Culture, Communication, Contraception

Final programme

11th Congress of the European Society of Contraception and Reproductive Health

The Hague, The Netherlands

19-22 MAY 2010

www.contraception-esc.com

Синхронный перевод на русский язык будет обеспечиваться на протяжении всех пленарных заседаний, сессий конгресса и ключевых лекций

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Congress secretariat

For all information regarding the Society, individual or group registrations, the scientific programme, abstracts, sponsorship, please contact:

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congress@contraception-esc.com
www.contraception-esc.com/thehague.htm

Congress venue

World Forum Convention Center
Churchillplein 10
2517 JW Den Haag
Nederland
www.worldforumcc.com/wfcc/uk

Accommodation

Hotelmatch
T +31 88 0400400
ESC@hotelmatch.nl
www.hotelmatch.nl/ESC_reservation.html

Introduction

Dear colleagues and friends,

Allow us to welcome you to The Hague for the 11th Congress of the European Society of Contraception and Reproductive Health (19-22 May 2010). The time was right to organise an ESC congress in the Netherlands, because we feel that the Dutch have been playing a pivotal role in transforming the ESC from a mainly medical society to a more multidisciplinary European platform where all bio-psycho-social and cultural aspects of contraception and reproductive/sexual health are a focus of interest.

The title of the congress “Culture, Communication, Contraception” reflects that contraceptive and reproductive health care in multicultural Europe must address the different needs of different individuals in different situations. There is a growing requirement for preventive strategies that take into account the specific cultural, sub cultural, economic, ethnic and religious characteristics of subpopulations within the European community. It is the diversity of multicultural Europe that challenges our creativity to provide new solutions, new methods and innovative approaches.

There is no better place in Europe to discuss these topics than the beautiful city of The Hague, which is not only the residence of the Dutch Royal family and the Dutch Government, but also the city were no less than 7 United Nations bodies and numerous headquarters of international organisations reside. The words peace, justice and safety are synonyms for The Hague.

We are confident that the 11th ESC Congress will stay in your memory for a long time.

Rik HW van Lunsen
Congress President

Rob Beerthuizen
Congress President

General information

Organisation

Executive Committee of the ESC

J. Bitzer (President)
D. Apter (Vice-President)
S. Randall (Secretary General)
D. Cibula (Assistant Secretary)
M. Lech (Treasurer)
K. Sedlecky (Assistant Treasurer)

Organising Committee

R. Beerthuizen (the Netherlands), Co-President
R.H.W. van Lunsen (the Netherlands), Co-President
F. Roumen (the Netherlands), Vice President
O. Loeber (the Netherlands), Secretary
S. Randall (United Kingdom), Assistant Secretary
P. Scholten (the Netherlands), Treasurer
M. Lech (Poland), Assistant Treasurer
F. Beerthuizen-Vermeulen (the Netherlands), Member
C. Picavet (the Netherlands), Member
I. Shiripinda (the Netherlands), Member
S. van der Doef (the Netherlands), Member
C. Wijsen (the Netherlands), Member

International Scientific Committee

J.J. Amy (Belgium)
D. Apter (Finland)
J. Bitzer (Switzerland), President
A. Glasier (United Kingdom)
G. Lazdane (WHO)
I. Lete (Spain)
S. Mann (United Kingdom)
G. Merki (Switzerland)
K. Sedlecky (Serbia)
D. Serfaty (France)
R. van Lunsen (the Netherlands), Vice-President

Board of Directors of the ESC

J.J. Amy (Belgium)
D. Apter (Finland)
I. Batar (Hungary)
D. Baumane – Auza (Latvia)
R. Beerthuizen (the Netherlands)
A. Ber (Israel)
J. Bitzer (Switzerland)
I. Blidaru (Romania)
T.A. Carmo Bombas (Portugal)
D. Cibula (Czech Republic)
P.G. Crosignani (Italy)
G. Crvenkovic (Croatia)
V. Cupanik (Slovakia)
B. Frey Tirri (Switzerland)
K. Gemzell – Danielsson (Sweden)
H. Guner (Turkey)
M. Kishen (United Kingdom)
D. Lazaris (Greece)
M. Lech (Poland)
I. Lete Lasa (Spain)
E. López Arregui (Spain)
C. McNicholas (Ireland)
H. Missey Kolb (France)
F. Moustéou (France)
G. Okoev (Armenia)
P. Patroclou (Cyprus)
B. Pehlivanov (Bulgaria)
K. Petersen (Denmark)
T. Rabe (Germany)
S. Randall (United Kingdom)
N. Salakos (Greece)
H. Satiroglu (Turkey)
K. Sedlecky (Serbia)
D. Seidman (Israel)
I. Sivin (USA)
A. Stolfa Gruntar (Slovenia)
M. Tarasova (Russia)
V. Vanagiene (Lithuania)
A. Volpe (Italy)
P. Weiss (Czech Republic)
V. Yaglov (Russia)

The Hague

The Hague, city of many faces

The worldly sophistication of the city centre, the beach and the nightlife sizzle of Scheveningen and the easygoing elegance of Kijkduin, The Hague offers a unique blend of versatility, service and quality. City of 21st century architecture and daring innovations, of both art and business, and most of all, city of style; International style, that is.

Being the Royal residence and the political centre of the Netherlands, the city of The Hague is a national icon. The monumental government buildings, the palaces and the embassies, the fashionable stores, the statues and fountains; they represent the city's classical face. But just a stone's throw away, in stark contrast, the breathtaking shapes of the new millennium are evident in the latest architecture and design. It's no accident that many renowned national and international businesses and organisations have elected The Hague as their home base.

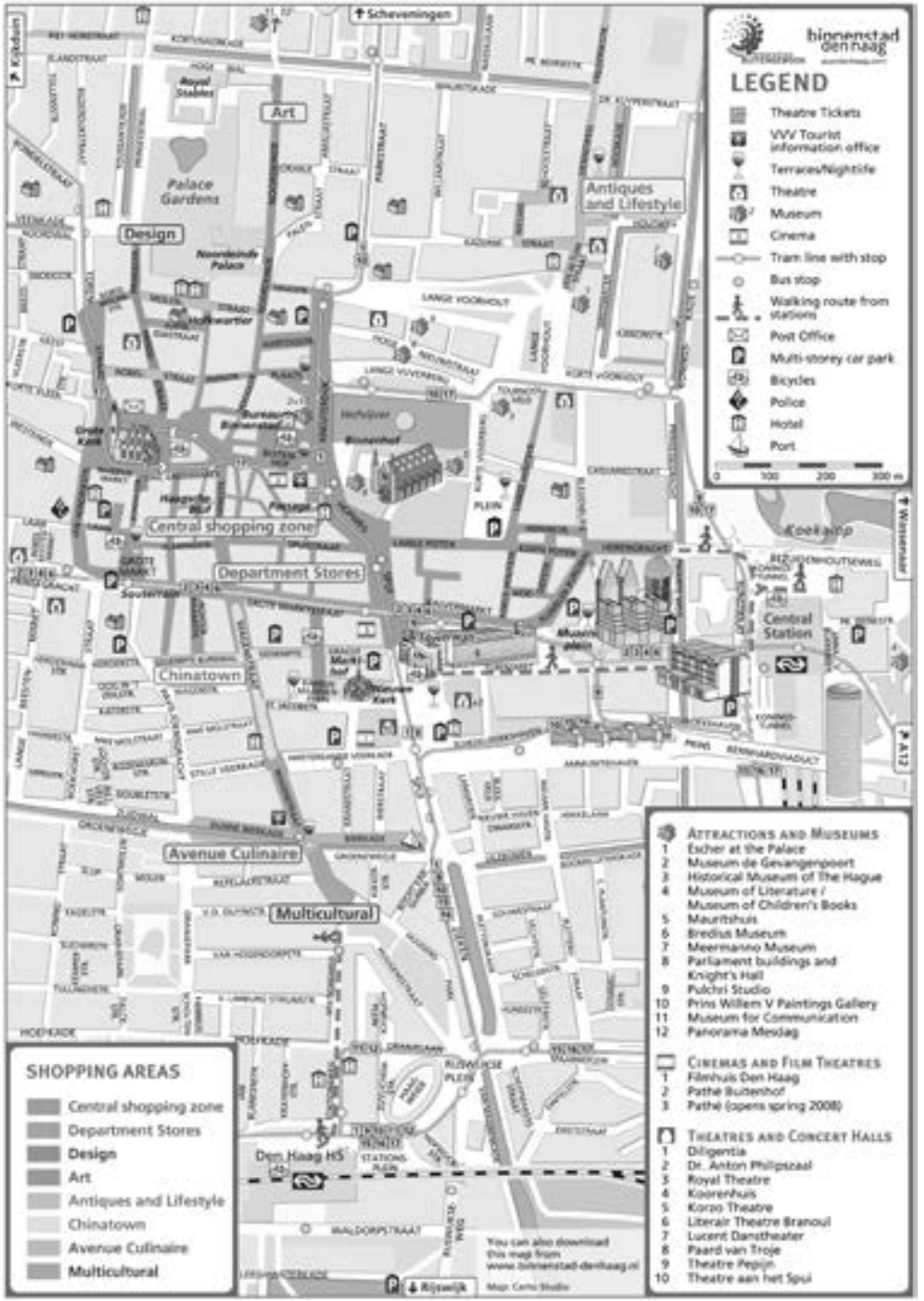
The Hague's unique location by the North Sea gives it an extra dimension where recreation is concerned.

City of culture

The Hague is ideal for those who love culture. In addition to paintings by Dutch masters like Rembrandt, Vermeer, Jan Steen and Frans Hals, the museums of The Hague offer an extensive collection of works by van Gogh and his contemporaries. The municipal Museum of the city boasts the largest Mondriaan collection in the world. The many art galleries and shops, as well as the antique shops and the antique market are ideal for art aficionados.

The Hague is home base to Nederlands Dans Theater and Residentie Orkest, both renowned around the world. The City's many other theatres offer a wide selection of music, dance and plays. At Scheveningen's Fortis Circustheater, the famous musicals of the world come to life each night.

World Forum
Convention Center



Practical information

Badges: Congress badges should be worn by all participants at all times during the congress and while visiting the exhibition area. No badge, no entry.

Badges are colour-coded as follows:
- Participants: ESC members: Yellow
- Participants: non-members: White
- Exhibitors: Blue
- Organisers and staff: Red

Book of abstracts: You will find the book of abstracts in your congress bag.

Certificate of attendance: A certificate of attendance will be available in your personal envelope and will be delivered together with your badge upon arrival.

Currency : The currency in the Netherlands is the Euro (€). All Congress fees and rates are charged in Euro. No other currency will be accepted during the Congress.

Electricity: Electric appliances in the Netherlands work with 220 volts, ca. 50 Hz and plugs conform to the European system of round pins with two holes.

Evaluation form: In order to allow the organisers to learn from past experiences they would be very grateful if you would be willing to give them the necessary feedback. You may be asked to take part in a short interview related to the organisation.
An evaluation form is available in your congress bag. Kindly complete the form and return it to the registration desk. The congress organisers appreciate your valuable feedback.

Exhibit and sponsors: See also “exhibit and sponsors” later in this final programme. Coffee breaks will be served in the exhibition area (Lobby and Amazon Foyer - 1st Floor). Delegates are encouraged to visit the stands and to recognise the valuable support which these companies have provided towards the congress.

