INTRODUCTION BY THE CHAIRMAN

It gives me great pleasure to introduce the first Annual Report for Europa Uomo which sets out, for our members, supporters, interested parties and the health authorities, what we have achieved in the past twelve months and our future plan.

2014/5 represented a year of huge progress for the organisation on several dimensions. We had a strong year in making us the patient voice of prostate cancer in Europe.

Details of key elements of our exciting work follow later in the report; our impact continues to grow, although the challenges of inequality of treatment of prostate cancer still exist especially in the eastern part of Europe.

The Board and I have completed our review of our strategy to move us ahead for the next few years.

I am committed for an open dialogue with our membership, a two-way communication via our newsletter and other types of media forums.

During the year we revised our website and thanks go to our new webmaster Nancy Verbrugghe. We are reviewing our communication strategy and will be in touch with our findings.

My thanks to go to all our sponsors for the contributions to our funds - details are including in the report and on our website.

We have accepted the Code of Practice of the EMA for funding details – see our website www.europa-uomo.org.

I believe we need to ensure that our funding continues to grow in order to make men in Europe more aware of early diagnosis and the best treatment available in each state.

You will note the prostate cancer figures for Europe for 2012 - see Appendix 1 attached. There is a lot of work to be done for the future of prostate patients.

The Board elected Louis Denis as ex-officio member from OCA together with Günter Feick from the members. My thanks go to Louis for all his help during the year to move us ahead of the game.

Thanks also go to Hein Van Poppel and Alberto Costa our other professional ex-officio members who help us in so many ways.

My thanks also to the Officers and the Board members for their assistance during the year.

As patient advocates we must be proud of our success and this goes to the Liaison Officers and all in the member’s organisation - without them we can’t function as strongly as we do.

Finally, my thanks to go to Brigitte Dourcy-Belle-Rose and Anja Vancauwenbergh, our staff in Antwerp and the Director of OCA Luc Dewilde.

Ken Mastris
Chairman Europa Uomo
Background

The formal establishment of Europa Uomo in 2003 led to the growth of an organisation representing prostate cancer patient organisations in 23 countries. The process of development of the organisation from its early nurturing by the European School of Oncology (ESO) and the strategic link-up with the European Association of Urologists (EAU) was also accompanied by financial support. Europa Uomo has also developed its relationship with the pharmaceutical industry and obtained significant support from that quarter.

For legal reasons it proved necessary to move the legal registration of Europa from Italy to Belgium and this process was quite protracted, but was completed by the adoption of revised statutes in London 2014. This was followed by the registration of Europa Uomo in Belgium. Since then the Board has undertaken a number of initiatives to place the organisation on a more developed organisational footing. These measures included the approval by the General Assembly of a set of Bye-Law or House Rules at the Warsaw GA in 2015.

The Board has developed guidelines for the operation of the Liaison Officers Club and has expanded the membership of this group.

The year under report also saw the conclusion of a process to ensure that the funding of the organisation was secured on a multi-annual basis.
Board Membership

The Board has seven elected members. Each member is elected by the General Assembly for a term of three years (renewable for a further term of three years). At the GA in 2015 there were three vacancies occurring on the Board. One of the outgoing Board members, Tor Tausvik, did not stand for re-election and a second vacancy arose from the resignation, in late 2014, of Hans Ransdorp. The three-year term of a third member, Ken Mastris had also expired and he offered himself for re-election. There were two other nominees for the Board, André Deschamps and John Dowling, both of whom were elected, as was Ken Mastris who was elected for a second term.

The new Board met before the end of the General Assembly and following officers were elected: Chairman: Ken Mastris, Vice-Chairmen: Ekke Büchler and André Deschamps, Treasurer: Christian Arnold and Secretary: John Dowling. The other members of the Board for 2015-16 are Malcom Duncan and Max Lippuner. In addition, Günter Feick is an ex-officio member as are the three partner ex-officios Prof. Hein Van Poppel (EAU), Dr. Alberto Costa (ESO) and Prof. Louis Denis (OCA).

