



# ETCO News

## *in this issue ...*

- Information from the ETCO Board
- Calendar of events

## ETCO News

ETCO News is published by the European Transplant Coordinators Organization. The editor welcomes articles and announcements pertaining to organ donation and transplant coordination related matters. Send typed copy and CD-ROM to:

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## *Information from the ETCO Board. What is new...*

### News from the Scientific Committee

In order to establish clear rules for the activities of the Scientific Committee of ETCO, several documents have been drawn up and were unanimously approved by the 6 members who attended the Board Meeting in Amares in February this year.

The first contains the bylaws of the Scientific Committee, the second aims at standardizing the assessment of abstracts sent to ETCO meetings, and the third establishes the requirements for scientific activities to obtain the endorsement of ETCO.

### Bylaws of the Scientific Committee of ETCO

#### **Definition. Scientific Committee of ETCO**

The Scientific Committee of ETCO advises on scientific matters, identifies research priorities and helps in the organization of ETCO meetings and research. The Scientific Committee reports all its activities to the ETCO Board.

The ETCO Board will have the opportunity to review and endorse all the activities of the Scientific Committee.

#### **Composition of the ETCO Scientific Committee**

The Scientific Committee shall consist of a Chairman, a Vice-Chairman and 4 Members. A Secretary shall be elected among the scientific committee Members.

The members shall consist of:

- a - One representative of the ETCO Committees.
- b - One representative of the Scientific Committee of the official ETCO Journal.
- c - Two paid-up members of ETCO.
- d - For specific activities such as the preparation of the ETCO Annual meeting and Congress the Scientific Committee can include up to 3 extra members invited by the ETCO Board.

#### **Members eligible for election to the scientific committee**

1. ETCO members with no payment arrears.
2. Certified European Transplant Coordinators.
3. Members who have proven scientific background in-

cluding publications, years of experience, participation in training activities.

4. Balanced geographical representation of ETCO members' countries of origin.

5. Fluent English.

- Length of tenure of each member of the Scientific Committee will be a maximum of 4 years.
- The Chairman of the Scientific Committee will be nominated by the ETCO Board. The chairman will then propose the remaining members for Board approval.
- The President and Secretary of the Board can participate in the meetings and decisions of the ETCO Scientific Committee.

**Commitments of the ETCO scientific committee**

1. Definition of Scientific Policy, Fields and Activities of ETCO.

2. Coordination with the scientific activities of the Committees.

3. Coordination with the Scientific Committee of the Journal "Organs, Tissues and Cells".

4. Preparation of the scientific program of ETCO Annual Meetings and Congresses in conjunction with the corresponding LOC , to decide:

- Main topics
- Round table topics
- Chairmen, speakers, etc.
- Presentation format
- Courses, workshops, forums or any educational activity to be organized pre, post and during the meeting.

5. Selection of the winners of the Scientific Awards at ETCO Annual Meetings and Congresses.

6. Assessment of abstracts presented to the ETCO Annual Meetings and Congresses. Some relevant scientific members of ETCO can also participate in the assessment.

7. Assessment during and after the meeting of the quality of the activities during ETCO Annual Meetings and Congresses: Round Tables, Presentation of Abstracts (in different formats), Courses, teaching activities, etc.

8. Formulation of regulations for:

- Assessing the quality of abstracts before the annual meeting
- Assessing the quality of abstracts after presentation
- Assessing the quality of Round Tables, Courses, etc. during the Annual Meeting.

9. Promotion of research activities within ETCO

- The Scientific Committee will convene at least once a year.
- The Secretary of the Scientific Committee will be responsible for the agenda and minutes of the Scientific Committee meetings.

**Rules for Abstract Assessment for ETCO Annual Meetings**

1. The Scientific Committee will prepare a list of experts in specialist areas related to donation and transplantation to assess the abstracts of the annual meeting.

2. Each abstract will be independently evaluated by 2 to 3 specialists in the same field of knowledge as the abstracts.

3. Before sending the abstract for assessment, any conflict of interests between the reviewers and the authors will be ruled out.

4. In the case of more than 4 points of discrepancy between the reviewers' scores of an abstract, the scientific committee will reassess it.

