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1.	Bayer plc	3	55	It should be noted that the different brands of levonorgestrel 52ug intrauterine systems (IUS) have important differences in both the range and duration of their licensed indications.[1,2] The MHRA has published a drug safety update to bring this to prescribers attention.[3] Mirena® has three licenced indications – for contraception and heavy menstrual bleeding for 5 years, and for protection from endometrial hyperplasia during oestrogen replacement therapy for 4 years. In contrast, Levosert® has a licence for contraception and management of heavy menstrual bleeding for 3 years, and is not licenced for protection from endometrial hyperplasia. The devices also have different introducers, requiring different insertion techniques. In light of these important differences the MHRA recommended branded prescribing.[3] This difference in licensed duration should also be taken into consideration in the economic evaluation. An analysis of the continuation rates of long-acting reversible contraceptives in UK general practice using data from The Health Improvement Network (THIN), has shown that by the 4th and 5th year after insertion, the cumulative discontinuation rate of the levonorgestrel-releasing IUS only was only 29.7% and 34.6% respectively (Mirena® was the only levonorgestrel-releasing IUS available in the UK at the time of the study).[4] (1) Bayer plc. Mirena® 20 micrograms/24 hours Intrauterine Delivery System. Summary of Product Characteristics. 2015. Available from: http://www.medicines.org.uk/emc/medicine/1829. (Last accessed: 19/8/2016).	Thank you for your comment and the information on references. Inclusion of evidence during the guideline development will be led by criteria set out in the review protocols, and specific interventions and their durations will be defined in the review protocols by the guideline committee during development. It is commonplace to include discontinuation rates in our protocol outcomes and in economic analyses undertaken for guidelines.

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				(2) Allergan Ltd. Levosert® 20 micrograms/24 hours Intrauterine Delivery System. Summary of Product Characteristics. 2016. Available from: http://www.medicines.org.uk/emc/medicine/30120. (Last accessed: 19/8/2016). (3) Medicines and Healthcare products Regulatory Agency. Drug Safety Update. Levonorgestrel-releasing intrauterine systems: prescribe by brand name. 2016. Available from: https://www.gov.uk/drug-safety-update/levonorgestrel-releasing-intrauterine-systems-prescribe-by-brand-name. (Last accessed: 19/8/2016). (4) Cea Soriano L, Wallander MA, Andersson S, Filonenko A, Garcia Rodriguez LA. The continuation rates of long-acting reversible contraceptives in UK general practice using data from The Health Improvement Network. Pharmacoepidemiol Drug Saf 2015; 24(1):52-58.	
2.	Bayer plc	3	55	In addition to the publications identified in the surveillance review, please find reference to several further key publications related to the levonogestrel-releasing IUS that may be relevant to this update.[5-7] (5) Gupta JK, Daniels JP, Middleton LJ, Pattison HM, Prileszky G, Roberts TE et al. A randomised controlled trial of the clinical effectiveness and cost-effectiveness of the levonorgestrel-releasing intrauterine system in primary care against standard treatment for menorrhagia: the ECLIPSE	Thank you for your comment and the information on references. Inclusion of evidence during the guideline development will be led by criteria set out in the review protocols, and specific interventions and their durations will be defined in the review protocols by the guideline committee during development.

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				trial. *Health Technol Assess* 2015; 19(88):i-118. (6) Lethaby A, Hussain M, Rishworth JR, Rees MC. Progesterone or progestogen-releasing intrauterine systems for heavy menstrual bleeding. *Cochrane Database Syst Rev* 2015;(4):CD002126. (7) Jensen J, Mansour D, Lukkari-Lax E, Inki P, Burock K, Fraser IS. Bleeding patterns with the levonorgestrel-releasing intrauterine system when used for heavy menstrual bleeding in women without structural pelvic pathology: a pooled analysis of randomized controlled studies. *Contraception* 2013; 87(1):107-112.	
3.	Bayer plc	3	55	As noted in the 8 year surveillance review, a combined oral contraceptive (estradiol valerate/dienogest) has been licensed for the treatment of heavy menstrual bleeding in women without organic pathology who desire oral contraception, since the publication of the guideline.[8] In addition to the publications identified in the surveillance review, please find reference to 3 further publications that may be relevant to this update.[9-11] (8) Bayer plc. Qlaira®, film-coated tablets. Summary of Product Characteristics. 2016. Available from: http://www.medicines.org.uk/emc/medicine/21700. (Last accessed: 19/8/2016). (9) Fraser IS, Parke S, Mellinger U, Machlitt A, Serrani M,	Thank you for your comment and the information on references. Inclusion of evidence during the guideline development will be led by criteria set out in the review protocols, and specific interventions and their durations will be defined in the review protocols by the guideline committee during development.