General Assembly: Paid-up members are welcome to attend the General Assembly:
Atlantic, World Forum Convention Center, The Hague
Friday 21 May 2010 at 16:30

Proxy vote forms must be registered with the ESC desk at the Congress at the latest 4 hours before the GA starts. The form will be stamped and returned to the proxy vote holder. As they enter the GA, they should hand in this stamped form in exchange for a voting pad, which will allow them to have 2 identical votes.

Hotel accommodation: Hotelmatch is in charge of all hotel reservations and will have an accommodation desk within the registration area (ground floor) with the aim to help you with any questions related to accommodation.

Insurance, liability: ESC does **not** accept liability for individual medical, travel or personal insurance, and participants are strongly advised to take out their own personal insurance policies in their country of origin.

Lunches: Participants who register on site for a Meet the Expert session (max. 15 participants) or participate to the lunchtime symposium on Thursday will have a lunch box provided. Lunch boxes will also be provided during the Expert Group sessions (Registration is needed for the workshop of the Expert Group on non-hormonal methods of contraception - max 30 participants).

Please find here some lunch facilities:
within the World Forum:
- Famous Tables café (Ground Floor)
- Pangea In House Restaurant (Ground Floor)

within walking distance from the World Forum:
- La Bruschetta - Aert van der Goesstraat 9 - 2582 AH Den Haag
- Da Enzo Marchese - Aert van der Goesstraat 43 - 2582 AJ Den Haag
- Brasserie Meys - Frederik Hendrikplein 36 - 2582 AX Den Haag
- Lunchroom Tasty - Frederik Hendriklaan 58 - 2582 BD Den Haag
- Lunchroom Plasman - Frederik Hendriklaan 106 - 2582 BG Den Haag
- Koemans Snacks en Broodjes - Frederik Hendriklaan 182 - 2582 BK Den Haag
- Boosty - Frederik Hendriklaan 294 - 2582 BN Den Haag

Meet the Expert sessions: Meet the Expert sessions are organised on Thursday, from 12:30 - 13:30. Attendance to those sessions is limited to 15 persons maximum. Please register at the registration desk for these Meet the Expert sessions.

Expert Group on Non-hormonal methods of contraception: please register on site at the registration desk for the workshop: what are the minimum standards of care that a healthcare professional (HCP) (in sexual health) in primary/community settings should provide? This workshop (Friday, 12:25 - 13:25) is limited to 30 persons maximum.

On site registrations:
All amount are payable in euro

ESC members	630
Non-members	730
Nurses, midwives, social workers, counsellors (non-MD), medical students	
ESC members	420
Non-members	520
Congress Dinner	100
Extra person(s) attending	
the Opening Ceremony and Cocktail	40
the Congress dinner	100

Opening hours of the registration desk :
- Wednesday, May 19 12:00 - 18:30
- Thursday, May 20 08:00 - 18:00
- Friday, May 21 08:30 - 16:00
- Saturday, May 22 08:30 - 12:00

Preview room for invited speakers (Volga 1 - 1st Floor): Speakers are kindly invited to submit their slides - either on CD-rom, memory stick or laptop - at the latest 60 minutes before their presentation to the preview room: Volga 1 - 1st Floor, and before their session starts. Last minute preview facilities will be available.

Registration package: The registration package for the participants includes:
- admission to the scientific sessions and the exhibition area
- access to the opening ceremony
- abstract book
- final programme
- certificate of attendance
- coffee and tea during breaks
- welcome cocktail (Wednesday May 19, 2010)
- lunch box if registered on site for one of the activities during lunch time

Translation: The official language of the congress will be English.
Simultaneous translation is foreseen into Russian:
- plenary sessions in the World Forum Theater
- keynote lectures in the World Forum Theater
- congress sessions in the World Forum Theater and Atlantic.

Some of the Society sessions might be held in the language of the organising country.

Scientific programme

High standard scientific programme: the Scientific Committee has endeavoured to put together a high standard, well balanced scientific programme, offering current topics and excellent speakers. To make the programme even more attractive, a considerable proportion will be interactive with the audience.

Keynote lectures are plenary sessions which are scheduled for 30 minutes. Leading experts will present specific subjects.

Each congress day starts with a ***plenary session*** during which no parallel activity is scheduled. An international panel of experts will critically assess the state of scientific knowledge pertaining to a specific topic.

Congress sessions (State of the art) : in each of these 6 sessions, three or four experts will provide up to date information on a topic, with plenty of opportunity for questions. There will be one selected free communication added to each session.

Fora are meant as interactive sessions, introduced by two/three experts in the field and followed by an in depth discussion with the audience.

A ***WHO workshop*** will teach participants how to implement and apply WHO tools and guidelines.

Meet the Expert sessions are scheduled on Thursday and are organised as informal, round table discussions during lunch with a maximum of 15 participants. A variety of topics will be covered. Participants will receive a free lunch box. Please register in advance at the registration desk for these meet the expert sessions.

ESC Expert Groups are scheduled on Friday lunch time. They are organised by five Expert Groups and the Nurses/paramedicals special interest group. The format of the sessions may differ from each other. They will focus on the highlights in their area of expertise.

Please register on site at the registration desk for the session of the Expert Group on Non-hormonal methods of contraception: workshop: what are the minimum standards of care that a healthcare professional (HCP) (in sexual health) in primary/community settings should provide? This workshop (Friday, 12:25 - 13:25) is limited to 30 persons maximum.

Society sessions are organised by national and international societies or organisations with aims similar to the ESC and will discuss a specific item within their area of interest. Society sessions may be organised in a language other than English.

Symposia will be the platform for the pharmaceutical companies.

Free Communication sessions: a selection of the submitted free communications are either integrated into the congress sessions or scheduled into separate free communication sessions. Abstracts of selected free communications can be found in the Book of Abstracts.

A Young Scientist session aims to provide a special platform for paper presentations by young scientists. The session is primarily targeted at Fellows and Ph.D. students, but the only inclusion criterion was the age < 35 years.

Poster presentations are chosen from the submitted abstracts and will carry equivalent scientific status to free communications in the programme. The poster area is in the Basement: the Pacific and Atlantic Foyer. Posters will be on display for the full time of the Congress. Abstracts of selected posters can be found in the Book of Abstracts. Poster can be mounted on Wednesday 19 May, between 12:00 and 19:00. Contact the Poster Managers in the poster area for assistance.




Awards

The ESC Medal will be awarded to honour outstanding national or international recognised activity in contraception, abortion, sexual or reproductive health. The ESC Medal will be awarded during the Opening Ceremony on Wednesday.

The ESC Diploma is established to honour outstanding organisational support and activity within the ESC itself in accordance with the aims of the Society. The ESC Diploma will be awarded during the Closing Session on Saturday.

A Young Scientist session will provide a special platform for presentations by young scientists (below 35 years of age). Each presenter in this session will compete for the ***ESC Young Scientist Award.***

The Best Free Communication Award will be awarded during the Closing Session on Saturday.

The Best Poster Awards: A selection of the best posters will be presented in the 'Best Poster' session. From this session, the candidates for the Best Poster Awards will be chosen. To be considered for these awards, posters will need to be in place for judging by 10:00 am on Thursday May 20. Authors should be at their poster during coffee breaks. Poster presenters should check on Friday (latest at 12:00) if their poster has been selected by looking for a balloon on their poster board. Those selected will have to prepare a presentation for the Best Poster Session on Friday Afternoon from 14:00 to 14:30. The talk should be limited to 5 minutes, documented with a maximum of 5 Powerpointpoint slides. Poster presenters are asked to submit their presentation to the preview room as soon as possible. The Best Poster awards will be awarded during the Closing Ceremony on Saturday.

The ESC Best Public Poster Award: In your personal envelope (among others containing your badge), you will find two voting ballots. Please indicate on each ballot a poster number you would like to nominate. Since you have two ballots, you can nominate two different posters. Please drop both ballots in the poster voting bin at the registration desk.

The ESC Best Public Poster Award will be awarded during the Closing Ceremony on Saturday. One ballot will be drawn randomly and this participant receives a fee waiver for the 12th ESC Congress, Athens, Greece.

Social programme

Wednesday, May 19, 2010 - Opening Ceremony - 18:00
- Welcome Reception - 19:30

The Opening Ceremony is supported by the City of The Hague.

All participants are warmly invited to join us for the Opening Ceremony that takes place in the main auditorium. It will be an entertaining and eventful introduction to the congress. During the ceremony, the ESC Medal will be awarded for the third time. After the Opening Ceremony, we will officially open the industrial exhibition and invite our delegates to the Welcome Reception. Attendance at the Opening Ceremony and Welcome Reception are complimentary.

Friday, May 21, 2010 - Congress Dinner - 20:00

The 11th ESC Congress will not only be about science, but also about having a good time. Sign up for this event and enjoy a fantastic evening at "Beach Club Doen" in the company of your friends and colleagues. We will offer an exquisite blend of excellent food and entertainment. The dinner site provides you a spectacular view of the sandy beaches of Scheveningen (The Hague). Food will be served as a so-called "walking dinner", but seating is possible for those who wish. Allow yourself to be surprised by the informal chique.
The buses will leave from the entrance of the World Forum Convention Center at 19:30 for Beach Club Doen (Strandweg 9, 2586 JK Scheveningen).
Return transfer to the hotels will be arranged.

Dress code: smart casual
The tickets for this unique event are 100 euro each.

Saturday, May 22, 2010 - Closing session and Award Ceremony - 12:00

.....very promising.....

The last session but not the least. The ESC Diploma will be awarded. During this Ceremony, presentations will be made to the winners of the 2010 ESC Poster Award, the Public Poster Award, the Best Free Communication Award as well as the winner of the Young Scientist Award. ***At the end of the Ceremony, we will say goodbye to The Hague with a special Dutch gift*** and welcome Athens.