The current Board met in September, November, March and April and is due to have its final meeting of this year on 17 June, on the eve of the General Assembly in Hoorn. The Board also had a number of phone conferences.

In addition to the responsibilities in the statutes for Chairman, Treasurer and Secretary the other Board members took on particular portfolios. Ekke Büchler and Max Lippuner took responsibility for developing membership, Malcolm Duncan took responsibility for the editorial board and communications, André Deschamps took on the management of our representation at other bodies and conferences by Board members and LOCs. Günter Feick retained responsibility for projects.

Professor Louis Denis provided great assistance to Europa Uomo in the role of Strategic Consultant since November 2014. Louis Denis stepped down from that role in September 2015. Subsequently, he was appointed ex-officio member of the Board in March 2016 on the basis of a partnership agreement with the Oncology Centre Antwerp.
Implementation of the Bye-Laws

The General Assembly in Warsaw 2015, adopted a comprehensive set of Bye-Laws to assist in developing the organisation by complementing the Statutes where they were insufficiently detailed. One of the tasks of the new Board was to give effect to these Bye-Laws. This proved more difficult than might have been thought when they were adopted and some of the timelines set out in the bye-laws have proved optimistic in practice. Treasurer, Christian Arnold, has established the Financial Board for Europa Uomo and the Board approved his nomination of Joaquim Domingos and Hugo Boliau to the financial board.

Strategy

One of the requirements under the bye-laws was that the Board should develop its work plan and circulate to member organisations within four months of the General Assembly. The adoption of an overall strategy had been under consideration by a previous Board in 2014 and there was extensive discussion at the GA in Warsaw last June. The new Board decided to try to conclude its discussions on the strategy and work plan. The matter was the subject of numerous papers and finally a working party under the leadership of Günter Feick produced a draft report which was adopted, with some amendments, by the Board in April and is on the Agenda for discussion and approval at the GA in Hoorn in June 2016.

A draft report for consideration by the General Assembly is on the Agenda for the GA and is attached to this report. (Appendix 2)

Proposed amendment of the Bye-Laws

In the course of implementation, concern was expressed on some aspects of the Bye-Laws. As a result, the Board has brought forward two proposed amendments to the Bye-Laws for consideration by the 2016 General Assembly. One concerns the reporting requirement to provide a listing of all payments and lodgements to the Board each quarter. The Treasurer has pointed out that this is more onerous than would be the case for a commercial company and beyond the capacity of Europa Uomo with a part-time secretariat and a volunteer treasurer. He suggested that it should be sufficient to report to the Board each quarter on the cash bank balances and whether income and expenditure are in line with budget.

The second proposed change concerns the procedures for the appointment of ex-officio members. In the Bye-Laws as adopted in 2015, there are two procedures for the nomination and appointment of ex-officio members of the Board – one by the Board in Bye-Law 10.1.8 and the second by partnership organisations such as the EAU in Bye-Law 10.1.10. Concern was expressed that as the bye-laws appeared to be in conflict and appeared to require the Board to nominate the ex-officio being appointed from a partner organisation. The amendment being put before the GA is to make it clear that appointments made by partner organisations under Bye-Law 10.1.10 are unaffected by the earlier Bye-Law.
Funding of Europa Uomo and accounts

The funding of Europa Uomo comes from small contributions from member organisations through their annual dues, contributions from partner organisations, especially the European Association of Urologists (EAU), and a number of pharmaceutical companies.

The policy of the Board has been to raise sufficient funds to carry out its tasks. The pattern of annual fund-raising had recently given rise to certain difficulties. A change of approach was initiated and, with the crucial assistance of Prof. Louis Denis, our Treasurer, Christian Arnold, together with input from Chairman, Ken Mastris, a series of multi-annual agreements have been put in place with our sponsors.

The newly established Finance Board will be examining how the future funding of Europa Uomo should be secured when the present agreements begin to unfold in 2018.

