrate that a defined number of procedures have been successfully undertaken and are able to demonstrate to Medicare that the requirements have been satisfied.

Following further discussion, the Working Group suggested that the relevant professional associations review this strategy.

Are there any mechanisms which could be utilised to ensure that only appropriately trained surgeons used the devices?

In view of the advice given in response to the previous question, the Working Group had nothing further to add.

Item 4 Appointment of additional member to UDWG

The Chair advised that when establishing the UDWG, the TGA considered that a membership of six (6) would provide the most appropriate balance and cross section of expertise. However, during the recruitment process, it was only possible to identify five (5) suitable members for the Working Group. A decision was made to proceed on this basis and to seek advice from members in relation to a sixth potential member during the first meeting.

Following discussion, including the noting of how this first meeting progressed, the meeting formed the view that the UDWG already included a sufficient cross section of expertise which facilitated a robust discussion of the issues under consideration. In view of this, members agreed there was no need for the TGA to proceed with the recruitment of a sixth member.

Item 5 Other Business

5.1 UDWG Contact List

The Secretary advised that it is standard practice for committee contact lists to be developed by the TGA and circulated to members (only) for information. It was noted that these lists include personal information (such as home telephone numbers). Members agreed that the UDWG Contact List be circulated amongst the Working Group.

Item 6 Next Meeting

The Chair advised that an approximate time for the next teleconference meeting would be included in the draft Minutes which would be prepared during the following fortnight and circulated to members for comment.

Members agreed that being contacted by the secretariat with a 'doodle poll' was the most efficient way to set a meeting date that all would be available to participate in. It is proposed to convene the second meeting of the UDWG at 6.30pm during the weeks commencing either 14 or 21 October 2013.

Meeting close

The Chair closed the meeting at 8.50 pm and thanked members for their participation.

Dr Jane Cook
Chair
Urogynaecological Working Group