5. A letter will be sent to reviewers inviting them to participate before the abstracts are sent. After the assessment has been returned, a letter of acknowledgement will be sent, signed by the president of the Scientific Committee.

**Document for Requesting ETCO Endorsement for Scientific Activities**

ETCO agrees to the possible endorsement of scientific activities such as congresses, consensus conferences and courses previously presented to the ETCO board.

ETCO may endorse events organized by ETCO committees as well as scientific events organized by other entities who apply to ETCO and fulfill the requirements.

The ETCO board may, after previous consultation with the ETCO Scientific Committee, endorse any scientific activity that is considered of interest to ETCO members and other professionals within the field of organ and tissue donation and transplantation.

**1. Request for scientific endorsement**

The president of the organizing committee of the event, on behalf of the organizing committee, will send an official request for endorsement to the ETCO office.

The documentation for this request must fulfill the following requirements:

1. It must be directed to the ETCO president
2. It must reach the ETCO office a minimum of 4 months before the commencement of the scientific event.
3. The request must be accompanied by the draft/definitive scientific program.

4. The request must clearly specify:

- The entity/society organizing the event
- The aims of the scientific event
- The profile of the professionals targeted
- Information regarding previous requests for endorsement from other societies and organizations for this event
- Information regarding previous requests for Educational Credits for this event (to official entities)

**2. Internal procedures in ETCO for the request.**

The ETCO board will send the information to the ETCO scientific Committee chairperson for the project to be assessed. The ETCO secretary will respond to the requesting entity no later than 30 days after receiving the request.

Once the endorsement has been accepted, the scientific program of the event may include "With the endorsement of ETCO" and also the ETCO logo. The ETCO logo can

only accompany the logo of other societies and scientific organizations or non-profit entities.

Once the final program has been edited, a copy must be sent to the ETCO office.

ETCO may assign a member of ETCO to coordinate between ETCO and the Organizing committee.

ETCO expects a reduced registration fee for ETCO members.

### 3. Distribution of information of the Event

ETCO may cooperate by advertising the event:

- through the ETCO web page by including information and links to the event
- through the ETCO Newsletter

Granting scientific endorsement does not oblige ETCO to distribute information regarding the scientific event, subsidize the organizing committee or provide the postal addresses or email contacts of ETCO members.

### 4. Validity of the endorsement.

The scientific endorsement will be valid for the date specified in the request for the activity and remain so for the period of one year.

### New ETCO Executive Officer

I take this opportunity to introduce myself. My name is Jane Lewis, and after presenting my candidature I was interviewed by the President of ETCO and asked to become Executive Officer by the Secretary, starting in April. I am English by birth and family, Australian by upbringing and friends (I have a degree in Psychology and Sociology from the Australian National University) and live in Catalonia in the north east of Spain where I have made my own family and more friends.

I am a medical translator and editor of medical research papers: among other things I am part of a team that translates the monthly Spanish journal "Archivos de Bronconeumologia" and I translate and edit for the Research Institute at Mataró Hospital. My contact with the medical world has increased gradually, first teaching doctors English and training them in verbal presentation of papers, and then little by little translating and correcting their research papers. I have worked with 3 hospitals in Barcelona.

I was working as the English executive officer of the European Association of Chief Executive Officers (Secretaries) of Town Councils while Spain held the presidency and where I did a lot of translating and interpreting for the president. I speak English, Spanish and Catalan and have lived in India, the United States, and Malaysia as well as Australia and Spain. As an Anglo-Saxon living in the Mediterranean I have learned that cultural respect is essential for understanding.

I feel privileged to work for an organization with people from all over the world who work towards improving the quality of people's lives. I find it interesting and exciting to be a link facilitating their communication.

Please bear with any initial mistakes I make while learning how ETCO works and who you all are. I look forward to meeting you in Poland.

### ETCO Congress in Prague 2007

The 15<sup>th</sup> ETCO Biannual Congress will be organized in conjunction with the 13<sup>th</sup> ESOT Congress in Prague, Czech Republic. The Congress will be held from 28 September until 3 October 2007.