The accounts for the 2015 are shown in the following pages.

Summary:

- Income at “normal” level after weak year 2014
- 3 year contracts with sponsors
- Expenditure similar in % to previous years
- Positive balance of € 45.000

In accordance with Belgian law for not-for-profit organisations it is necessary that these financial reports be considered and approved by the General Assembly so that the Board may be discharged.

Europa Uomo is compliant with the EMA guidelines on the funding of recognised patient organisations in terms of the number of pharma companies from whom it draws financial support and that it is not more than 25% dependent on any one source.
Balance at December 31 2015

ASSETS

Bankaccounts

Business compactaccount 128.393,25
Savings account 50.229,25

178.622,50

Account receivable

Grant Pharma 25.000,00
Grant Pharma 25.000,00

50.000,00

Deferred expenses

Expenses Heathrow terminal paid in 2015 for 2016 591,53

Total assets 229.214,03

Liabilities

Deferred income and accrued expenses

Memberships paid in 2015 for 2016 300,00

Maintenance website December 2015 paid in 2016 405,00

Refund travelling expenses EMUC Barcelona paid in 2016 332,72

1.037,72

Capital of the association

Balance at 31/12/2014 182.257,57
Balance 2015 45.918,74

Capital at 31/12/2015 228.176,31

Total liabilities 229.214,03
Income distribution

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<td>1.0%</td>
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<tr>
<td>Other contributions</td>
<td>5,050</td>
<td>2.5%</td>
</tr>
<tr>
<td><strong>Total income</strong></td>
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Expenditure distribution

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<td>6%</td>
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<td>Refund travelling costs</td>
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<td>25%</td>
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<tr>
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<td>€ 2,374</td>
<td>2%</td>
</tr>
<tr>
<td>Other costs</td>
<td>€ 1,458</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€ 156,232</td>
<td>100%</td>
</tr>
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</table>
Profit and loss 2013-2015
Budget 2016 and 2017

The budgets for 2016 and 2017 will be almost similar. We expect the same income level in both years.

Depending on the actions as per our strategic plan the expenditure may vary from the figures below especially in 2017.

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<th>Income</th>
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<th>2015</th>
<th>Delta 2015</th>
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<td>€ 30.000</td>
</tr>
<tr>
<td>Grants and donations pharma</td>
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<td>€ 165.000</td>
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<td>Membership fees</td>
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<td>€ 2.100</td>
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<tr>
<td>Other contributions</td>
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<td>€ 5.050</td>
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<tr>
<td>Total income</td>
<td>€ 200.100</td>
<td>100%</td>
<td>€ 202.150</td>
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<table>
<thead>
<tr>
<th>Expenditure</th>
<th>Budget 2016</th>
<th>2015</th>
<th>Delta 2015</th>
</tr>
</thead>
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<td>€ 50.000</td>
<td>27%</td>
<td>€ 38.348</td>
</tr>
<tr>
<td>Other meeting costs</td>
<td>€ 70.000</td>
<td>38%</td>
<td>€ 54.721</td>
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<td>€ 2.374</td>
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<tr>
<td>Other costs</td>
<td>€ 6.665</td>
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<td>€ 1.458</td>
</tr>
<tr>
<td>Total expenditure</td>
<td>€ 184.115</td>
<td>100%</td>
<td>€ 156.232</td>
</tr>
</tbody>
</table>

| Total income                    | € 200.100  |
| Total expenditure               | € 184.115  |
| Balance                         | € 15.985   |
Liaison Officers

The concept of the Liaison Officers Club – otherwise known as LOCs - was developed in the year prior to the Warsaw General Assembly in 2015. The enabling provisions were set out in the Bye-Laws adopted at that GA. Since then the initial group of LOCs has been expanded and a procedure has been developed governing how the LOCs will be deployed on behalf of Europa Uomo and the reporting arrangements when they represent the organisation at meetings and conferences.