Wednesday, May 19

18:00	Opening session
19:30	Opening reception

Meet the expert sessions (registration on site at the registration desk - max. 15 participants)

Skills in intercultural sexual health communication - Yangtze
Preventive strategies for ethnic minorities - Antarctica
Skills in sexual health education - Asia
Management of side effects of contraceptives - Europe 1
Sexual counselling in family planning consultations - Europe 2
Future of contraception - Mississippi
Media: an important tool - North America
Preventive strategies for adolescence - Central America
Emergency contraception: the lack of impact on abortion rates - South America
How to measure quality of life - Everest 1
How to deal with repeat abortion - Kilimanjaro 1
Peer education of adolescents - Everest 2
Practical aspects of medical abortion - Kilimanjaro 2
Cancer risks and contraception - Summit Foyer

Thursday, May 20

	World Forum Theater	Atlantic	Amazon	Yangtze	Mississippi	Everest
08:30	Plenary session 1 Diversity and SRH in multicultural Europe					
10:00	**Break and poster viewing**					
10:30	Sponsored symposium MSD	Congress session 1 New formulations in hormonal contraception	Free Communications 1	Society Session 1 Faculty of Sexual and Reproductive Healthcare (UK)	Society Session 2 International Federation of Professional Abortion and Contraception Associates	
12:00	Sponsored symposium Bayer Schering Pharma	Meet the Expert sessions	**Lunch**			
14:00	Sponsored symposium Bayer Schering Pharma	Congress Session 2 Determinants of contraceptive behaviour	Workshop WHO documents and guidelines	Society Session 3 German Society of Contraception	Society Session 4 Francophone Society of Contraception	
15:30	**Break and poster viewing**		Sponsored lecture Laboratoire HRA			
16:00	Keynote 1 Culture, Communication, Contraception					
16:30	Congress session 3 Prevention: Beyond the Double Dutch	Forum 1 Contraceptive use: perspective from Europe	Free Communications 2	Free Communications 3	Society Session 5 Association of Reproductive Health Professionals (USA)	Society Session 6 Italian Society of Contraception

Friday, May 21

	World Forum Theater	Atlantic	Amazon	Yangtze	Mississippi
08:30	Plenary Session 2 Evidence based sexual and reproductive health care				
10:00	**Break and poster viewing**				
10:30	Sponsored symposium Bayer Schering Pharma	Congress Session 4 Culture, religion, reproduction and sexuality	Free Communications 4 Young Scientists	Forum 2 Contraception and bone	Society Session 7 Spanish Society of Contraception
12:00	ESC Medal Lecture				
12:15	Expert group sessions	**Lunch**			
13:30	Keynote 2 A tribute to Margaret Sanger				
14:00	Sponsored symposium MSD	Congress Session 5 To bleed or not to bleed	Best Poster Session Sponsored symposium Pantarhei Bioscience	Society Session 8 the Netherlands SAN/RNG/STI-AIDS	Society Session 9 Swiss Society of Contraception
15:30	Keynote 3 Contraception and sexuality: a review				
16:00	**Break and poster viewing**				
16:30		General Assembly (Members only)			

Saturday, May 22

	World Forum Theater
08:30	Plenary Session 3 Education and training for family planning professionals
10:00	**Break**
10:30	Congress Session 6 Contraception and gynaecological disease
12:00	Closing session and Award ceremony
12:45	Congress adjourn

Expert Group sessions

Expert Group on Sexual and reproductive health and education - Atlantic
Expert Group on STI - Amazon
Expert Group on Abortion - Yangtze
Expert Group on Hormonal contraception - Mississippi
Expert Group on Non-hormonal methods of contraception - Everest (**registration on site at the registration desk)**
Nurses/paramedicals special interest group session - Kilimanjaro

Scientific programme

Continuing Medical Education Credits

The European Society of Contraception and Reproductive Health (ESC) is accredited by the European Accreditation Council for Continuing Medical Education (EACCME) to provide the following CME activity for medical specialists. The EACCME is an institution of the European Union of Medical Specialists (UEMS), www.uems.net. The 11th Congress of the European Society of Contraception and Reproductive Health is designated for a maximum of (or 'for up to') **15 hours of European External CME credits**. Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity. EACCME credits are recognised by the American Medical Association towards the Physician's Recognition Award (PRA). To convert EACCME credits to AMA PRA category 1 credit, contact the AMA (www.ama-assn.org).

Wednesday, May 19

World Forum Theater (WFT)

18:00 **Opening Session**

Cultural programme

Welcome address by the Congress Presidents
R. Beerthuizen (the Netherlands) - R. van Lunsen (the Netherlands)

Welcome address by the ESC President
J. Bitzer (Switzerland)

Welcome address by the deputy Mayor for Public Health, Welfare and Equal Opportunity of The Hague
B. van Alphen (The Netherlands)

ESC Medal Ceremony - J. Lippes (USA)
Introduction, *I. Batar (Hungary)*

Welcome address by the former State Secretary for Health, Welfare and Sport
Dutch view on sexual health
M. Bussemaker (The Netherlands)

19:30 **Opening Reception**

Thursday, May 20

08:30 -10:00 **WFT** **Plenary session 1**
Diversity and sexual/reproductive health (SRH) in multicultural Europe
Chair: J. Bitzer (Switzerland) - R. van Lunsen (the Netherlands)

08:30 • IS-01 Intercultural communication in SRH
V. Claeys (IPPF)
09:00 • IS-02 Virginity: a gender issue?
B. van Moorst (the Netherlands)
09:30 • IS-03 Immigration and contraception: adaptation to different family and cultural models
A. Volpe (Italy)

10:00 - 10:30 **Break and poster viewing**

10:30 - 12:00 **WFT** **Sponsored symposium MSD**
Oral contraceptives: where we've been and where we're going
Chair: D. Mansour (UK)

10:30 Where we are today
D. Mansour (UK)
10:45 • SP1-2 Estradiol: a new option for Combined Oral Contraceptives
F. Stanczyk (USA)
11:05 • SP1-3 Nomegestrol acetate – a new and different progestin
A. Mueck (Germany)
11:25 • SP1-4 Estradiol and NOMAC – a natural combination
T. Korver (the Netherlands)

Atlantic **Congress session 1**
New formulations in hormonal contraception
Chair: D. Serfaty (France) - R. Sitruk-Ware (USA)

10:30 • IS-04 Clinical experience with estetrol containing combined OC
H. Coelingh Bennink (the Netherlands)
10:50 • IS-05 Androgen Restored Contraception
H. Termeer (the Netherlands)
11:10 • IS-06 Oestradiol-containing combined contraceptives
G. Merki (Switzerland)

11:30 • IS-07 Selective progesterone receptor modulators
N. Chabbert-Buffet (France)

11:50 • FC-01 Preliminary results from a phase III study of the nestorone®/ethinyl estradiol contraceptive vaginal ring: a new, long acting (one year) user controlled contraceptive method
R. Merkatz (USA)

Amazon

Free Communication Session 1
Abortion, Long-acting reversible contraceptive methods, Emergency contraception, Education and training for family planning professionals
Chair: I. Blidaru (Romania) - E. Lopez Arregui (Spain)

10:30 • FC-02 Reducing the buccal dose of misoprostol in mifepristone medical abortion up to 63 days LMP
T. Tsereteli (Georgia)

10:43 • FC-03 Awareness and periconceptional use of folic acid Results of a European study in women of childbearing age
A. Von Stenglin (Germany)

10:56 • FC-04 Follow up and review of 946 sub-dermal Implanon® inserted in the first half of 2008
H. Mahmoud (UK)

11:09 • FC-05 Knowledge, attitude and use of emergency contraception improves among young at risk women after community outreach by lay-counselors in a developing country
P. Steyn (South Africa)

11:21 • FC-06 Home self-administration of vaginal misoprostol for medical abortion at 50 to 63 days compared with gestation of below 50 days
H. Kopp Kallner (Sweden)

11:34 • FC-07 Increasing the proportion of women using Long Acting Reversible Contraception (LARC) within a geographical area in Scotland
A. Brown (UK)

11:47 • FC-08 Social inequalities in rates of induced abortion in Spain: a multilevel approach
G. Perez (Spain)

Yangtze

Society Session 1 : Faculty of Sexual and Reproductive Healthcare (FSRH - UK)
Chronic medical conditions and contraception: A transnational take on how conditions are managed in different European countries
Chair : N. Mullin (UK) - D. Cibula (Czech Rep.)

10:30 Introduction
C. Robinson (President FSRH)

10:40 • SS1-1 IUS in women with breast cancer
K. Gemzell - Danielsson (Sweden)

11:00 • SS1-2 Obesity and COC
P.G. Crosignani (Italy)

11:20 • SS1-3 SLE and contraception for women - Guidelines from WHO Medical Eligibility Criteria and UK Medical Eligibility Criteria
A. Glasier (UK)

11:40 • SS1-4 Hormonal contraception and diabetes
S. Skouby (Denmark)

Mississippi

Society Session 2 : International Federation of Professional Abortion and Contraception Associates (FIAPAC)
Update in abortion care
Chair: M. Parachini (Italy) - A. Verougstraete (Belgium)

10:30 • SS2-1 Medical abortion
C. Fiala (Austria)

10:55 • SS2-2 Cervical priming
R. Moullier (France)

11:20 • SS2-3 Pain management
E. Aubény (France)

11:40 • SS2-4 Myths
S. Rowlands (UK)

12:00 - 14:00 **Lunch and poster viewing**

WFT

Sponsored symposium Bayer Schering Pharma including lunch (12:15 - 13:45)
Qlaira® - The first estradiol-based pill
Chair: J. Calaf (Spain)

12:15 Introduction
J. Calaf (Spain)

12:20 Rationale for the development of Qlaira®
A. Kubba (UK)

12:38	Qlaira® – clinical aspects of a new oral contraceptive *I. Milsom (Sweden)*
12:56	Qlaira® – clinical data on reducing menstrual blood loss *D. Mansour (UK)*
13:16	Bayer Schering Pharma: your expert partner in women's healthcare *Ph. Smits (Germany)*
13:30	Q&A session

Meet the Expert sessions including lunch (12:30 - 13:30)
Please register in advance at the registration desk

Yangtze • IS-08	Skills in intercultural sexual health communication *B. van Moorst (the Netherlands) - R. van Lunsen (the Netherlands)*
Antarctica • IS-09 • IS-10	Preventive strategies for ethnic minorities *E. Osmanagic (Bosnia Herzegovina) - V. Cupanik (Slovakia)*
Asia • IS-11	Skills in sexual health education *O. Loeber (the Netherlands) - C. Picavet (the Netherlands)*
Europe 1 • IS-12	Management of side effects of contraceptives *F. Roumen (the Netherlands) - G. Merki (Switzerland)*
Europe 2 • IS-13	Sexual counselling in family planning consultations *J. Alder (Switzerland) - B. Pehlivanov (Bulgaria)*
Mississippi • IS-14	Future of contraception *Ph. Bouchard (France) - R. Sitruk-Ware (USA)*
North America • IS-15	Media: an important tool *B. Pinter (Slovenia) - E. Erös (Hungary)*
Central America • IS-16	Preventive strategies for adolescence *K. Sedlecky (Serbia) - D. Apter (Finland)*
South America • IS-17	Emergency contraception: the lack of impact on abortion rates *A. Webb (UK) - B. Frey Tirri (Switzerland)*
Everest 1 • IS-18	How to measure quality of life *M. A. Gomez (Spain) - I. Lete (Spain)*
Kilimanjaro 1 • IS-19 • IS-20	How to deal with repeat abortion *A. Verougstraete (Belgium) - V. Yaglov (Russia)*
Everest 2 • IS-21	Peer education of adolescents *E. Aubény (France) - S. Tschudin (Switzerland) and representatives peer education associations*
Kilimanjaro 2 • IS-22	Practical aspects of medical abortion *K. Gemzell-Danielsson (Sweden) - H. Missey-Kolb (France)*
Summit Foyer • IS-23	Cancer risks and contraception *D. Lazaris (Greece) - A. Mueck (Germany)*

14:00 - 15:30

WFT

Sponsored Symposium Bayer Schering Pharma
Innovations in Contraception
Chair: M. Cronin (Germany)

14:00	Innovations in contraception *M. Cronin (Germany)*
14:08	YAZ®: the innovative 24/4 drsp oral contraceptive *N. Panay (UK)*
14:32	Introducing a new dimension to contraception: adding folate to the pill *W. Holzgreve (Germany)*
15:00	A fresh look at Mirena®: motivating women and dispelling myths *A. Evans (UK)*
15:25	Q&A session

Atlantic

Congress Session 2
Determinants of contraceptive behaviour
Chair: C. McNicholas (Ireland) - H. Guner (Turkey)