For more information see [www.esot2007.cz](http://www.esot2007.cz)

### Latvia – Host of the Next Annual ETCO Meeting in 2008

The 5<sup>th</sup> ETCO Meeting in 2008 is to be held in Latvia. In due course more information will be announced via [www.etco.org](http://www.etco.org)

### ETCO web information

We are continuing to work on the website [www.etco.org](http://www.etco.org). We hope you are finding it a source of useful information – any feedback is welcome on how it can be improved. We would like to see it become a dynamic interface between ETCO members and undertake to check webmail daily. Ideas and suggestions can be sent through the web site or directly to:

Dr. Jose Maria Dominguez-Roldan, MD, PhD, CETC  
ETCO Board member responsible for the website  
e-mail: [jmdominguez@telefonica.net](mailto:jmdominguez@telefonica.net)

### [www.organsandtissues.net](http://www.organsandtissues.net)

*Organs and Tissues* is now available on-line. Current paid-up ETCO members may download full papers free of charge after registering on the web, using a personal code available from ETCO secretariat on request. They must fill in the form to register to download the full paper using a username and pin which is available in 24-48 hours from the *Organs and Tissues* publishers: Editrice Compositori Srl, via Stalingrado 97/2, 40128 Bologna, Italy, phone ++39-051-3540111, fax ++39-051-327877.

By clicking on the ETCO logo on the home page you can access the ETCO News section.

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# Calendar of events

July 15-18, 2006

## **43<sup>rd</sup> ERA-EDTA Congress**

Glasgow

Information: Congress Secretariat, ERA-EDTA Congress Office, via Spolverini 2, 43100 Parma, Italy

Phone: +39-0521-989078, fax: +39-0521-959242

E-mail: congress@era-edta-org, website: www.eraedta2006.org

July 22-27, 2006

## **World Transplant Congress - First Joint Meeting of the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST) and the Transplantation Society**

Hynes Convention Center, Boston, USA

Information: Congress Secretariat, M. Pamela Ballinger, phone: +1 856 642 4439

E-mail: pballinger@ahint.com, website: www.WTC2006.org

August 17-20, 2006

## **16<sup>th</sup> World Congress of the World Society of Cardio-Thoracic Surgeons (WSCTS 2006)**

Ottawa Congress Centre, Ottawa, Ontario, Canada

Information: WSCTS Secretariat Office, University of Ottawa Heart Institute, 40 Ruskin Street, Room H554, Ottawa, Ontario, K1Y 4W7 Canada

Phone: +1 (613)761-5116, fax: +1 (613) 761-4478

E-mail: info@wscts2006.com, website:

<http://www.wscts2006.com>

November 20-24, 2006

## **Advanced International Training Course on Transplant Coordination**

Transplant Procurement Management - TPM Project IL3 - Universitat de Barcelona

c/ Ciutat de Granada 131

08018 Barcelona, Spain

Phone: +34 93 403 76 87, fax: +34 93 403 99 20

E-mail: tpmproject@fbg.ub.es, website: www.tpm.org

September 29-October 3, 2007

## **13<sup>th</sup> ESOT Congress & 15<sup>th</sup> ETCO Congress**

Prague

Information: Congress Secretariat, Guarant International, Opletalova 22, 110 00 Prague 1, Czech Republic

Phone: +420 284001444, fax: +420 284001448

E-mail: esot2007@guarant.cz, website: [www.esot2007.cz](http://www.esot2007.cz)



# EUROPEAN TRANSPLANT COORDINATORS ORGANIZATION

## 2006 ETCO/Membership Application Form

Please send to:

**ETCO Executive**  
Office Carrer Joan Maragall 12, E-08360 Canet de Mar,  
Barcelona, Spain - Fax: +34 937942658

Or ask an application form via  
e-mail: [secretariat@etco.org](mailto:secretariat@etco.org)

**Membership for which I am applying** (cfr. ETCO House Rules):

1 yr membership  
for 2006

2 yr membership  
for 2006 & 2007

Ordinary membership

*Ordinary members are private individuals whose main function in their salaried occupation is to act as a coordinator in the field of organ and tissue transplantation*

– Individual payment

50.- EUR

75.- EUR

– Institutional payment (max. 6 persons)

250.- EUR

375.- EUR

Corresponding membership

*Corresponding members are private individuals whose activities are regarded as useful to ETCO but who do not meet the criteria to be considered as an "Ordinary member"*

*After receiving your information the ETCO Treasurer will decide if your application meets the criteria to become a "Corresponding member"*

Sponsoring membership

*Please inform us if your company is interested to help ETCO with financial support, the ETCO Treasur will contact you*

Name:

First name:

Mr.  Ms.  Mrs.  Dr.  Prof.  Other

Other credentials:  CETC  RN  Other...