At its meeting in September 2015 the Board appointed Vice-Chairman, André Deschamps, as the co-ordinator of LOCs and a copy of the procedures adopted is attached as an appendix to this report. (Appendix 3)

The current cohort of Liaison Officers is Louis Denis, Paul Enders, Erik Briers, Roger Wotton, Will Janssen, Maria Luisa Domingos, Brigitte Dourcy-Belle-Rose, Joaquim Domingos.
European Prostate Awareness Day (EPAD) – Brussels, September 2015

One of the public projects undertaken by the Board in 2015 was the EPAD function held in September in the European Parliament Building in Brussels. The MEP Philippe De Backer sponsored Europa Uomo’s use of the forum and co-chaired the session with Prof. Hein Van Poppel.

The attendance totalled 67 representatives from clinical, academic and patient interests from many countries. A wide range of short presentations were made by leading researchers and clinicians. In addition, there were patient viewpoints presented by Ken Mastris and Ian Banks from Mens’ Health.
Conferences & Meetings Attended

Members of the Board and Liaison Officers attend a wide range of meetings on behalf of Europa Uomo. Usually it is thought sufficient to send one or two representatives but on occasions, because of the nature of the conference, additional representatives attend. It is hoped that the new reporting procedures for Board representatives and LOCs will enable the Board to review where best to deploy its limited resources.

In order to maximise the value to be obtained a small number of conference are used to arrange meetings of the Board. This also provides the Board with the opportunity to obtain the most up to date information from the Conference sessions.

A listing of meetings and conferences attended by Europa Uomo representatives is set out in an appendix (Appendix 4) to this report. In addition, short accounts on two of the meetings attended by the Board as set out below.

European Multidisciplinary Meeting on Urological Cancers (EMUC) – Barcelona, Nov. 2015

The EMUC meeting was held in November in Barcelona and was attended by the Board and a number of LOCs. Our Chairman, Ken Mastris, was a speaker at one of the panel sessions.

EMUC brings together a range of specialists from urology, radiation oncology, medical oncology, pathology and epidemiology. Prostate cancer is one of the main areas of interest at the meeting so it provides an excellent learning opportunity for Board members to hear leading clinicians and researchers present on the latest developments in prostate cancer diagnosis and treatments.

A meeting of the Board was held during EMUC and it was joined in a number of sessions by those Liaison Officers who had been able to travel to Barcelona. The Board agreed to the adoption of new provisions which would apply in the future to all Board members and LOCs representing Europa Uomo.

European Association of Urologists Congress – Munich, March 2016

The EAU is biggest congress of its type in Europe with some 14,000 attendees – not only urologists but many scientists and clinicians in various fields of endeavour associated with a range of urological diseases – prostate disease being prominent among them. The Board of Europa Uomo traditionally attends the Congress in conjunction with the holding of a Board meeting.

The opening day of the congress featured a series of presentations by our partner organisation – the European School of Oncology.

The occasion of the EAU Congress not only provides an opportunity for the Board to meet about its own business, but Board members, together with LOCs, have the valuable opportunity to
take part in special presentations by leaders in the field of prostate cancer diagnosis and treatment on various aspects of prostate cancer.

**Conference Presence**

At many of these conferences Europa Uomo is often provided with a stand or booth where information about Europa Uomo can be provided to conference delegates. At many of these meetings the organisation’s stand has been manned by Joaquim Domingos and Maria Louisa Domingos sometimes assisted by local representatives.
European Medicines Agency (EMA)

The Agency is a function of the European Commission and is the body which assesses medicines for use within the EU, Norway and Liechtenstein (European Economic Area – EEA), which are submitted by sponsors for use across the EEA. At the present time the Agency provides for patient representation on a number of its committees. The Pharmacovigilance Committee and the Committee for Advanced Therapies are the two principal scientific committees. During the year a member of our German affiliate BPS, Udo Uhrmann, applied for the vacant patient position on the Pharmacovigilance Committee and was supported by Europa Uomo. His application has been successful, in that he has been appointed as an Alternate member to the Committee for a five-year term.