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				Jensen J. Effective treatment of heavy and/or prolonged menstrual bleeding without organic cause: pooled analysis of two multinational, randomised, double-blind, placebo-controlled trials of oestradiol valerate and dienogest. *Eur J Contracept Reprod Health Care* 2011; 16(4):258-269. (10) Jensen JT, Parke S, Mellinger U, Machlitt A, Fraser IS. Effective treatment of heavy menstrual bleeding with estradiol valerate and dienogest: a randomized controlled trial. *Obstet Gynecol* 2011; 117(4):777-787. (11) Fraser IS, Romer T, Parke S, Zeun S, Mellinger U, Machlitt A et al. Effective treatment of heavy and/or prolonged menstrual bleeding with an oral contraceptive containing estradiol valerate and dienogest: a randomized, double-blind Phase III trial. *Hum Reprod* 2011; 26(10):2698-2708.	
4.	Biocompatibles UK Ltd	2	37	BTG would like the committee to consider, under the heading of "Groups that will be covered" the trying to conceive cohort of patients	Thank you for this comment. We have considered it and agree with your suggestion. Women wishing to preserve their fertility will be given special attention during guideline development and formulation of recommendations, and this has been added to the scope.
5.	Biocompatibles UK Ltd	3	72-76	BTG think that more could be done to enable referring physicians to offer a range of treatments to their patients. Considering Gynaecologists have the primary responsibility for	Thank you for your comment. Training of healthcare professionals is currently outside the remit of NICE clinical guidelines, therefore this

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				managing this group it is only natural for them to consider therapies that are within their skill set. Providing more education, training, governance, and nurturing a multi-disciplinary approach would potentially provide better outcomes for patients and improved satisfaction	topic was not prioritised for inclusion in this update. NICE guidelines assume that doctors will meet the GMC requirement to refer a patient to another professional when this serves the patient's needs. We note that recommendations on training of healthcare professionals were made in the original guideline (CG44, published 2007) and our guideline committee will carry out an editorial review of this section during guideline development. However, due to time and resource constraint, this update will focus on the diagnosis and management of heavy menstrual bleeding where new evidence has been published since 2007.
6.	Biocompatibles UK Ltd	5	129	Supporting education, training & governance, and providing patients with more treatment options/informed choice via multidisciplinary outpatient clinics, would improve patient satisfaction, potentially improve clinical outcomes, and increase competition.	Thank you for your comment. We noted that recommendations on information provision, training and governance were made in the original guideline (CG44, published 2007). Our guideline committee will carry out an editorial review of these sections during guideline development so they will conform to current practice.
7.	BOSTON SCIENTIFIC	General	General	The draft scope currently excludes women with Pelvic Congestion –this is a heavily undiagnosed and challenging	Thank you for your comment. We have considered this suggestion, however, due to

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				condition to identify-and is associated with very heavy bleeding in a wide age range of women -19-55	time and resource constraint, the scoping group has decided to retain the focus on heavy menstrual bleeding (HMB) and to exclude gynaecological conditions where HMB is not the main presenting symptom. Regarding pelvic congestion, we believe that there are issues of definition of this syndrome which would make formulation of recommendations difficult. By addressing the management of HMB for women with fibroids, adenomyosis and no identifiable pathology ('dysfunctional bleeding'), this guideline will cover the majority of women with the condition, and this is the intention of NICE clinical guidelines.
8.	British Society of Interventiona l Radiology	General	General	Thanks for this opportunity to comment. We feel strongly that any guidance on heavy menstrual bleeding should look at all the areas of practice around controlling bleeding as it will be give a very disjointed unbalanced view on treatment options. There this should include focussed ultrasound and treatments for Pelvic congestion syndrome may also contribute to heavy menstrual bleeding and should be considered within the review and scope.	Thank you for your comment. We have considered this suggestion, however, due to time and resource constraint, the scoping group has decided to retain the focus on heavy menstrual bleeding (HMB) and to exclude gynaecological conditions where HMB is not the main presenting symptom. Regarding pelvic congestion, we believe that there are issues of definition of this syndrome