14:00 • IS-24	Computer assisted decision making on contraceptive use *R. French (UK)*
14:20 • IS-25	Information about SRH: sources used by teenagers *D. Apter (Finland)*
14:40 • IS-26	Determinants of user failures *C. Moreau (France)*
15:00 • IS-27	Lessons from behavioural medicine *J. Bitzer (Switzerland)*
15:20 • FC-09	The potential impact of satisfying the unmet need for contraception *G. Sedgh (USA)*

Amazon **Workshop**
WHO documents and guidelines

14:00 • IS-28 International perspective on the need for guidelines
P. van Look (Switzerland)
14:30 • IS-29 Regional experience of implementation of WHO tools and guidelines in the area of SRH
G. Lazdane (WHO Europe)
15:00 Adaptation and application of WHO guidelines in UK
C. Smith (UK)

Yangtze **Society Session 3** :
German Society of Contraception
Session will be held in German
Chair : T. Rabe (Germany) - C. Liedtke (Germany)

14:00 OC and cancer risk
C. Liedtke (Germany)
14:15 • SS3-2 Contraception – communication in special risk populations
A. Mueck (Germany)
14:30 • SS3-3 Endometriosis and hormonal contraception
A.E. Schindler (Germany)
14:45 • SS3-4 New aspects on natural family planning – myths and facts
P. Frank-Herrmann (Germany)
15:00 • SS3-5 The sexual life of German medical students: Investigation of the prevalence of sexual dysfunction and the impact of contraception
L.M. Wallwiener (Germany)
15:15 • SS3-6 New developments in hormonal contraception for women
T. Rabe (Germany)

Mississippi **Society Session 4** :
Société Francophone de Contraception (SFC)
Session will be held in French

Intérêt des contraceptions réversibles de longue durée actuelles et futures
Présidents: H. Chelli (Tunisie), D. Serfaty (France)

14:00 • SS4-1 Les méthodes de contraception de longue durée actuelles et futures
D. Serfaty (France)
Discutants: J.F. Meyé - J.C. Moreau
14:22 • SS4-2 L'anneau vaginal annuel à la nestorone
R. Sitruk-Ware (Etats-Unis)
Discutants: B. Dao - M. Traoré
14:44 Les contraceptifs estroprogestatifs injectables mensuels
P. Hall (OMS)
Discutants: N. Homasson - R. Dreyfus
15:06 Stérilisation ou contraception de longue durée?
J. Berubé (Canada)
Discutants: Y. Hyjazi - M. Brincat

Discussion générale animée par J.Abboud (Liban), M.O.Abdelkader (Mauritanie), J.Bitzer (Suisse), M.Bouzekrini (Algérie), U.Gaspard (Belgique), B.Guifo-Tagné (Cameroun), D.Hinh (Vietnam), N.Ogowet-Igumu (Gabon), C.Welffens-Ekra (Côte d'Ivoire), M.Yacoubi (Maroc).

15:30 - 16:00 **Break and poster viewing**

Amazon **Sponsored Lecture Laboratoire HRA Pharma**

• SP2-1 Ellaone® Ulipristal Acetate, the new reference for emergency contraception - Higher efficacy and increased time window for use: clinical evidence
A. Brown (UK)

16:00 - 16:30 **WFT** **Keynote Lecture 1**
Chair: D. Lazaris (Greece) - K. Petersen (Denmark)

• IS-31 Culture, Communication, Contraception
R. van Lunsen (the Netherlands)

16:30 - 18:00 **WFT** **Congress Session 3**
Prevention: beyond the 'double Dutch'
Chair: M. Lech (Poland) - D. Apter (Finland)

16:30 • IS-32 Policies for the prevention of unintended pregnancies in Europe
M. Larsson (Sweden)
16:50 • IS-33 Combined prevention of unintended pregnancy and STI
G. Lazdane (WHO)

17:10 • IS-34 What about boys?
M. Ekstrand (Sweden)
17:30 • IS-35 How to deal with sexual coercion and violence?
B. Schei (Norway)
17:50 • FC-10 Risk factors for men to become involved in repeated abortions
M. Makenzius (Sweden)

Atlantic **Forum 1**

• IS-36 Contraceptive use : perspective from Europe
K. Sedlecky (Serbia) - T. Bombas (Portugal)

Amazon **Free Communication Session 2**
Chair: B. Stray-Pedersen (Norway) - G. Freundl (Germany)

16:30 • FC-11 Early use effects on the risk of venous thromboembolism after initiation of oral contraceptive use
J. Dinger (Germany)
16:43 • FC-12 Sexuality and sexual behavior of Lithuanian post-menopausal women
B. Zilaitiene (Lithuania)
16:56 • FC-13 Intrauterine devices and the risk of uterine perforations: Interim results from the EURAS-IUD study
K. Heinemann (Germany)
17:09 • FC-14 Sexual and reproductive health behaviors in the United States: New data from the National Survey of Family Growth
L. Finer (USA)
17:22 • FC-15 Mother knows best? A survey on contraception use and attitudes among mothers and their daughters
D. Seidman (Israel)
17:35 • FC-16 Breast cancer risk associated with the use of levonorgestrel-containing intrauterine devices compared to copper intrauterine devices
J. Dinger (Germany)
17:43 • FC-17 Persistent use of withdrawal in Turkey: 1978-2008
I. Koc (Turkey)

Yangtze **Free Communication Session 3**
Chair: A. Stolfa Gruntar (Slovenia) - A. Ber (Israel)
16:30 • FC-18 HPV diagnosis: is there an impact on women's sexual and mental health?
N. Salakos (Greece)
16:43 • FC-19 Reducing serious infection following medical abortion
J. Trussell (USA)
16:56 • FC-20 On the sword and the sheath. Blood loss and pain at first coitus in women from different cultural backgrounds.
O. Loeber (the Netherlands)
17:09 • FC-21 An oral contraceptive comprising estradiol valerate/dienogest is effective in the treatment of heavy and/or prolonged menstrual bleeding: a pooled analysis
I. Fraser (Australia)
17:22 • FC-22 'Repeat Abortion' - defining the problem and addressing the issue
A. Furedi (UK)
17:35 • FC-23 Can the bleeding pattern during consecutive use of the LNG-IUS be predicted?
K. Gemzell-Danielsson (Sweden)
17:48 • FC-24 Complications in the removal of subdermal contraceptive implants for seven years. Migration of the implants
J.F. Garrido (Spain)

Mississippi **Society Session 5** : Association of Reproductive Health Professionals (ARHP)

16:30 • SS5-1 Emergency contraception
P. Rodriguez (USA)
17:15 • SS5-2 The impact of environmental contaminants on reproductive health
P. Rodriguez (USA)

Everest — **Society Session 6** :
Italian Society of Contraception (SIC)
Chair: C. Nappi (Italy), G. Scarselli (Italy)

16:30 • SS6-1 Hormonal Contraception in premenopausal women
A. Cagnacci (Italy)
16:50 • SS6-2 LNG-IUS based therapy: when and how to use it
C. Di Carlo (Italy)
17:10 • SS6-3 Individualization of hormonal contraception
M.C. Musacchio - A. Di Sabatino (Italy)
17:30 • SS6-4 Use of hormonal contraception as therapeutic and to prevent disease
A. Tirelli (Italy)

Friday, May 21

08:30 -10:00 **WFT** — **Plenary Session 2 : Evidence based sexual and reproductive health care**
Chair: P. G. Crosignani (Italy) - R. Beerthuizen (the Netherlands)

08:30 • IS-37 Building research into clinical practice
M. Kishen (UK)
09:00 Guidelines in family planning
J. Bitzer (Switzerland)
09:30 • IS-39 Critical appraisal of contraceptive research
I. Sivin (USA)

10:00 - 10:30 **Break and poster viewing**

10:30 - 12:00 **WFT** — **Sponsored Symposium Bayer Schering Pharma**
Benefits and risks of oral contraception: responsible prescribing and counselling
Chair: S. Shapiro (South Africa) -
M. Cronin (Germany)

10:30 Introduction
S. Shapiro (South Africa)
10:40 Overview of the benefits and risks of oral contraceptive use
A. Szarewski (UK)
11:00 Cardiovascular side effects of OC use
J. Dinger (Germany)
11:25 Responsible OC prescribing
D. Mansour (UK)
11:45 Q&A session
11:55 Summary
S. Shapiro (South Africa) - M. Cronin (Germany)

Atlantic — **Congress Session 4**
Culture, religion, reproduction and sexuality
Chair: O. Loeber (the Netherlands) - D. Seidman (Israel)

10:30 • IS-40 Religion and sexuality
W. Gianotten (the Netherlands)
10:50 Power, politics and contraception
D. Patel (UK)

11:10 • IS-42 How to explain the differences in contraceptive use in Europe
J. Bitzer (Switzerland)
11:30 Ethics and sexual rights
C. Coll (Spain)
11:50 • FC-25 Exploring the linkages between Gender Based Violence (GBV) and spread of HIV/Sexually Transmitted Infection (STI) among women in Bangalore city, India
G.K. Dayaprasad (India)

Amazon **Free Communication Session 4 - Young scientist session**
Chair : S. Randall (UK) - H. Satiroglu (Turkey)

10:30 • FC-26 Hormonal contraception and female sexual desire: a randomized within-subject crossover study with a low-dose combined oral contraceptive, a progestin-only-pill, and the vaginal ring
E. Elaut (Belgium)
10:43 • FC-27 Knowledge of HPV and attitudes to HPV vaccination among Swedish high school students
M. Gottvall (Sweden)
10:56 • FC-28 Gender based violence (GBV) - an important factor influencing high risk sexual behavior among transgenders in Bangalore city, India
G.K. Dayaprasad (India)
11:09 • FC-29 In vitro spermicidal activity of peptides from amphibian skin: dermaseptin S4 and derivatives
A. Zairi (Tunisia)
11:21 • FC-30 Unexpected large perinatal health inequalities in an urban, multi-ethnic population in the Netherlands
J. Poeran (the Netherlands)
11:34 • FC-31 Emergency Contraception (EC): how it works in Ukraine
A. Yermachnko (Ukraine)
11:47 • FC-32 Paradoxical messages on sexuality - reflections on the impact of pornography on young people among personnel at schools and youth clinics
M. Mattebo (Sweden)

Yangtze **Forum 2**
Contraception and bone: should we worry?
P. Bouchard (France) - K. Schaudig (Germany) - P. Rodriguez (USA)

Mississippi **Society Session 7** :
Spanish Society of Contraception (SEC)
Session will be held in Spanish

Chair: E. de la Viuda García (Spain)

10:30 • SS7-1 The influence of the beginning of sexual relations and of contraception in the Spanish women's life
JV. González Navarro (Spain)
10:52 • SS7-2 The influence of mass media in the diffusion of the contraceptive methods
I. Lete Lasa (Spain)
11:14 • SS7-3 Updating tromboembolism and its relationship with combined hormonal contraceptives
F. Martinez San Andrés (Spain)
11:36 • SS7-4 Contraception and quality of life
E. Pérez Campos (Spain)

12:00 - 12:15 **WFT** • IS-45 **ESC Medal Lecture**
J. Lippes (USA)

12:15 - 13:30 **Lunch and poster viewing**

ESC Expert Groups including lunch (12:25 - 13:25)

Atlantic **1. Expert Group on Sexual and reproductive health and education**

• IS-46 **Forum: Standards of sexual education across Europe**
Moderators: O. Loeber (the Netherlands) - S. Reuter (UK)

Topics (among others): when to start sexuality education, who should provide this, what should the contents be, what is the role of policy makers, does it make a difference in what country one operates?