EMA also provides a forum - on the Patients’ and Consumers’ Working Party (PCWP) which meets with the representatives of the EMA on a quarterly basis. Europa Uomo is represented on this Working Party by Ken Mastris. During the past year John Dowling and André Deschamps have acted as alternates for the Chairman when he was unable to attend.

The EMA terms for the reporting of all trials of medicinal and device products is proceeding to a long-awaited conclusion, but the fact that will be no obligation on the sponsoring company to publish the reports in multi-language formats will limit the value of this otherwise welcome move. The EMA appears to accept industry’s contention that such a requirement will impose an undue burden on the sponsoring companies.

The EMA asked the British Health Research Agency (HRA) to develop guidelines for the forthcoming inclusion of a layman’s summary explanation of the trial in all trial reports. The HRA established a task force to draw up the guidelines with representatives from the PCWP and from the Healthcare and Professional Working Party. The task force reported back to the EMA in November 2015. Europa Uomo was among the small number of patient organisation represented on the task force. The layman’s summary has the same drawback as the all-trials reports in that it will normally be available only in the language used/selected by the sponsor.

In early 2016 the EMA invited patient organisations who are interested in renewing their membership of the EMA’s Patients’ and Consumers’ Working Party to apply for a further term of membership of the Working Party. This application was duly submitted in April 2016.
Membership of Europa Uomo

Membership is open to prostate cancer patient organisations in Europe. Twenty-three countries are currently represented by Europa Uomo. At successive General Assemblies concern has been expressed at the slow progress in developing Europa Uomo membership in the eastern and southern states of Europe. The Board has also considered the matter and two of its members, Ekke Büchler and Max Lippuner took on responsibility for this important area. In association with the planned 2017 General Assembly in Vienna, a seminar has been organised which is aimed at eastern countries.

It was especially welcome for the Board to receive an application for membership of Europa Uomo from the Estonian Prostate Cancer Society. The Board is recommending that the General Assembly approve the Estonian application.

Newsletter and Website

Under the new Bye-Laws the various communications functions come under the aegis of an Editorial Board which is chaired by Malcolm Duncan. This has responsibility for oversight of the Newsletter, the Website and the development of a Facebook page. In addition to Malcolm in the Chair, the editorial board also includes the webmaster Nancy Verbrugghe, Günter Feick and Louis Denis.

Malcom Duncan also undertakes the onerous task of editing the newsletter: Did You Know? The newsletter is produced four times a year but also special issue have been produced such as the EPAD edition in September 2015. Malcolm is ably assisted in the production of the newsletter by Anja Vancauwenbergh in the secretariat in Antwerp. Read Malcolm’s communication report in Appendix 5.

Code of conduct

The Board decided early 2016 to undersign the code of conduct as developed by EMA. This code guarantees that the necessary rules are in place to act as a professional and responsible organisation.

In undersigning, EUomo joins many other patient organisations.

The code of conduct is attached (Appendix 6).
List of attachments to this Annual Report

1. Prostate Cancer figures for Europe for 2012
2. Strategy document
3. LOC procedure
4. List of meetings attended
5. Communications report
6. Code of Conduct
## Prostate Cancer Figures for Europe for 2012

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<th>COUNTRY</th>
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Attachment 1
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References


Notes
The data for Serbia include Kosovo. If Kosovo is selected from the map, the combined data for both countries will be returned.

Strategy document EUOMO

As presented to the GA June 2016
Chapter 1: Background

Does Europa Uomo Need a Strategy?

Establish the Need

- Any organization needs a strategy to survive and thrive.
- Purely voluntary organizations tend not to survive. They are like restaurants which have a talented chef but with a terrible business sense – 80% fail in the first three years.
- A voluntary organization, and particularly an all-volunteer organization, is evermore in need of a strategy because it lacks the capacity of a business or corporate entity in terms of a professional executive to plan and execute tasks on a continuous basis.
- An international voluntary organization has the additional difficulty of language and geographical dispersal to contend with.
- A voluntary organization is always susceptible to running out of energy and/or splitting. An effective strategy will establish markers or mileposts. Reaching these mileposts in some fashion will energize volunteers to renewed effort and reduce the scale and extent of internal dissension and turnover which is otherwise likely to emerge.