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					which would make formulation of recommendations difficult. By addressing the management of HMB for women with fibroids, adenomyosis and no pathology ('dysfunctional bleeding'), this guideline will cover the majority of women with the condition, and this is the intention of NICE clinical guidelines. Regarding focussed ultrasound, specific interventions for HMB and outcomes will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
9.	British Society of Interventional Radiology	General	General	Education and training all those who are advising on treatments should also be included in this to ensure that the range of options is given to woman with heavy menstrual bleeding.	Thank you for your comment. Training of healthcare professionals is currently outside the remit of NICE clinical guidelines, therefore this topic was not prioritised for inclusion in this update. We note that recommendations on training of healthcare professionals were made in the original guideline (CG44, published 2007) and our guideline committee will carry out an editorial review of this section during guideline development. However, due to time and resource constraint, this update will focus on

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					the diagnosis and management of heavy menstrual bleeding where new evidence has been published since 2007.
10.	Faculty of Sexual and Reproductive Healthcare (FSRH)	**4**	103	Use of combined oral contraception is a very cost effective way of treatment heavy menstrual bleeding for many women and can be continued until the age of 50 years in women who have no contraindications.	Thank you for your comment. Specific interventions and outcomes will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
11.	Faculty of Sexual and Reproductive Healthcare (FSRH)	**8**	194	Please consider renaming the Clinical Knowledge Summary to be 'heavy menstrual bleeding' rather than 'menorrhagia', to take into account the more modern terminology.	Thank you for your comment. The scoping group are in agreement. We will draw this to the attention of the relevant team within NICE.
12.	Faculty of Sexual and Reproductive Healthcare (FSRH)	**8**	202	Endometrial polyps are being increasingly detected on ultrasound in women with heavy menstrual bleeding. Please include the diagnosis and management of polyps in the guidance.	Thank you for your comment. Heavy menstrual bleeding due to polyps is not excluded from the scope. Where relevant and necessary, the guideline committee will discuss the assessment or management of polyps and the specifics will be defined in relevant review protocols.
13.	Faculty of Sexual and Reproductive Healthcare (FSRH)	**9**	214	The inclusion of adenomyosis is welcome and clear guidance on the diagnosis and management of this will be helpful.	Thank you for your comment.

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14.	FEmISA	General	General	This review is apparently being managed by RCOG on behalf of NICE? FEmISA has written to a number of Presidents of RCOG about the lack of compliance by gynaecologist with the current NICE Guidelines on HMB, particularly informing women of their treatments options and the pros and cons of each treatment and their suitability for anything other than hysterectomy. Some of these complaints stem from lack of knowledge by gynaes about UAE/UFE and MRgFUS, so there is also a question of training. In his response the past President of RCOG said that 'they are only guidelines' and he did not propose that the College id anything to encourage gynaecologist to comply. In view of this attitude where RCOG acts as a trade union and protects members interests in preference to those of patients RCOG is unsuitable to run this review. Another less partisan organisation should lead it.	Thank you for your comment. The National Guideline Alliance is commissioned and funded by NICE to develop clinical guidelines. It is hosted by the RCOG but is independent. The RCOG is a separate stakeholder for the purposes of guideline development.
15.	FEmISA	1	18	Add - Interventional Radiologists offering treatment for gynaecological conditions	Thank you for your comment. We have considered it and agree with your suggestion. "Healthcare professionals in radiology services" has now been added to the scope.
16.	FEmISA	2	34	Add - Women with pelvic venous congestion, which can also cause HMB and other symptoms, but is rarely properly diagnosed and even more rarely treated effectively	Thank you for your comment. We have considered this suggestion, however, due to time and resource constraint, the scoping group has decided to retain the focus on heavy menstrual bleeding (HMB) and to exclude gynaecological conditions where HMB is not the main presenting symptom.

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					Regarding pelvic congestion, we believe that there are issues of definition of this syndrome which would make formulation of recommendations difficult. By addressing the management of HMB for women with fibroids, adenomyosis and no pathology ('dysfunctional bleeding'), this guideline will cover the majority of women with the condition, and this is the intention of NICE clinical guidelines.
17.	FEmISA	3	59	Medication is often prescribed for longer than specified in the medicine's marketing authorisation and is not effective at treating fibroids>3cm	In August 2016 a NICE Standing Committee, separate from this part of the update of Clinical Guideline 44, made 2 recommendations regarding progesterone receptor modulators for fibroids of 3cm or greater in diameter: 1.5.11 Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below. 1.5.12 Consider ulipristal acetate 5 mg (up to 4 courses) for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre.