Participants, interested in providing sexuality education and policy makers are invited to join this discussion.

Amazon

2. Expert Group on STI
Contraception & STIs in women over 40

This group will review a topic that is often overlooked. These women may have missed out on sex education but put themselves at risk of unwanted pregnancies and sexually acquired infections.

• IS-47 Epidemiology
B. Frey Tirri (Switzerland)

• IS-48 STI prevention
P. Horner (UK)

• IS-49 Contraceptive options
P.A. Mardh (Sweden)

Yangtze

3. Expert Group on Abortion

Workshop: Remaining barriers to safe abortion and possible solutions
Chair: E. Aubény (France)

• IS-50 12:25 Problems-remaining barriers
C. Fiala (Austria)
12:40 Advances in recent years
K. Guthrie (UK)

• IS-52 12:55 Possible solutions
K. Gemzell-Danielsson (Sweden)
13:05 Discussion

Aims: *to explore existing barriers in Europe to quality abortion care and review possible solutions*
Objectives: *to provide participants with information which may positively influence their practice at home and to identify issues which could lead to national/international clinical/ scientific collaboration to improve evidence based high quality abortion care.*
What can participants expect? *Sharing international knowledge of good and poor practice with opportunities to learn something positive to take home to improve local abortion care.*

Mississippi

4. Expert Group on Hormonal contraception

Male fertility control - where are we?
Chair : D. Serfaty (France) - J.-J. Amy (Belgium)

12:30 • IS-53 Why do we need male contraceptive methods?
K. Vogelsong (WHO)

12:45 • IS-54 Hormonal Contraceptive methods for men today and tomorrow
E. Nieschlag (Germany)

13:00 • IS-55 Future technologies for male contraception
R. Sitruk-Ware (Population Council)

13:15 Discussion
S. Skouby (Denmark)

Everest

5. Expert Group on Non-hormonal methods of contraception

• IS-56

Workshop: What are the minimum standards of care that a healthcare professional (HCP) (in sexual health) in primary/community settings should provide?
Chair : I. Batar (Hungary) - P. Weiss (Czech Republic)

Please register in advance at the registration desk (max 30 p.)

Moderators: S. Jones (Practicing nurse, UK), J. Alder (Psychosexual counsellor, Switzerland), C. McNicholas (GP, Ireland), R. Beerthuizen (Gynecologist, the Netherlands)

Learning objectives:
by the end of the workshop the participants will:
* understand and be able to provide basic advice and information on all non hormonal methods;
* recognise which methods the HCP can provide in his/her practice. This would be dependant on what training the HCP has had or what training the HCP may need, what facilities are present, what the local arrangements are;
* when and/or for what methods the HCP should refer the client to a specialist

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Kilimanjaro

Nurses/midwives/paramedicals special interest group meeting
Chair: S. Mehigan (UK)

The ESC would like to invite all nurses/midwives/paramedics to this meeting to discuss their role within the ESC. This meeting will be in English.

The ESC has always included non doctors as members, recognising the multidisciplinary focus of work within sexual health. To date, this group is not represented on the Board or in any of the Expert Groups.

So, how can we best raise the profile of nurses/midwives/ paramedics?
Should there be a separate group or more encouragement to be involved within the current committees and groups?
Why would we want a separate group?
What would we call it?
What would be its role?
Who could be members?
What is the role of nurses/midwives/paramedics in different countries?

13:30 - 14:00 **WFT** **Keynote Lecture 2**
Chair: M. Tarasova (Russia) - K. Sedlecky (Serbia)

• IS-57 A tribute to Margaret Sanger
J.-J. Amy (Belgium)

14:00 - 15:30 **WFT** **Sponsored Symposium MSD**
Making informed CHOICES in contraception: the role and importance of counseling
Chair: J.M. Foidart (Belgium)

14:00 Contraception for the individual woman
J.M. Foidart (Belgium)
14:10 Contraceptive use and the importance of contraceptive counseling
D. Mansour (UK)
14:35 Studies of post-counseling contraceptive use
F. Palma (Portugal)
14:55 Preliminary results from the CHOICE data
A. Yeshaya (Israel)

Atlantic **Congress Session 5**
To bleed or not to bleed; tailor made bleeding patterns in contraception
Chair: A. Glasier (UK) - I. Batar (Hungary)

14:00 • IS-58 What women want
H. Critchley (UK)
14:20 How to manage bleeding problems during contraceptive use?
D. Serfaty (France)
14:40 • IS-60 Contraceptives for menstrual disorders
R. Hurskainen (Finland)
15:00 • IS-61 Changing the 21/7 paradigm in contraceptive regimen
A. van Heusden (the Netherlands)
15:20 • FC-33 Contraceptive health education research program in women considering combined hormonal contraception: CHOICE (Contraceptive Health Research of Informed Choice Experience) results from the Ukraine
V. Kaminsky (Ukraine)

Amazon **Best Poster Session**
14:00 - 14:30 Chair : S. Randall (UK) - N. Salakos (Greece)

Amazon **Sponsored symposium Pantarhei Bioscience**
14:30-15:30 **Androgens and the Pill**
Chair: B. Fauser (the Netherlands) -
H. Coelingh Bennink (the Netherlands)

14:30 Endocrine effects of the pill on androgen metabolism
Y. Zimmerman (the Netherlands)
14:50 Effect of the pill on sexual function
E. Laan (the Netherlands)
15:10 Clinical effects of adding DHEA to the pill
F. Roumen (the Netherlands)

Yangtze **Society Session 8 :** Rutgers Nisso Group, STI AIDS Netherlands, and the Dutch Foundation for Contraception
Communication about sexuality and contraception in a multicultural context
Chair: C. Wijsen *(the Netherlands)* -
P. Scholten *(the Netherlands)*

14:00 • SS8-1 Secrecy vs communication and risk vs trust in the use of vaginal microbicides in Africa
R. Pool (Spain)
14:30 • SS8-2 Communication between partners about sexuality and contraception
M. De Neef (the Netherlands)
15:00 • SS8-3 Reproduction and STI/HIV prevention strategies of migrant Women in the Netherlands
I. Shiripinda (the Netherlands)

Mississippi **Society Session 9 :**
Swiss Society of Contraception
Special considerations in contraception
Chair: G. Merki-Feld (Switzerland) –
J. Bitzer (Switzerland)

14:00 • SS9-1 Combined hormonal contraception - its significance relative to other treatment options for women with premenstrual symptoms?
S. Tschudin (Switzerland)

14:30 • SS9-2 Less increase in bone density in young users of contraceptive pills – myth or truth ?
G. Merki-Feld (Switzerland)

15:00 • SS9-3 Progestagen-only contraception - an alternative to combined pill preparations in women with increased risk for venous and arterial thrombosis?
K. Schaudig (Germany)

15:30 - 16:00 **WFT** **Keynote Lecture 3**
Chair: D. Cibula (Czech Rep.) -
K. Gemzell-Danielsson (Sweden)

• IS-62 Contraception and sexuality: a review
J. Bancroft (USA)

16:00 - 16:30 **Break and poster viewing**

16:30 - 18:30 **Atlantic** **ESC General Assembly (members only)**

20:00 **Congress Dinner (optional)**

Saturday, May 22

08:30 -10:00 **WFT** **Plenary Session 3**
Education and training for family planning professionals
Chair: S. Mann (UK) - F. Roumen (the Netherlands)

08:30 The ESC course
M. Lech (Poland)

08:52 Top five cited papers (in the EJCRHC) and how to put them into clinical practice
J.-J. Amy (Belgium)

09:14 • IS-65 A new curriculum for specialists in SRH
A. Gebbie (UK)

09:36 • IS-66 E-learning in SRH
C. Wilkinson (UK)

10:00 - 10:30 **Break**

10:30 - 12:00 **WFT** **Congress Session 6**
Contraception and gynaecological disease
Chair: I. Lete (Spain) - I. Blidaru (Romania)

10:30 Hormonal contraception and endometriosis
G. Dunselman (the Netherlands)

10:50 Contraception for women with uterine myomas
H.J. Ahrendt (Germany)

11:10 • IS-69 PCO, metabolic syndrome and contraception
S. Skouby (Denmark)

11:30 Contraception after cancer
D. Cibula (Czech Rep.)

11:50 • FC-34 Uterine volume and menstrual patterns in users of LNG-IUS intrauterine system with idiopathic menorrhagia or menorrhagia due to leiomyomas. A cohort prospective study of 8 years.
J. Magalhaes (Brazil)

12:00 - 12:45 **WFT** **Closing Session and Award Ceremony**

Cultural programme

Congress Highlights
J. Bitzer (Switzerland)
R. van Lunsen (the Netherlands)
R. Beerthuizen (the Netherlands)

The Hague Declaration
J. Bitzer (Switzerland)

ESC Diploma Ceremony - E. Aubény (France)
Introduction, A. Webb (UK)

Young Scientist Award
Best Poster Awards
Public Poster Award
Ballot Public Poster Award (random draw)
Best Free Communication Award
Introduction, D. Apter (Finland)

A tribute to Aletta Jacobs
S. Wieringa, director "Aletta, Institute for women's history"

Invitation 12th ESC Congress, Athens, Greece
D. Lazaris (Greece)

Special Dutch gift

Exhibit and sponsors

The exhibition area is situated on the first floor: Lobby and Amazon Foyer.

Coffee breaks will be served in the exhibition area. Delegates are encouraged to visit the exhibition stands and to recognise the valuable financial support which these companies have provided towards the congress.