Function:

### Work address:

Employer:

Dept./division:

Street/nr.:

Postal code/City:

Country:

E-mail address:

Phone nr.:

Fax nr.:

Website address:

*Unless you click "no", you herewit give permission to include your name and all work coordinats in the membership directory, and you agree that this information may be used for diffusion of material related to transplantation.*

no

*Please contact the Executive Office in case you want to change this preference.*

### Home address:

Street/nr.:

Postal code/City:

Country:

E-mail address:

Phone nr.:

Fax nr.:

Preferred mailing address:  Home

Work

**Application must be accompanied by cheque, money order or credit card information** (tick preference):

by sending a crossed cheque to ETCO Executive Office (see above-mentioned address)  
*(please note that this requires a considerable amount of bank charges)*

by bank-to-bank transfer to: Fortis Bankmaatschappij, Kantoor St. Jacob, B-3000 Leuven, Belgium  
IBAN-code: BE67 2300 0752 4287 BIC-or SWIFT-code: GEBABEBB Fortis Bank  
Account nr.: 230-0075242-87 (Please mention «your name 2006 or 2006 & 2007»)

by charging my VISA/ MASTER / EURO Card with the amount of \_\_\_\_\_ EUR

Card holder: \_\_\_\_\_ Card nr.: \_\_\_\_\_ Exp. date: \_\_\_ / \_\_\_ Signature: \_\_\_\_\_



## EUROPEAN TRANSPLANT COORDINATORS ORGANIZATION

On behalf of the entire membership, ETCO would like to thank several companies:

### MAJOR SPONSORS



Hoffmann-La Roche Basel



Thanks to the generous support of all these companies,  
together with the membership fee of our loyal membership,  
ETCO can further develop as a professional organisation.

With the amount several expenses will be covered: administrative working costs and office support, Board Meetings, Certification Committee, Web Page Committee and other initiatives.

*If your company is prepared to help ETCO once again with financial support, please contact:*

*ETCO Treasurer, Antonio Lopez-Navidad, CETC, MD, PhD, Chief of Department,  
Hospital de la Santa Creu i Sant Pau, Organ & Tissue Procur. for Transpl.,  
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## INSTRUCTIONS TO AUTHORS

### CONTRIBUTIONS AND COPYRIGHTS

Articles in English must be sent to *Francesca Di Palma*, by e-mail to [f.dipalma@compositori.it](mailto:f.dipalma@compositori.it) or by post on CD-ROM to Editrice Compositori, Via Stalingrado 97/2, 40128 Bologna, Italy. Submissions accepted for publication will be edited. Papers must be accompanied by a statement signed by all authors that the material has not been published elsewhere and is not currently being considered for publication elsewhere (abstracts and letters excluded). Copyrights of the article accepted for publication will be transferred to the Publisher. Unpublished papers will not be returned to authors, unless specifically requested on submitting it. Proofs are sent to all authors for correction and must be returned by fax within two days.

### PAPERS

Papers must be sent as files on CD-ROM or as attached files by e-mail. As a rule, manuscripts should not exceed 15 pages. The first page must contain: 1) title of the paper; 2) full names of authors; 3) author affiliations (department or institution where the work was carried out); 4) full postal address (phone, fax and e-mail) of the author who will receive correspondence and prints; 5) max 5 key words for indexing. The second page must contain a short abstract of the paper.

### FIGURES AND TABLES

Figures and tables must be cited in the text and numbered consecutively and separately with Arabic numerals. Authors should provide good quality pictures of all figures and tables in .jpg, .tif, .ppt or .xls formats. A list of captions for the figures and tables must be submitted on a separate sheet with Arabic numerals corresponding to the pictures.