Review the Experience to date

- Against the odds Europa Uomo was not only formally established in 2003 with an initial critical mass, but it has survived and grown. The initial struggle to establish the Coalition was successful in terms of attracting new members, establishing relationships with other patient organizations and probably most importantly with the clinicians, in particular the European Association of Urologists.
- There was also the vital “seed” money and ongoing administrative support from the School of Oncology in Milan and its head Dr Alberto Costa.
- Prof. Louis Denis’s role as Secretary for almost 10 years proved an inspiring choice. His status as a scientist in prostate cancer research, his direct manner of dealing with management, his organizational skills and above all his huge range of contacts proved invaluable at this formative stage.
- To counterbalance Prof Denis there was the urbane Dubliner, Tom Hudson. As a former Chief Executive of the Irish Cancer Society, Tom’s decade as Chairman of the Coalition utilized his enormous range of contacts and friends in the European, indeed world, cancer organizations, pharma companies and individuals who were instrumental in opening doors for the fledging Coalition as it struggled to develop in its formative years. Tom’s managerial and diplomatic skills
and his good humor were put to great use in the cause of the patient and in particular the cause of the Coalition.

- In the period 2012-14 the Coalition had its most fragile period since its founding as both Chairman and Secretary stepped down from their office. The period was marked by a degree of turmoil and an unsettling turnover at officer level. Louis Denis returned for a year as Strategic Consultant to help stabilize the ship and he has now stepped back again to the ‘back benches’ as they say in parliamentary language.
- The handover from the “founding fathers” is always problematic in a voluntary organization, especially as it had no executive level personnel who could have provided the organizational continuity during the transfer.

What does the future hold in terms of strategy?

Strategy is the art of setting out what it is you want to achieve. And tactics are the means and steps you employ to meet the strategic goals. In Japan a company making heavy duty tracked vehicles had a vision statement which drove its strategy and it was two words: *Beat Caterpillar*

We are not clinicians and therefore “beating prostate cancer” would be an over-reach, but what we want to achieve is that men have the opportunity:

(i) to obtain high quality dispassionate advice from a clinician,  
(ii) an accurate diagnosis,  
(iii) if required, excellent treatment in a multi-disciplinary high volume facility,  
(iv) systematic and informed follow-up, and  
(v) bearing in mind that in some cases the best treatment may be no treatment at all.

Tactically we have to fashion multi-layered programs and plans focusing on

(a) building capacity within the organization and its affiliates through seminars, conferences and symposia both centrally and nationally;  
(b) organizing membership in every corner of Europe from Greenland to possibly the Urals;  
(c) build an effective and forceful secretariat with an employed executive;  
(d) each year we should adopt a rolling 3 year plan. This is the time period for those elected to the Board. It would allow the individual Board members to set down reasonable and practicable objectives which would have a sufficient time span to allow for adjustments in the light of experience.

Ideally, Board members should seek to set out for themselves SMART objectives (Specific, Measurable, Achievable, Realistic and Time bound) for the fulfillment of their portfolios. The Board itself should each year set a small number of objectives—no more than three—which it wishes to achieve. Before each GA it should report on how successful it has been in achieving its objective.