Opening hours exhibit:

- Wednesday, May 19 18:00 - 21:00
- Thursday, May 20 08:30 - 18:00
- Friday, May 21 08:30 - 16:30
- Saturday, May 22 08:30 - 12:30

Major sponsors:

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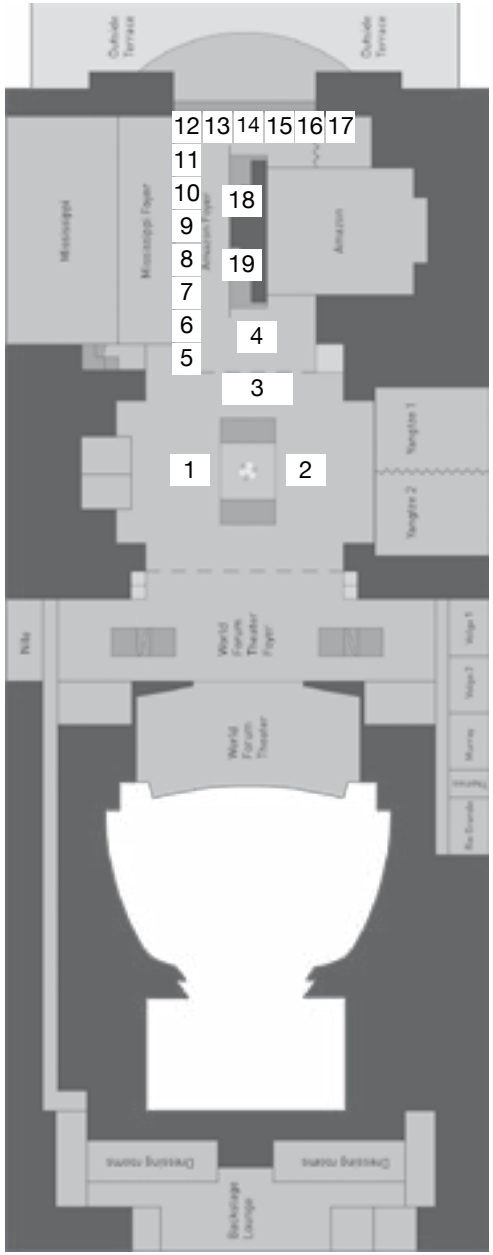
Wisepress Online Bookshop

Exhibit plan

1st Floor



1. MSD
2. Bayer Schering Pharma
3. 12th ESC Congress, 2012, Athens
   Bids ESC Congress 2014
4. HRA Pharma
5. Gedeon Richter
6. Time Research Limited
7. Nordic Pharma
8. Informa Healthcare
9. Kessel
10. Prosan
11. Wisepress Online Bookshop
12. FSRH (Faculty of Sexual and
    Reproductive Healthcare)
13. IPPF (International Planned
    Parenthood Federation)
    YSafe (Youth Sexual Awareness
    for Europe)
14. WHO (World Health Organization)
15. UNFPA (United Nations
    Population Fund)
16. ARHP (Assiociation of Reproductive
    Health Professionals)
17. RHM (Reproductive Health Matters)
18. Bloemhovekliniek
19. Eurim-Pharm

QLAIRA®

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT Qlaira®, film-coated tablets **2. QUALITATIVE AND QUANTITATIVE COMPOSITION** each wallet (28 film-coated tablets) contains in the following order: 2 dark yellow tablets each containing 3 mg estradiol valerate 5 medium red tablets each containing 2 mg estradiol valerate and 2 mg dienogest 17 light yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest 2 dark red tablets each containing 1 mg estradiol valerate 2 white tablets do not contain active substances. Excipient: lactose (not more than 50 mg per tablet). For a full list of excipients, see section 6.1. **3. PHARMACEUTICAL FORM** Film-coated tablet (tablet).Dark yellow film-coated tablet, round with biconvex faces, one side is embossed with the letters "DD" in a regular hexagon. Medium red film-coated tablet, round with biconvex faces, one side is embossed with the letters "DJ" in a regular hexagon. Light yellow film-coated tablet, round with biconvex faces, one side is embossed with the letters "DH" in a regular hexagon. Dark red film-coated tablet, round with biconvex faces, one side is embossed with the letters "DN" in a regular hexagon. White film-coated tablet, round with biconvex faces, one side is embossed with the letters "DT" in a regular hexagon. **4. CLINICAL PARTICULARS 4.1 THERAPEUTIC INDICATIONS** Oral contraception. **4.2 POSOLOGY AND METHOD OF ADMINISTRATION How to take Qlaira®** Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. Tablet taking is continuous. One tablet is to be taken daily for 28 consecutive days. Each subsequent pack is started the day after the last tablet of the previous wallet. Withdrawal bleeding usually starts during the intake of the last tablets of a wallet and may not have finished before the next wallet is started. In some women, the bleeding starts after the first tablets of the new wallet are taken. **How to start Qlaira®** No preceding hormonal contraceptive use (in the past month): Tablet-taking has to start on day 1 of the woman's natural cycle (i.e. the first day of her menstrual bleeding). Changing from a combined hormonal contraceptive (combined oral contraceptive /COC), vaginal ring, or transdermal patch: The woman should start with Qlaira® on the day after the last active tablet (the last tablet containing the active substances) of her previous COC. In case a vaginal ring or transdermal patch has been used, the woman should start using Qlaira® on the day of removal. Changing from a progestogen-only method (progestogen-only pill, injection, implant) or from a progestogen-releasing intrauterine system (IUS): The woman may switch any day from the progestogen-only pill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), but should in all of these cases be advised to additionally use a barrier method for the first ***9 days*** of tablet-taking. Following first-trimester abortion: The woman may start immediately. When doing so, she needs not take additional contraceptive measures. Following delivery or second-trimester abortion: For breastfeeding women see section 4.6. Women should be advised to start at day 21 to 28 after delivery or second-trimester abortion. When starting later, the woman should be advised to additionally use a barrier method for the first ***9 days*** of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of COC use or the woman has to wait for her first menstrual period. **Management of missed tablets** Missed (white) placebo tablets can be disregarded. However, they should be discarded to avoid unintentionally prolonging the interval between active-tablet taking. The following advice only refers to missed active tablets: If the woman is ***less than 12 hours*** late in taking any tablet, contraceptive protection is not reduced. The woman should take the tablet as soon as she remembers and should take further tablets at the usual time. If she is ***more than 12 hours*** late in taking any tablet, contraceptive protection may be reduced. The woman should take the last missed tablet as soon as she remembers, ***even if this means taking two tablets at the same time.*** She then continues to take tablets at her usual time. Depending on the day of the cycle on which the tablet has been missed (see chart below for details), ***back-up contraceptive measures*** (e.g. a barrier method such as a condom) have to be used according to the following principles:

Day	Color Content of estradiol valerate (EV)/ dienogest (DNG)	Principles to follow if missing one tablet for more than 12 hours:
1 – 2	Dark yellow tablets (3.0 mg EV)	• Take missed tablet immediately and the following tablet as usual (even if this means taking two tablets on the same day) • Continue with tablet-taking in the normal way • Use back-up contraception for the next 9 days
3 – 7	Medium red tablets (2.0 mg EV + 2.0 mg DNG)	
8 – 17	Light yellow tablets (2.0 mg EV + 3.0 mg DNG)	
18 – 24	Light yellow tablets (2.0 mg EV + 3.0 mg DNG)	• Discard current wallet, and start immediately with the first pill of a new wallet • Continue with tablet-taking in the normal way • Back-up contraception for the next 9 days
25 – 26	Dark red tablets (1.0 mg EV)	• Take missed tablet immediately and the following tablet as usual (even if this means taking two tablets on the same day) • No back-up contraception necessary
27 – 28	White tablets (Placebos)	• Discard missed tablet and continue tablet-taking in the normal way • No back-up contraception necessary

Not more than two tablets are to be taken on a given day. If a woman has forgotten to start a new wallet, or if she has missed one or more tablets during days 3–9 of the wallet, she may already be pregnant (provided she has had intercourse in the 7 days before the oversight). The more tablets (of those with the two combined active ingredients on days 3–24) that are missed and the closer they are to the placebo tablet phase, the higher the risk of a pregnancy. If the woman missed tablets and subsequently has no withdrawal bleed at the end of the wallet /beginning of new wallet, the possibility of a pregnancy should be considered. **Paediatric population** No data available for use in adolescents below 18 years. **Advice in case of gastro-intestinal disturbances** In case of severe gastro-intestinal disturbances (e.g., vomiting or diarrhoea), absorption may not be complete and additional contraceptive measures should be taken. If vomiting occurs within 3-4 hours after active tablet-taking, the next tablet should be taken as soon as possible. This tablet should be taken within 12 hours of the usual time of tablet-taking, if possible. If more than 12 hours elapse, the advice concerning missed tablets, as given in section 4.2 "Management of missed tablets", is applicable. If the woman does not want to change her normal tablet-taking schedule, she has to take the corresponding tablet(s) needed from another pack. **4.3 CONTRAINDICATIONS** Combined oral contraceptives (COCs) should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during COC use, the product should be stopped immediately. Venous thrombosis present or history (deep venous thrombosis, pulmonary embolism). Arterial thrombosis present or in history (e.g. myocardial infarction) or prodromal conditions (e.g. angina pectoris und transient ischaemic attack). Cerebrovascular accident present or in history. Presence of severe or multiple risk factor(s) for venous (see 4.4) or arterial thrombosis such as: diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinemia, Hereditary or acquired predisposition for venous or arterial thrombosis, such as APC-resistance, antithrombin-III-deficiency, protein C deficiency, protein S deficiency, hyperhomocysteinemia and antiphospholipid-antibodies (anticardiolipin-antibodies, lupus anticoagulant). Pancreatitis or a history thereof if associated with severe hypertriglyceridemia. Presence or history of severe hepatic disease as long as liver function values have not returned to normal. Presence or history of liver tumours (benign or malignant). Known or suspected sex-steroid influenced malignancies (e.g. of the genital organs or the breasts). Undiagnosed vaginal bleeding. History of migraine with focal neurological symptoms. Hypersensitivity to the active substances or to any of the excipients. **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE Warnings** If any of the conditions/risk factors mentioned below are present, the benefits of COC use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start taking it. In the event of aggravation, exacerbation or first appearance of any of these conditions or risk factors, the woman should contact her physician. The physician should then decide whether COC use should be discontinued. No epidemiological studies on the effects of estradiol/ estradiol valerate containing COC's exist. All the following warnings and precautions are derived from clinical and epidemiological data of ***ethinyl estradiol*** containing COCs. Whether these warning and precautions apply to Qlaira® is unknown. Circulatory Disorders: Epidemiological studies have shown that the incidence of VTE in users of oral contraceptives with low oestrogen content (<50 µg ethinylestradiol) ranges from about 20 to 40 cases per 100,000 woman-years, but this risk estimate varies according to the progestogen. This compares with 5 to 10 cases per 100,000 woman-years for non-users. The use of any combined oral contraceptive (including Qlaira®) carries an increased risk of venous thromboembolism (VTE) compared with no use. The excess risk of VTE is highest during the first year a woman ever uses a combined oral contraceptive. The incidence of VTE associated with pregnancy is estimated as 60 cases per 100,000 pregnancies. VTE is fatal in 1-2% of cases. The risk of VTE during use of Qlaira® is currently unknown. Epidemiological studies have also associated the use of ethinylestradiol containing COCs with an increased risk for arterial (myocardial infarction, transient ischaemic attack) thromboembolism. Extremely rarely, thrombosis has been reported to occur in other blood vessels, e.g. hepatic, mesenteric, renal, cerebral or retinal veins and arteries, in COC users. There is no consensus as to whether the occurrence of these events is associated with the use of COCs. Symptoms of venous or arterial thrombotic/thromboembolic events or of a cerebrovascular accident can include: unilateral leg pain and/ or swelling; sudden severe pain in the chest, whether or not it radiates to the left arm; sudden breathlessness; sudden onset of coughing; any unusual, severe, prolonged headache; sudden partial or complete loss of vision; diplopia; slurred speech or aphasia; vertigo; collapse with or without focal seizure; weakness or very marked numbness suddenly affecting one side or one part of the body; motor disturbances; "acute" abdomen. The risk for venous thromboembolic events in COCs users increases with: increasing age, a positive family history (venous thromboembolism ever in a sibling or parent at relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any COC use. prolonged immobilisation, major surgery, any surgery to the legs, or major trauma. In these situations it is advisable to discontinue the pill (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Antithrombotic treatment should be considered if the pills have not been discontinued in advance. obesity (body mass index over 30 kg/ m^2). There is no consensus about the possible role of varicose veins and superficial thrombophlebitis in the onset or progression of venous thrombosis. The risk of arterial thromboembolic events or of a cerebrovascular accident increases with: increasing age; smoking (women over 35 years should be strongly advised not to smoke if they wish to use an COC); a positive family history (arterial thromboembolism ever in a sibling or parent at a relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any COC use; obesity (body mass index over 30 kg/m^2); dyslipoproteinaemia; hypertension; migraine; valvular heart disease; atrial fibrillation; The presence of one serious risk factor or multiple risk factors for venous or arterial disease, respectively, can also constitute a contra-indication.