### REFERENCES

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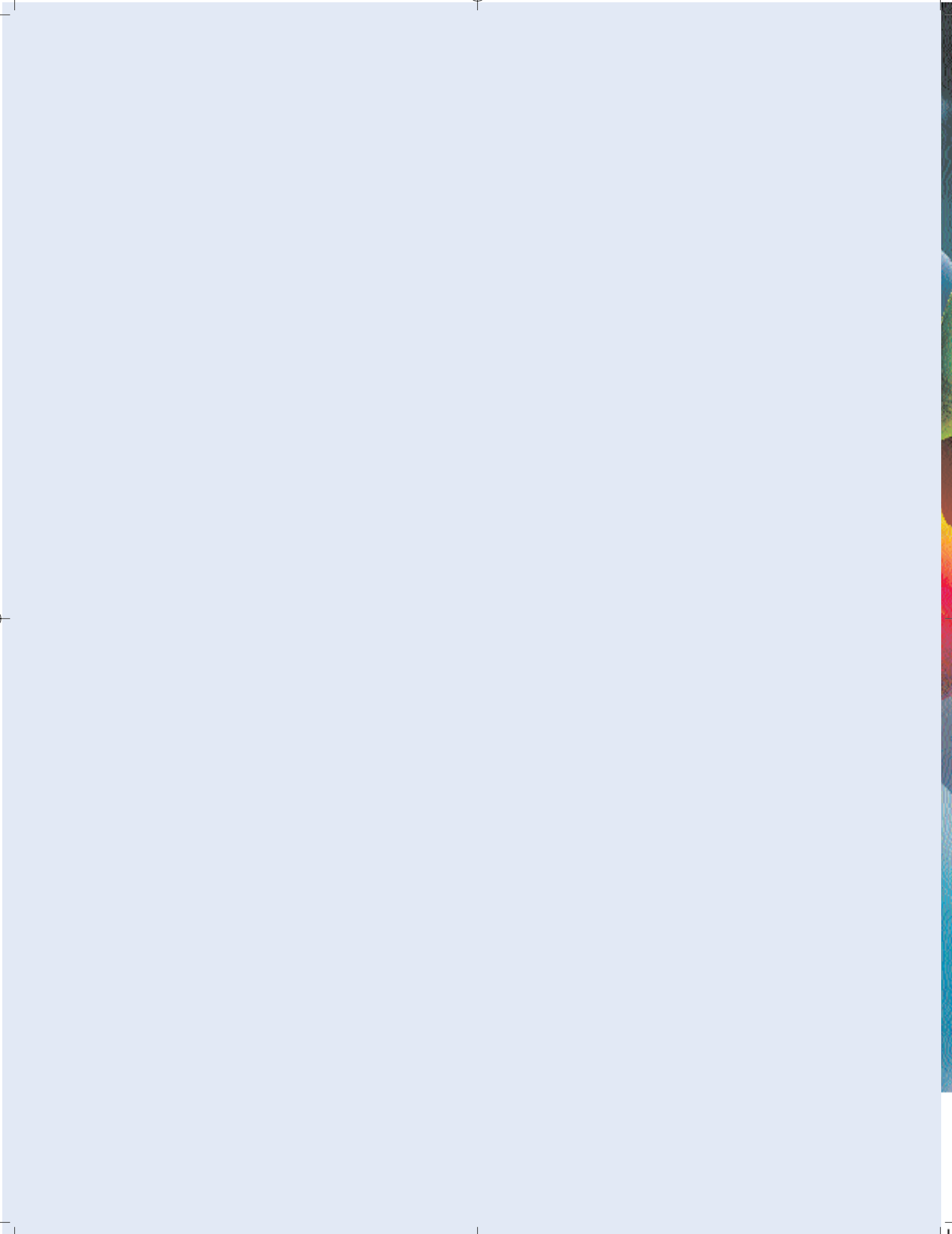
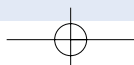
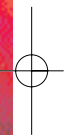
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# think thymo™

Thymoglobuline® is a selective immunosuppressive agent (anti-human T-lymphocytes), whose mechanisms of action include:

- Lymphocyte depletion probably constitutes the primary mechanism of the immunosuppression induced by rabbit anti-human thymocyte immunoglobulin. Thymoglobuline® recognizes most of the molecules involved in the T-cell activation cascade during graft rejection such as: CD2/CD3, CD4, CD8, CD11a, CD18, CD25, HLA-DR and HLA class I.