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					Where relevant the Guideline Committee will take into account the duration of treatment when making recommendations.
18.	FEmISA	3	62	Add – Interventional radiology treatments including uterine artery/fibroid embolisation and Magnet resonance-guided focused ultrasound [MRgFUS] both for the treatment of fibroids	Thank you for your comment. Specific interventions and outcomes will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
19.	FEmISA	3	63	Pelvic venous congestion also needs to be added	Thank you for your comment. We have considered this suggestion, however, due to time and resource constraint, the scoping group has decided to retain the focus on heavy menstrual bleeding (HMB) and to exclude gynaecological conditions where HMB is not the main presenting symptom. Regarding pelvic congestion, we believe that there are issues of definition of this syndrome which would make formulation of recommendations difficult. By addressing the management of HMB for women with fibroids, adenomyosis and no pathology ('dysfunctional bleeding'), this guideline will cover the majority of women with the condition, and this is the intention of NICE clinical guidelines.

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20.	FEmISA	3	72	The education and information provision is currently inadequate and being ignored by many gynaecologists. Our survey shows that most women are not informed of their treatment options or sent information before their outpatient's appointment. Many women are offered no choice in treatment at all and told by the gynaecologist that their only option is hysterectomy. The information for patients needs to be improved and needs to outline their treatment options and all the pros and cons of each.	Thank you for your comment. We believe by developing this updated guideline, education and information provided by health care professionals working in the field will be improved. We also note that recommendations on education and information provision to women with heavy menstrual bleeding were made in the original guideline (CG 44, published 2007). Our guideline committee will carry out an editorial review of this section during guideline development so they conform to current practice. NICE guidelines assume that doctors will meet the GMC requirement to refer a patient to another professional when this serves the patient's needs.
21.	FEmISA	3	74	Gynaecologists have no training on interventional radiology treatments – UAE/UFE and MRgFUS. They lack sufficient knowledge to assess whether a women is suitable for these treatments and we have evidence from patients that many are told they are unsuitable and can only have hysterectomy, when this is untrue. We have written to the president of RCOG about this lack of knowledge and training but did not receive a reply about this.	Thank you for your comment. We acknowledge that there is variation in practice across the country and this is one of the issues that NICE clinical guidelines aim to address. This is done by making recommendations based on the best available evidence, and combined with the guideline committee members' expertise and

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				FEmISA advocates multidisciplinary fibroid outpatient clinics as set up at Heartlands Hospital Birmingham. Here Interventional Radiologists and gynaecologists work together and offer information to women on the all the fibroid treatment available which they can discuss with the clinicians expert in providing the treatments and make an informed choice.	experience. NICE guidelines assume that doctors will meet the GMC requirement to refer a patient to another professional when this serves the patient's needs.
22.	FEmISA	3	76	From an FOI for acute NHS hospitals and CCGs there is little if any governance on compliance with quality standards, particularly NICE Guidelines. The public, patients and tax payers have a right to expect minimum quality standards of NICE Guidelines compliance and governance standards to ensure this.	Thank you for your comment. We understand that in practice the adherence to NICE clinical guidelines and quality standards is not ideal. The NICE Implementation Team is working closely with local commissioners to improve the public's access to NICE clinical guidelines and quality standards. NICE guidelines assume that doctors will meet the GMC requirement to refer a patient to another professional when this serves the patient's needs.
23.	FEmISA	4	105	It must be noted that many women, particularly Afro-Caribbean women can have symptomatic fibroids in their 20s and need management and treatment for decades. Newer progesterone receptor modulators for fibroids of 3 cm or more in diameter do not treat fibroids, but mask symptoms by putting women into chemical menopause and although they can given longer – 2 years instead of 6 months, they do not treat the fibroids, but	Thank you for your comment. We note that fibroids can affect young women, and special consideration will be given during guideline development to women who wish to preserve their fertility. Regarding Afro-Caribbean women, the scoping group felt that additional consideration was not necessary as the

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				suppress symptoms.	concern relates to age at diagnosis rather than ethnicity. In August 2016 a NICE Standing Committee, separate from this part of the update of Clinical Guideline 44, made 2 recommendations regarding progesterone receptor modulators for fibroids of 3cm or greater in diameter: 1.5.11 Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below. 1.5.12 Consider ulipristal acetate 5 mg (up to 4 courses) for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre. .
24.	FEmISA	5	110	2.2. this needs to include the diagnosis and treatment of pelvic venous congestion and for treatments MRgFUS and embolisation for fibroids, adenomyosis and pelvic venous congestion.	Thank you for your comment. We have considered the suggestion on pelvic venous congestion, due to time and resource constraint, the scoping group has decided to retain the focus on heavy menstrual bleeding (HMB) and to exclude gynaecological