The possibility of anticoagulant therapy should also be taken into account. COC users should be specifically pointed out to contact their physician in case of possible symptoms of thrombosis. In case of suspected or confirmed thrombosis, COC use should be discontinued. Adequate alternative contraception should be initiated because of the teratogenicity of anticoagulant therapy (coumarins). The increased risk of venous thromboembolism in the puerperium must be considered (for information on "Pregnancy and Lactation" see section 4.6). Other medical conditions which have been associated with adverse circulatory events include diabetes mellitus, systemic lupus erythematosus, hemolytic uremic syndrome, chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis) and sickle cell disease. An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC. Tumours: An increased risk of cervical cancer in long-term users of COCs (> 5 years) has been reported in some epidemiological studies, but there continues to be controversy about the extent to which this finding is attributable to the confounding effects of sexual behaviour and other factors such as human papilloma virus (HPV). A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women who are currently using COCs. The excess risk gradually disappears during the course of the 10 years after cessation of COC use. Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent COC users is small in relation to the overall risk of breast cancer. These studies do not provide evidence for causation. The observed pattern of increased risk may be due to an earlier diagnosis of breast cancer in COC users, the biological effects of COCs or a combination of both. The breast cancers diagnosed in ever-users tend to be less advanced clinically than the cancers diagnosed in never-users. In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of COCs. In isolated cases, these tumours have led to life-threatening intra-abdominal hemorrhages. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal hemorrhage occur in women taking COCs. Other conditions: Women with hypertriglyceridaemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs. Although small increase s in blood pressure have been reported in many women taking COCs, clinically relevant increases are rare. However, if a sustained clinically significant hypertension develops during the use of a COC then it is prudent for the physician to withdraw the COC and treat the hypertension. Where considered appropriate, COC use may be resumed if normotensive values can be achieved with antihypertensive therapy. The following conditions have been reported to occur or deteriorate with both pregnancy and COC use, but the evidence of an association with COC use is inconclusive: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria;systemic lupus erythematosus; hemolytic uremic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss. In women with hereditary angioedema exogenous estrogens may induce or exacerbate symptoms of angioedema. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal. Recurrence of cholestatic jaundice which occurred first during pregnancy or previous use of sex steroids necessitates the discontinuation of COCs. Although COCs may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using low-dose COCs (containing <0.05 mg ethinylestradiol). However, diabetic women should be carefully observed while taking COCs, particularly in the early stage of COC use. Worsening of endogenous depression, of epilepsy, of Crohn's disease and of ulcerative colitis has been reported during COC use. Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking COCs. Estrogens may cause fluid retention, and therefore patients with cardiac or renal dysfunction should be carefully observed. Patients with terminal renal insufficiency should be closely observed, since the level of circulating estrogens may be increased after administration of Qlaira®. This medicinal product contains not more than 50 mg lactose per tablet. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption who are on a lactose-free diet should take this amount into consideration. **Medical examination/consultation** A complete medical history (including family history) and physical examination should be taken prior to the initiation or reinstitution of COC use and pregnancy must be ruled out. Blood pressure should be measured and a physical examination should be performed, guided by the contra-indications (see section 4.3) and warnings (see section 4.4). The woman should also be instructed to carefully read the user booklet and to adhere to the advice given. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman. Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases. **Reduced efficacy** The efficacy of COCs may be reduced for example in the following events: missed active tablets (section 4.2), gastro-intestinal disturbances (section 4.2) during active tablet taking or concomitant medication (section 4.5). **Cycle control** With all COCs, irregular bleeding (spotting or breakthrough bleeding) may occur, especially during the first months of use. Therefore, the evaluation of any irregular bleeding is only meaningful after an adaptation interval of about 3 cycles. Based on patient diaries from a comparative clinical trial, the percentage of women per cycle experiencing intracyclic bleeding was 10 - 18% for women using Qlaira®. Users of Qlaira® may experience amenorrhea although not being pregnant. Based on patient diaries, amenorrhea occurs in approximately 15% of cycles. If Qlaira® has been taken according to the directions described in Section 4.2, it is unlikely that the woman is pregnant. If Qlaira® has not been taken according to these directions prior to the first missed withdrawal bleed or if the withdrawal bleeding is missed in two consecutive cycles, pregnancy must be ruled out before Qlaira® use is continued. If bleeding irregularities persist or occur after previously regular cycles, then non-hormonal causes should be considered and adequate diagnostic measures are indicated to exclude malignancy or pregnancy. These may include curettage. **4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION** Note: The prescribing information of concomitant medications should be consulted to identify potential interactions. Interaction studies have only been performed in adults. **Interactions of other medicinal products on Qlaira®:** Interactions between oral contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. The following interactions have been reported in the literature for COCs in general or were studied in clinical trials with Qlaira®. Dienogest is a substrate of cytochrome P450 (CYP) 3A4. Interactions can occur with phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly oxcarbazepine, topiramate, felbamate, HIV-medications (e.g. ritonavir and/or nevirapine), griseofulvin and the herbal remedy St. John's wort (hypericum perforatum). The mechanism of this interaction appears to be based on the hepatic enzyme-inducing properties (e.g. CYP 3A4 enzymes) of these drugs which can result in increased clearance of sex hormones. Maximal enzyme induction is generally not seen for 2 - 3 weeks but may then be sustained for at least 4 weeks after the cessation of drug therapy. In a clinical study the strong CYP 3A4 inducer rifampicin led to significant decreases in steady state concentrations and systemic exposures of dienogest and estradiol. The AUC (0 - 24h) of dienogest and estradiol at steady state, were decreased by 83% and 44%, respectively. Women on short-term treatment (up to one week) with any of the above-mentioned classes of medicinal products or individual active substances besides rifampicin should temporarily use a barrier method in addition to the COC, i.e. during the time of concomitant medicinal product administration and for 14 days after their discontinuation. For women on rifampicin a barrier method should be used in addition to the COC during the time of rifampicin administration and for 28 days after its discontinuation. In women on chronic treatment with hepatic enzyme-inducing active substances, another reliable, non-hormonal, method of contraception is recommended. Known CYP3A4 enzyme inhibitors like azole antifungals, cimetidine, verapamil, macrolides, diltiazem, antidepressants and grapefruit juice may increase plasma levels of dienogest. In a clinical study investigating the effect of CYP3A4 inhibitors (ketoconazole, erythromycin), steady state dienogest and estradiol plasma levels were increased. Co-administration with the strong CYP3A4 enzyme inhibitor ketoconazole resulted in a 186% and 57% increase of AUC (0 - 24h) at steady state for dienogest and estradiol, respectively. Concomitant administration of the moderate inhibitor erythromycin increased the AUC (0–24h) of dienogest and estradiol at steady state by 62% and 33%, respectively. The clinical relevance of these interactions is unknown. Contraceptive failures have also been reported with antibiotics, such as penicillins and tetracyclines. The mechanism of this effect has not been elucidated. **Interactions of Qlaira® on other medicinal products:** Oral contraceptives may affect the metabolism of certain other active substances. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporin) or decrease (e.g. lamotrigine). Pharmacokinetics of nifedipine were not affected by concomitant administration of 2 mg dienogest + 0.03 mg ethinyl estradiol thus confirming results of in vitro studies indicating that inhibition of CYP enzymes by Qlaira® is unlikely at the therapeutic dose. **Laboratory tests:** The use of contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, plasma levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. Changes generally remain within the normal laboratory range. **4.6 PREGNANCY AND LACTATION** Qlaira® should not be used during pregnancy. If pregnancy occurs during use of Qlaira®, further intake should be stopped. However, extensive epidemiological studies with ethinylestradiol containing COCs have revealed neither an increased risk of birth defects in children born to women who used COCs prior to pregnancy, nor a teratogenic effect when COCs were taken inadvertently during pregnancy. Animal studies do not indicate a risk for reproductive toxicity (see section 5.3). Lactation may be influenced by COCs as they may reduce the quantity and change the composition of breast milk. Therefore, the use of COCs should generally not be recommended until the nursing mother has completely weaned her child. Small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk. These amounts may affect the child. **4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES** Qlaira® has no influence on the ability to drive or use machines. **4.8 UNDESIRABLE EFFECTS** The table below reports adverse reactions (ARs) by MedDRA system organ classes (MedDRA SOCs). The most appropriate MedDRA term (version 10.0) to describe a certain adverse reaction is listed. Synonyms or related conditions are not listed, but should be taken into account as well. The frequencies are based on clinical trial data. The adverse reactions were recorded in 3 phase III clinical studies (N=2,266 women at risk for pregnancy) and considered at least possibly causally related to Qlaira® use. All ADRs listed in the category ‚rare' occurred in 1 to 2 volunteers resulting in < 0.1%. N= 2,266 women (100.0%). **See table on the next page!** Occurrence of amenorrhea and intracyclic bleeding based on patient diaries is summarized in section 4.4 Cycle control. The following serious adverse events have been reported in women using COCs, which are discussed in section 4.4 Special warning and precautions for use: Venous thromboembolic disorders; Arterial thromboembolic disorders; Hypertension; Liver tumours; Occurrence or deterioration of conditions for which association with COC use is not conclusive: Crohn's disease, ulcerative colitis, epilepsy, migraine, uterine myoma, porphyria, systemic lupus erythematosus, herpes gestationis, Sydenham's chorea, haemolytic uremic syndrome, cholestatic jaundice; Chloasma; Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers

System Organ Class	Common ([3] 1/100 to 1/10)	Uncommon ([3] 1/1,000 to <1/100)	Rare ([3] 1/10,000 to < 1/1,000)
Infections and infestations		Fungal infection, Vaginal candidiasis, Vaginal infection	Candidiasis, Herpes simplex, Presumed ocular histoplasmosis syndrome, Tinea versicolor, Urinary tract infection, Vaginitis bacterial, Vulvovaginal mycotic infection
Metabolism and nutrition disorders		Increased appetite	Fluid retention, Hypertriglyceridaemia
Psychiatric disorders		Depression/Depressed mood Libido decreased, Mental disorder, Mood change	Affect lability, Aggression, Anxiety, Dysphoria, Libido increased, Nervousness, Restlessness, Sleep disorder, Stress
Nervous system disorders	Headache[1]	Dizziness	Disturbance in attention, Paraesthesia, Vertigo
Eye disorders			Contact lens intolerance
Vascular disorders		Hypertension, Migraine[2]	Bleeding varicose vein, Hot flush, Hypotension, Vein pain
Gastrointestinal disorders	Abdominal pain[3]	Diarrhoea, Nausea, Vomiting	Constipation, Dyspepsia, Gastrooesophageal reflux disease,
Hepatobiliary disorders			Alanine aminotransferase increased Focal nodular hyperplasia of the liver
Skin and subcutaneous tissue disorders	Acne	Alopecia, Pruritus[4], Rash[5]	Allergic skin reaction[6], Chloasma, Dermatitis, Hirsutism, Hypertrichosis, Neurodermatitis, Pigmentation disorder, Seborrhoea, Skin disorder[7]
Musculoskeletal and connective tissue disorders			Back pain, Muscle spasms, Sensation of heaviness
Reproductive system and breast disorders	Amenorrhea Breast discomfort[8] Dysmenorrhoea Intracyclic bleeding	Breast enlargement, Breast mass, Cervical dysplasia, Dysfunctional uterine bleeding, Dyspareunia	Benign breast neoplasm, Breast cyst, Coital bleeding, Galactorrhea, Genital hemorrhage
	(Metrorrhagia)[9]	Fibrocystic breast disease, Menorrhagia, Menstrual disorder, Ovarian cyst, Pelvic pain, Premenstrual syndrome, Uterine leiomyoma, Uterine spasm, Vaginal discharge, Vulvovaginal dryness,	Hypomenorrhoea, Menstruation delayed, Ovarian cyst ruptured, Vaginal burning sensation, Uterine/vaginal bleeding incl. spotting, Vaginal odour, Vulvovaginal discomfort
Blood and lymphatic system disorders			Lymphadenopathy
General disorders and administration site conditions		Irritability, Oedema	Chest pain, Fatigue, Malaise
Investigations	Weight increased	Weight decreased	