T-cells are eliminated from the circulation by complement dependent lysis and, by an Fc-dependent opsonization mechanism mediated by the monocyte and phagocyte system.

- Rabbit anti-human thymocyte immunoglobulin, in addition to its effect of depleting T-cells, triggers other lymphocyte functions related to its immunosuppressive activity.
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Such diversity may provide the basis for the multifaceted impact of Thymoglobuline® on the immune system. So when it comes to treating your transplant patients, think thymo™.

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Transplant

**Thymoglobuline®**  
Rabbit anti-human thymocyte immunoglobulin



**QUALITÀ NEI ALI D'QUALITÀ IN COMPOSIZIONE**

Powder (per vial):  
 + Active substance:  
 Rabbit anti human thymocyte immunoglobulin 25 mg.  
 + Excipients:  
 Glycine 50 mg, Sodium Chloride 10 mg, Mannitol 50 mg.  
 Solvent (per vial):  
 Water for injections up to 5 mL

**PHARMACEUTICAL FORM**

Powder and solvent for solution for infusion.

**CLINICAL PARTICULARS**

**Therapeutic indications**  
 + In immunosuppression in transplantation: prophylaxis and treatment of graft rejection.  
 + Prophylaxis of acute and chronic graft versus host disease after hematopoietic cell transplantation.  
 + Treatment of steroid resistant acute graft versus host disease.  
 + Hematology: treatment of aplastic anemia.

**Dosology and method of administration**

**Dosology:**  
 The dosing depends on the indication, the administration regimen and the combination with other immunosuppressive agents.  
 The following dosages may be used as a reference.  
 Treatment can be discontinued without gradual tapering of the dose.  
 + In immunosuppression in transplantation  
 - Prophylaxis of acute graft rejection  
 1 to 1.5 mg/kg/dp for 2 to 3 days after transplantation of a kidney, pancreas or liver and for 2 to 5 days after heart transplantation, corresponding to a cumulative dose of 2-7.5 mg/kg in heart transplantation and 2-13.5 mg/kg for other organs.  
 - Treatment of acute graft rejection  
 1.5 mg/kg/dp for 3 to 14 days corresponding to a cumulative dose of 4.5-21 mg/kg.  
 + Aplastic anemia: 2.5 to 3.5 mg/kg/dp for 5 consecutive days corresponding to a cumulative dose of 12.5-17.5 mg/kg.  
 + Prophylaxis of acute and chronic graft versus host (GVH) disease:  
 In transplantation of grafts (bone marrow or haemopoietic stem cells from peripheral blood) from mismatched related or mismatched unrelated donors, it is recommended in adult patients that Thymoglobuline be administered, as a preliminary therapy, at a dose of 2.5 mg/kg/dp from day 4 to day 2 or 3, corresponding to a cumulative dose of 7.5-10 mg/kg.  
 + Treatment of steroid resistant acute graft versus host disease: the dosage must be determined on an individual basis. It is usually between 2 and 5 mg/kg/dp for 5 days.  
**Method of administration:**  
 Rabbit anti human thymocyte immunoglobulin is usually administered in the context of a therapeutic regimen combining several immunosuppressive agents.  
 Administer the daily doses of intravenous corticosteroids and antihistamines required prior to infusion of rabbit anti human thymocyte immunoglobulin.  
 Rabbit anti human thymocyte immunoglobulin is infused after dilution in isotonic 0.9% sodium chloride or 5% glucose solution.  
 Infuse slowly into a large vein. Adjust the infusion rate so that the total duration of infusion is not less than 4 hours.

**Contra-indications**

+ Acute infections contra-indicating any further immunosuppression;  
 + Known allergy to rabbit proteins or one of the constituents of the preparation.

**Special warnings and special precautions for use**  
 Rabbit anti human thymocyte immunoglobulin must always be used under strict hospital medical supervision.  
 Certain severe adverse reactions may be related to the rate of infusion. The recommended infusion rate given in the section "Dosology and Method of Administration" must be closely observed. Patients must be carefully monitored throughout infusion. Due to the risk of serum sickness-type reactions, special precautions should be taken in patients already having received rabbit immunoglobulins.  
 In the event of adverse reactions, either decrease the infusion rate or suspend infusion until the symptoms have resolved. Administration must be immediately and permanently discontinued if an anaphylactic reaction occurs. In the event of an anaphylactic reaction or shock, usual emergency treatment should be instituted promptly.