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					conditions where HMB is not the main presenting symptom, which pelvic congestion falls under. Regarding pelvic congestion, we believe that there are issues of definition of this syndrome which would make formulation of recommendations difficult. By addressing the management of HMB for women with fibroids, adenomyosis and no pathology ('dysfunctional bleeding'), this guideline will cover the majority of women with the condition, and this is the intention of NICE clinical guidelines. Specific interventions will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
25.	FEmISA	5	112	Treatment of HMB when pathology such as fibroids, adenomyosis and pelvic venous congestion needs to be included. The important issue that there is insufficient safety and efficacy data on myomectomy and this has never been formally reviewed as a treatment needs to be addressed. There is a dearth of data	Thank you for your comment. We have considered this suggestion, however, due to time and resource constraint, the scoping group has decided to retain the focus on heavy menstrual bleeding (HMB) and to exclude gynaecological conditions where HMB is not the main presenting symptom.

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				on safely adverse events and side effects for this treatment.	Regarding pelvic congestion, we believe that there are issues of definition of this syndrome which would make formulation of recommendations difficult. By addressing the management of HMB for women with fibroids, adenomyosis and no pathology ('dysfunctional bleeding'), this guideline will cover the majority of women with the condition, and this is the intention of NICE clinical guidelines. Specific interventions and outcomes, including adverse events, will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
26.	FEmISA	5	127	Blood loss is not the only symptom that needs to be assessed – commonly pro-longed periods, painful periods, bulk symptoms etc are all common symptoms suffered by women with fibroids that need to be treated effectively.	Thank you for your comment. This guideline will focus on the symptom of heavy menstrual bleeding, but specific outcomes will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
27.	FEmISA	5	128	Adverse events should include reintervention rates and other longer term issues such as sexual dysfunction and early	Thank you for your comment. Specific outcomes will be defined in review protocols by

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				menopause requiring HRT over 5 -10 years. Most studies do not cover a long enough period to show early menopause etc	the guideline committee during development. We will ensure that the committee takes your comment into consideration. We acknowledge the importance of looking at long-term outcomes, although we anticipate that the majority of studies would not report long-term outcomes. Duration of treatment effect and adverse events would normally be taken into account in any health economic analysis undertaken to inform recommendations. Even if economic analysis was not undertaken for a specific question, the Guideline Committee would take into account adverse events when making recommendations.
28.	FEmISA	5	130	This also needs to cover the time taken and ability to return to work or normal life and time needed from family members to care for the women in recovery	Thank you for your comment. Health Related Quality of Life (HQRoL) is an important outcome generally but can also be particularly important in informing any economic analysis (see p136 of the Developing NICE guidelines: the manual). The EQ-5D instrument which can be used to measure HRQoL includes a dimension on the ability to undertake usual activities and therefore it may not be necessary

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					to capture these separately. This list is intended to just cover the main outcomes that are expected to be assessed in the guideline evidence reviews. However, for each clinical review question the Guideline Committee agree outcomes that they consider most important for that particular question.
29.	FEmISA	9	202	MRI is a more cost effective and safer diagnostic tool than hysteroscopy and is normally required before UFE. This should be considered.	Thank you for your comment. Specific diagnostic strategies will be defined in the review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
30.	Gedeon Richter UK Ltd	**5**	62, 110	We assume that the use of ulipristal acetate 5mg prior to surgery for uterine fibroids will be considered in this section if it has not already been covered in the final version of the Standing Committee update on the use of PRMs [progesterone receptor modulators] for fibroids ≥3cm (which is due to be published on 24th Aug 2016)	Thank you for your comment. T In August 2016 a NICE Standing Committee, separate from this part of the update of Clinical Guideline 44, made 2 recommendations regarding progesterone receptor modulators for fibroids of 3cm or greater in diameter: 1.5.11 Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below. 1.5.12 Consider ulipristal acetate 5 mg (up to