[1]including tension headache, [2]including migraine with aura and migraine without aura, [3]including abdominal distension, [4]including pruritus generalized and rash pruritic [5]including rash macular, [6]including dermatitis allergic and urticaria, [7]including skin tightness, [8]including breast pain, nipple disorder and nipple pain, [9]including menstruation irregular

of liver function return to normal. In women with hereditary angioedema exogenous estrogens may induce or exacerbate symptoms of angioedema. The frequency of diagnosis of breast cancer is very slightly increased among OC users. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. Causation with COC use is unknown. For further information, see sections 4.3 and 4.4. In addition to the above mentioned adverse reactions, erythema nodosum, erythema multiforme, breast discharge and hypersensitivity have occurred under treatment with ethinylestradiol containing COCs. Although these symptoms were not reported during the clinical studies performed with Qlaira®, the possibility that they also occur under treatment cannot be ruled out. **4.9 OVERDOSE** There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in case of taking an overdose of active tablets are: nausea, vomiting and, in young girls, slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic. **5. PHARMACOLOGICAL PROPERTIES 5.1 PHARMACODYNAMIC PROPERTIES** Pharmacotherapeutic group: progestogens and estrogens, sequential preparations ATC code: G03AB. In clinical trials performed with Qlaira® in the European Union and in the USA/Canada the following Pearl indices were calculated: Pearl Index (18 - 50 years of age), Method failure: 0.42 (upper limit 95% CI 0.77), User + method failure: 0.79 (upper limit 95% CI 1.23), Pearl Index (18 - 35 years of age), Method failure: 0.51 (upper limit 95% CI 0.97), User + method failure: 1.01 (upper limit 95% CI 1.59). The contraceptive effect of COCs is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation, changes in the cervical secretion, and changes in the endometrium. The estrogen in Qlaira® is estradiol valerate, an ester of the natural human 17ß-estradiol (1 mg estradiol valerate corresponds to 0.76 mg 17 ß-estradiol). This estrogendiffers from the estrogens ethinylestradiol or its prodrug mestranol used in other COCs by the lack of an ethinyl group in 17alpha position. Dienogest is a nortestosterone derivative with no androgenic but rather an antiandrogenic activity of approximately one third of that of cyproterone acetate. Dienogest binds to the progesterone receptor of the human uterus with only 10% of the relativeaffinity of progesterone. Despite its low affinity to the progesterone receptor, dienogest has a strong progestogenic effect in vivo. Dienogest has no significant androgenic, mineralocorticoid or glucocorticoid activity in vivo. Endometrial histology was investigated in a subgroup of women (n=218) in one clinical study after 20 cycles of treatment. There were no abnormal results. **5.2 PHARMACOKINETIC PROPERTIES Dienogest** Absorption: Orally administered dienogest is rapidly and almost completely absorbed. Maximal serum concentrations of 90.5 ng/ml are reached at about 1 hour after oral administration of the Qlaira® tablet containing 2 mg estradiol valerate + 3 mg dienogest. Bioavailability is about 91%. The pharmacokinetics of dienogest are dose-proportional within the dose range of 1 - 8 mg. Concomitant food intake has no clinically relevant effect on the rate and extent of dienogest absorption. Distribution: A relatively high fraction of 10% of circulating dienogest is present in the free form, with approx. 90% being bound non-specifically to albumin. Dienogest does not bind to the specific transport proteins SHBG and CBG. The volume of distribution at steady state (Vd,ss) of dienogest is 46 l after the intravenous administration of 85 µg 3H-dienogest. Metabolism: Dienogest is nearly completely metabolized by the known pathways of steroid metabolism (hydroxylation, conjugation), mainly by CYP3A4. The pharmacologically inactive metabolites are excreted rapidly resulting in dienogest as the major fraction in plasma accounting for approximately 50% of circulating dienogest derived compounds. The total clearance following the intravenous administration of 3H-dienogest was calculated as 5.1 l/h. Elimination: The plasma half-life of dienogest is approximately 11 hours. Dienogest is extensively metabolized and only 1% of drug is excreted unchanged. The ratio of urinary to fecal excretion is about 3:1 after oral administration of 0.1 mg/kg. Following oral administration, 42% of the dose is eliminated within the first 24 h and 63% within 6 days by renal excretion. A combined 86% of the dose is excreted by urine and feces after 6 days. Steady-State Conditions: Pharmacokinetics of dienogest are not influenced by SHBG levels. Steady state is reached after 3 days of the same dosage of 3 mg dienogest in combination with 2 mg estradiol valerate. Trough, maximum and average dienogest serum concentrations at steady state are 11.8 ng/ml, 82.9 ng/ml and 33.7 ng/ml, respectively. The mean accumulation ratio for AUC (0 - 24h) was determined to be 1.24. **Estradiol valerate** Absorption: After oral administration estradiol valerate is completely absorbed. Cleavage to estradiol and valeric acid takes place during absorption by the intestinal mucosa or in the course of the first liver passage. This gives rise to estradiol and its metabolites estrone and estriol. Maximal serum estradiol concentrations of 70.6 pg/ml are reached between 1.5 and 12 hours after single ingestion of the tablet containing 3 mg estradiol valerate on Day 1. Metabolism: The valeric acid undergoes very fast metabolism. After oral administration approximately 3% of the dose is directly bioavailable as estradiol. Estradiol undergoes an extensive first-pass effect and a considerable part of the dose administered is already metabolized in the gastrointestinal mucosa. Together with the presystemic metabolism in the liver, about 95% of the orally administered dose

becomes metabolized before entering the systemic circulation. The main metabolites are estrone, estrone sulfate and estrone glucuronide. Distribution: In serum 38% of estradiol is bound to SHBG, 60% to albumin and 2 - 3% circulate in free form. Estradiol can slightly induce the serum concentrations of SHBG in a dose-dependent manner. On day 21 of the treatment cycle, SHBG was approximately 148% of the baseline, it decreased to about 141% of the baseline by day 28 (end of placebo phase). An apparent volume of distribution of approximately 1.2 l/kg was determined after iv. administration. Elimination: The plasma half-life of circulating estradiol is about 90 min. After oral administration,however, the situation differs. Because of the large circulating pool of estrogen sulfates and glucuronides, as well as enterohepatic recirculation, the terminal half-life of estradiol after oral administration represents a composite parameter which is dependent on all of these processes and is in the range of about 13 - 20 h. Estradiol and its metabolites are mainly excreted in urine, with about 10% being excreted in the stool. Steady-state conditions: Pharmacokinetics of estradiol are influenced by SHBG levels. In young women, the measured estradiol plasma levels are a composite of the endogenous estradiol and the estradiol generated from Qlaira®. During the treatment phase of 2 mg estradiol valerate + 3 mg dienogest, maximum and average estradiol serum concentrations at steady state are 66.0 pg/ml and 51.6 pg/ml, respectively. Throughout the 28 day cycle, stable minimum estradiol concentrations were maintained and ranged from 28.7 pg/ml to 64.7 pg/ml. Special Populations: Pharmacokinetics of Qlaira® were not investigated in patients with impaired renal or liver function. **5.3 PRECLINICAL SAFETY DATA** Preclinical data reveal no special risks for humans based on conventional studies of repeated dose toxicity, genotoxicity, and toxicity to reproduction. A carcinogenicity study with dienogest in mice and a more limited study in rats showed no increase in tumours, however, it is well known that due to their hormonal action, sex steroids can promote the growth of certain hormone-dependent tissues and tumours. **6. PHARMACEUTICAL PARTICULARS** 6.1 LIST OF EXCIPIENTS

Active film-coated tablets	Placebo (inactive) film-coated tablet
Tablet core:	
Lactose monohydrate Maize starch Pregelatinized maize starch Povidone K25 (E1201) Magnesium stearate (E572)	Lactose monohydrate Maize starch Povidone K25 (E1201) Magnesium stearate (E572)
Tablet coating	
Hypromellose type 2910 (E464) Macrogol 6000 Talc (E553b) Titanium dioxide (E171) Iron oxide red (E172) and/or Iron oxide yellow (E172)	Hypromellose type 2910 (E464) Talc (E553b) Titanium dioxide (E171)

6.2 INCOMPATIBILITIES Not applicable. **6.3 SHELF LIFE** 5 years. **6.4 SPECIAL PRECAUTIONS FOR STORAGE** This medicinal product does not require any special storage conditions. **6.5 NATURE AND CONTENTS OF CONTAINER** Transparent PVC/Aluminium blister in a cardboard wallet Presentation Pack sizes: 1 x 28 film-coated tablets, 3 x 28 film-coated tablets, 6 x 28 film-coated tablets, each wallet (28 film-coated tablets) contains in the following order: 2 dark yellow tablets and 5 medium red tablets and 17 light yellow tablets and 2 dark red tablets and 2 white tablets. Not all pack sizes may be marketed. **6.6 SPECIAL PRECAUTIONS FOR DISPOSAL** Any unused product or waste material should be disposed of in accordance with local requirements. **7. MARKETING AUTHORISATION HOLDER** <assigned locally> **8. MARKETING AUTHORISATION NUMBER(S)** <assigned locally> **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION** <assigned locally> **10. DATE OF REVISION OF THE TEXT** <assigned locally>

Please note! For current prescribing information refer to the package insert and / or contact your local Bayer Schering Pharma Organisation. Bayer Schering Pharma AG, European Business Unit Women's Healthcare, 13342 Berlin, Germany, www.bayerscheringpharma.de

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Qlaira®: Oral contraception with estradiol valerate and dienogest

Qlaira® is the first pill to deliver estradiol. This is uniquely combined with dienogest, a progestin with endometrial focus.[1-3]

References: 1. Sasagawa S et al., Steroids 2008; 73(2): 222–31, **2.** Oettel et al., Eur J Contracept Reprod Health Care 1999; 4(Suppl. 1): 2–13, **3.** Oettel M et al., Drugs Today 1999; 35(Suppl. C): 3–12.

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