For Example the Board’s objectives should be formulated in an annual Business Plan which should have a relatively small number of SMART items.
Chapter 2: SWOT analysis

Strengths

- Europa Uomo has established itself as the primary patient voice for prostate cancer issues in Europe.
- The Coalition is now represented on numerous bodies dealing with issues affecting prostate patients, this includes official organizations related to the European Union.
- The Coalition has enrolled membership from 23 countries.
- The Coalition is now registered under the Not for Profit legislation in Belgium.
- The Coalition now has internal rules – the bye-laws – as an adjunct to its statutes which provide the normative framework for day-to-day working.
- The organization has improved its internal and external communications with a revamping of its website, its quarterly newsletters and its internal Board Bulletin and Prostate Digest.
- The Board is experimenting with trying to improve its responsiveness to events by holding online meetings – if this can be done successfully, the Board will be able to function more effectively than its former pattern of holding only 3 plenary sessions per year.
- Under the new bye-laws, each member of the Board has been assigned specific areas of responsibility on which they will report to the Board and later to the General Assembly.
- The work plan for the Board will be made up of the individual Board member’s work programs to implement their portfolio responsibilities as well as the overall strategic objectives determined by the Board. Where those objective do not come within the portfolio of any particular Board member the Chairman is likely to look around at who might best assist.

Weaknesses

- The membership situation is problematic in two respects – insufficient geographical spread and an apparent low level of activity among some members.
- Firstly, there is poor representation from Eastern and Southern Europe, and secondly, where these countries are in membership their participation in the Coalition is not always optimal.
- The burdens of office fall on too few shoulders. When Louis Denis stepped back in 2012 his absence from the helm exposed a weakness in terms of executive capacity. This is not a criticism of office holders, but a reflection of the need to extend the size of the Board and for an executive capacity provision.
- The organization’s notable success in establishing itself as a representative patient organization has put a strain on the limited number of personnel it has with sufficient fluency in English and knowledge about prostatic disease diagnoses and treatments to deploy to the various forums to which Europa Uomo is now invited.
The organization was born to deal with prostate cancer, but as time has gone by it can be seen that this exclusivity is not helpful to Europa Uomo or to the men with prostatic diseases. Although the Larnaca General Assembly in October/November 2012 adopted statutes which broadened the remit of Europa Uomo, in actual fact the Coalition has not had the resources available which are indispensable to actively broaden its activities to cover the full range of prostatic diseases.

Arising immediately from the above reference, the question has been raised as to whether we should broaden our alliances and involvements, in a limited way initially, to encompass the whole field of men’s health so that in the holistic sense, prostatic diseases would be perceived as one aspect of men’s health, but one which will concern all men at some time in their lives. We know that there are myriad interrelationships which affect men’s health, be they diet, exercise, obesity, Type II diabetes, cardiovascular health, elimination of smoking, monitoring and self-monitoring as well as the prostatic diseases plus LUTS. This is a field that we may aspire to play in but where we currently are not a player. We have to ask ourselves and answer the question Are we lessening our impact by neglecting the wider aspect of men’s health.

The lack of a full-time or part-time executive is an organizational weakness for a 12 year old organization with an extensive reach. We have relied on the office in Antwerp, and in particular on Prof. Louis Denis, to an extent which is dangerous in organizational terms. His application and commitment have proved unique but it is up to the Coalition to ensure that it never again becomes so dependent on any one individual. As Prof. Denis has said himself – it is not appropriate for a person in their mid-80s to be driving an organization like Europa Uomo. The Coalition must address this issue now or it will not progress to the next phase of development.

Opportunities

The field is open to the Coalition. As far as Europe and Prostate Cancer is concerned there is huge scope to develop the Coalition as the loud and effective voice of the prostate cancer patients in Europe.

The Coalition should critically examine our participation with other patient organizations. Eliminate from our calendar any which do not appear to be worthwhile given our resources and add any which would better broaden the Coalition’s effectiveness.

Perhaps a small taskforce could look at how we should develop our role in relation to non-cancerous prostatic diseases and to LUTS in particular, Also, this taskforce should examine what role the Coalition could play in the wider men’s disease areas.

We should be prepared to examine the experience of any other prostate cancer organizations, including those within our membership, which have broadened their remit to include prostatic
diseases and/or men’s health. Following such examination we should draw appropriate conclusions and draw up a development program based on that experience where relevant.