Blood cell count should be monitored for 2 weeks following treatment discontinuation. In patients presenting with initial relative thrombocytopenia ( $< 150.10^9$  platelets/L) and particularly in heart transplant recipients, the platelet count should also be monitored.  
 In organ transplantation: a reduction of dosage should be considered in the event of a platelet count  $< 80.10^9/L$  or a leukocyte count  $< 2.5.10^9/L$ ;  
 - in the event of severe and unrelenting thrombocytopenia ( $< 50.10^9/L$ ) or leukopenia ( $< 1.5.10^9/L$ ) discontinue treatment.  
 In conditioning protocols, the risk of infection is markedly increased. The risk of occurrence of the initial malignant disease is increased. These factors must therefore be taken into account.  
 In aplastic anemia, the immunosuppressive treatment contributes to the risk of infection (in particular fungal infection) associated with the aplastic anemia itself.  
 The increased risk of lymphoproliferative disorders is to be taken into account.

**Interactions with other medicinal products and other forms of interaction**  
 + Contraindications to be taken into account:  
 - Opportunistic, bacterial or mycoplasma infections: risk of over-immunosuppression with a risk of lymphoproliferation;  
 - Live attenuated vaccines: risk of opportunistic infection which may potentially be fatal. This risk is enhanced in subjects who are immunocompromised due to the underlying disease (aplastic anaemia);  
 + Rabbit anti human thymocyte immunoglobulin may induce formation of antibodies which react with other rabbit immunoglobulins;  
 + Rabbit anti human thymocyte immunoglobulin may interfere with ELISA tests involving rabbit antibodies over a period of 2 months.

**Pregnancy and Lactation**

The safety during pregnancy and lactation has not been established. Must not be prescribed unless absolutely required.

**Undesirable effects**

Adverse reactions reported during and subsequent to Thymoglobuline infusion:  
 + Systemic adverse reactions which may present as chills, fever, hypotension, tachycardia, vomiting and depression. Local adverse reactions such as pain at the infusion site and peripheral thrombophlebitis have also been reported;  
 + delayed allergic reactions such as serum sickness (fever, pruritus, rash as well as joint and muscle pain) may occur 7 to 15 days post-treatment initiation. In moderate/severe allergic reactions are exceptional;  
 + the most frequent and most serious adverse reactions occur after the first infusion. The mechanism of some of these adverse reactions is probably related to cytokine release.  
 Prevention with corticosteroids and antihistamines and a decrease in the infusion rate or use of a higher volume of solvent (isotonic 0.9% sodium chloride or 5% glucose solution) may enable the incidence and severity of certain adverse reactions to be reduced;  
 + adverse reactions associated with the presence of antibodies including cross reactions such as neutropenia and thrombocytopenia have been reported during and subsequent to treatment with rabbit anti human thymocyte immunoglobulin. The reactions may occur during the first 2 days of treatment or after the end of treatment. The mechanism of these effects involves the presence of antibody inducing cross reactions with neutrophils or platelets. Monitoring of the white blood cell and platelet counts enables the severity and frequency of such reactions to be reduced;  
 + adverse effects associated with over-immunosuppression including infections (bacterial, fungal, viral and parasitic) and rare neoplastic malignancies (particularly lymphoproliferative syndrome) have been reported during and after rabbit anti human thymocyte immunoglobulin treatment. It is important to note that concomitant or previous immunosuppressive treatment may contribute to the over-immunosuppression observed;  
 + the risk of lymphoproliferative disorders is enhanced by concomitant treatment with other immunosuppressive agents;  
 + In conditioning protocols, the risk of infection linked to the administration of Thymoglobuline is markedly increased.

**Over dose**

Treatment overdosage of Thymoglobuline ( $> 5$  mg/kg/dp) may induce leukopenia and thrombocytopenia. Prolonged use (greater than 3 weeks) of rabbit anti human thymocyte immunoglobulin may induce severe infections and increase the risk of lymphoma.