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					4 courses) for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre. .
31.	INSIGHTEC	General	General	MRgFUS is a well-established treatment for uterine fibroids and is a clinical alternative to UAE. It should thus be considered as a treatment alternative	Thank you for your comment. Specific interventions for HMB and outcomes will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
32.	Johnson & Johnson Medical Ltd.	General	General	Johnson & Johnson Medical welcome this update to the HMB Clinical Guideline. With regards to the key issues and questions, when reviewing the most clinically and cost-effective surgical treatment for HMB, we would particularly welcome a review of the different surgical approaches for hysterectomy i.e. open vs laparoscopic, and the impact on patient outcomes.	Thank you for your comment. Specific interventions for HMB, including different approaches for hysterectomy, and outcomes will be defined in review protocols by the guideline committee during development. We will ensure that the committee takes your comment into consideration.
33.	RCOG	General	General	Thank you for asking us to review this scope. We feel it is well written and covers all the relevant aspects. We look forward to seeing the guideline in due course.	Thank you for your comment.
34.	Royal College of General Practitioners	General	General	This is a welcome and important update in line with changing evidence and available diagnostic tests and treatments that may have implications for primary care. The RCGP does not have specific comments to make about the document.	Thank you for your comment.

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35.	Royal College of Pathologists	General	General	The draft scope will be considering recommendation of use of progesterone receptor modulators (PRM) in the management of heavy menstrual bleeding. These agents can cause changes in the endometrium that are collectively referred to as PRM associated endometrial changes (PAECs) and may mimic endometrial hyperplasia. If a biopsy is taken from a woman on PRM, it is important that the clinician provides this information so that the pathologist reporting on the biopsy will avoid this diagnostic pitfall.	Thank you for your comment. The effectiveness of progesterone receptor modulators (PRM) in treating women of reproductive age with fibroids greater than 3cm in diameter was assessed in another update undertaken by the NICE Standing Committee (Addendum to Clinical Guideline 44, Heavy Menstrual bleeding: assessment and management). This addendum will be published in near future. For the current update, specific interventions or outcomes will be defined in review protocols by the Guideline Committee during the development and recommendations will be made based on the best available evidence.
36.	The Hysterectomy Association	2	43	The scope should include women who experience heavy menstrual bleeding for any reason.	Thank you for your comment. NICE clinical guidelines generally are focused on the majority of the population with the prevalent condition or major conditions not addressed before; due to time and resource constraint it is not possible to address every aspect of a condition. Women with fibroids, adenomyosis or no identifiable pathology are prioritised for inclusion in this scope.
37.	The Hysterectom	3	77	The scope should be considering cost effectiveness of treatment if evidence is provided that costs have been increased by	Thank you for your comment. Clinical and cost effectiveness of interventions will be considered

Heavy menstrual bleeding (update)

Consultation on draft scope
Stakeholder comments table

02/08/2016 to 02/09/2016

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	y Association			providers as this will impact significantly on the underlying value of the treatment.	during guideline development. Line 77 stated that the clinical and cost effectiveness of progesterone receptor modulators for fibriods of 3cm or more will not be considered, because this question has been separately reviewed and updated by the NICE Standing Committee (Addendum to Clinical Guideline 44, Heavy Menstrual bleeding: assessment and management). This addendum was published in August 2016.
38.	The Hysterectomy Association	8	196	Is it possible to ascertain the cost to GDP of menstrual disorders on the economy?	Thank you for this comment. Cost of Illness to GDP does not form a part of NICE methods, because to do so would discriminate against people who are not economically active.
39.	The Hysterectomy Association	9	206	A statement has been made that costs may have changed due to changes in clinical practice and technology and yet my comment 2 notes that there is no consideration of cost effectiveness due to take place!	Thank you for your comment. Both clinical and cost effectiveness of different interventions will be considered and this has been stated in the scope under "Key areas that will be updated" and "Key issues and questions".

Heavy menstrual bleeding (update)

Consultation on draft scope
Stakeholder comments table

02/08/2016 to 02/09/2016

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Document processed	Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Number of comments extracted	Comments
Draft Scope	Bayer plc	**Current Situation** • Bayer does not have direct or indirect links with, or funding from, manufacturers, distributors or sellers of smoking products but Bayer provides pesticides for crops, which would therefore include tobacco crops. • Bayer is a member of the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) (http://www.coresta.org/) within the scope of recommendations of pesticides used for protection of tobacco plants. • It is also a member of country and EU business federations such as the Confederation of British Industry (CBI) and 'Business Europe', which	3	

Heavy menstrual bleeding (update)

Consultation on draft scope
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		include tobacco companies. **Past Situation** • In 2006, Bayer and its subsidiary Icon Genetics piloted a new process for producing biotech drugs in tobacco plants. Icon Genetics was acquired by Nomad Bioscience GmbH from Bayer in 2012.		

Registered stakeholders