**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic properties**  
 2. Pharmacotherapeutic group: Rabbit anti human thymocyte immunoglobulin is a selective immunosuppressive agent (acting on T lymphocytes).  
 b. The mechanism of action is as follows:  
 + Lymphocyte depletion probably constitutes the primary mechanism of the immunosuppression induced by rabbit anti human thymocyte immunoglobulin. Thymoglobuline recognizes most of the molecules involved in the T cell cell adhesion cascade during graft rejection such as CD2, CD3, CD4, CD8, CD11a, CD11c, CD25, HLADR and HLA class II. T cells are eliminated from the circulation by complement dependent lysis and, by an Fc dependent opsonization mechanism mediated by the monocyte and phagocyte system.  
 + Rabbit anti human thymocyte immunoglobulin, in addition to its effect of depleting T cells, triggers other lymphocyte functions related to its immunosuppressive activity.

In vitro, at concentrations of 0.1 mg/mL, Thymoglobuline activates T cells and stimulates their proliferation (in the same manner for the CD4+ and CD8+ subsets) with synthesis of IL-2 and IFN- $\gamma$  and expression of CD25. This mitogenic activity primarily involves the CD-2 pathway. At higher concentrations, rabbit anti human thymocyte immunoglobulin inhibits the proliferative response of lymphocytes to other mitogens with post-transcriptional blockade of IFN- $\gamma$  and CD-25 synthesis but no decrease in IL-2 synthesis.  
 + In vitro, Thymoglobuline does not activate B-cells. The low risk of B-cell lymphoma observed in patients treated with Thymoglobuline may be explained by the following mechanisms: no activation of B-cell growth, as a result, non-differentiation of plasma cells; antiproliferative activity against B-cells and certain lymphoblastoid cell lines.  
 + In the course of immunosuppression in the context of organ transplantation, patients treated with rabbit anti human thymocyte immunoglobulin experience profound lymphopenia (defined as a more than 50% depletion compared to the baseline value) as early as 1 day post-treatment initiation. The lymphopenia persists throughout treatment and, after the course of therapy, about 40% of patients recover more than 50% of the initial lymphocyte count at 3 months.  
 + Monitoring of lymphocyte subsets (CD2, CD3, CD4, CD8, CD14, CD19 and CD25) has confirmed the broad range of T cell specialities of Thymoglobuline. Over the first 2 weeks of treatment, the absolute count for all subsets except B lymphocytes and monocytes shows marked depletion (over 85% for CD2, CD3, CD4, CD8, CD25, CD56 and CD57) at the beginning of treatment, monocytes undergo less marked depletion. B lymphocytes are almost unaffected.  
 Most of the subsets show a recovery in more than 50% of their initial value before the end of the second month. CD4 cell depletion is very long lasting and persists at 6 months with, as a result, an increase in the CD4/CD8 ratio.  
 + Retrospective clinical studies have provided evidence strongly in favour of reducing the risk of acute GVH disease. However, no beneficial effects on patient survival have been demonstrated.

**Pharmacokinetic properties**

Following the intravenous infusion of 1.25 mg/kg of Thymoglobuline (in kidney transplant recipients), serum rabbit IgG levels of between 10 and 40  $\mu\text{g/mL}$  are obtained. The serum levels decline steadily until the following infusion with an estimated elimination half-life of 23 days. The trough rabbit IgG levels increase progressively reaching 20 to 170  $\mu\text{g/mL}$  at the end of an 11-day course of treatment. A gradual decline is subsequently observed following discontinuation of treatment with rabbit anti human thymocyte immunoglobulin. However, rabbit IgG remains detectable in 80% of patients at 2 months. Significant immunization against rabbit IgG is observed in about 40% of patients. In most cases immunization develops within the first 15 days observed in clinical trial. Patients presenting with immunization show a faster decline in trough rabbit IgG levels.

**SPECIFIC INDICATIONS FOR STORAGE**

Between +2°C and +8°C. Do not freeze.

**PRESCRIBING AND DISPENSING CONDITIONS**

List I  
 For hospital use only. Collectables

French MA 32709-2 (1984 - revised Feb. 2005)  
 Box of 1 powderial and 1 solvential.

Genzyme Europe BV  
 Goolweer 10  
 HL-1411 DD Harden