- The Liaison Officer concept could be developed over time to get a range of non-Board members to undertake matters on behalf of the Board and report back to it. Each affiliate could be asked to nominate one member with a fluency in verbal and written English to join the cadre of Liaison Officers for a fixed period of time to undertake designated activities on behalf of the Coalition.

Threats

- The fragility of the organization must be recognized. It is dependent for its vitality on too few people and without the support and continuity of an employed executive it is always exposed to the risk of collapse – whether this is due to a split or exhaustion is irrelevant.

- The very success of the Coalition could attract organizational ‘sharks’ e.g. from North America, which could establish and fund a rival organization.

- Another patient organization in Europe could attempt a takeover seeking to extend its remit.

- A perception of the fragility of the organization could undermine the ability of the Coalition to recruit an effective and dynamic executive. Nobody wants to join what might be perceived as a sinking ship.

- A democratic and open organization like Europa Uomo is also exposed to being abused from within by those who perceive it as being a vehicle to enhance their prestige and lifestyle.

- Lack of reality positioning in European health care

- Collaborators should balance interest of EUomo vs. their own organization or worse vs. their own person

- Solidarity is a missing key to patient progress
Chapter 3: Vision and mission

Vision

• A future where no man suffers or dies from prostate cancer

Mission

• Achieve better treatment, care and quality of life for all prostate cancer patients across Europe
• Provide an effective EU-wide voice representing the needs and priorities of National organisations
Chapter 4: Goals and action plans

Goal 1: Request early detection of prostate cancer

Current situation:

✓ Population based screening for prostate cancer is still discouraged by physicians and researchers even though the ERSPC study and prostate cancer mortality statistics reflect reduction in mortality rates upon PSA utilization for the early detection of prostate cancer.
✓ Access to PSA testing is discouraged in some EU countries and men are not informed about prostate cancer risks and treatment.

Proposed actions:

1.1 EUomo and EAU review options for organizing a risk adapted PSA based prostate cancer early detection
1.2 EUomo and their members find methods to inform men and all stakeholders.

Goal 2: Help establish Prostate Cancer Centers and raise quality at world top level in all European States

Current situation:

✓ International Consortium of Health Outcome Measurement (ICHOM): Patient Related Outcomes (PROs) for localized low/medium risk prostate cancer consented and published
✓ ICHOM PROs added to prostate cancer treatment guidelines and reports of certified prostate cancer centers, Germany
✓ PROs for advanced prostate cancer consented and published; Prof. Denis patient representative for Europe Movember finances determination of PROs
✓ Study “Compare and Reduce Variations” – 10 countries, 70 hospitals starts July 2016, central document mgt. UCLA; Movember financed
✓ In some EU states prostate cancer centers are in existence.

Proposed actions:

2.1 EUomo Board provides EAU and ESO with a statement of the patients' interest in treating prostate cancer in specialized and certified prostate cancer centers measuring outcome with identical indicators.
2.2 EUomo develops a concept of number and quality of prostate cancer centers needed in European states.
2.3 EUomo promotes whenever possible that the quality of life is the most important aspect for patients.

**Goal 3: Have in place and review therapy guidelines and patient information in all European States based upon best evidence**

This goal is subdivided into three elements:
- a. EUomo representation in the EAU guidelines working group
- b. Current medical, scientific guidelines and patient guidelines in all European states
- c. Proof of guidelines application

**Current situation:**
- ✓ EAU guidelines and patient information sheets are developed and available in 14 languages.
- ✓ EUomo representatives were member of the working group.
- ✓ Those guidelines are used as an input for guidelines in the country specific guidelines. For different reasons country specific guidelines are not always identical to the EAU guidelines.

**Proposed actions:**

3.1 EUomo continues to work together with EAU in order to assess the guidelines at regular intervals and adapt them according to the latest information.
3.2 EUomo supports the promotion of guidelines and patient information and the measurement of guidelines implementation. EUomo will take steps for cooperation between the IMAGE group and EUomo.

**Goal 4: Encourage new support groups in new European States**

**Current situation:**
- ✓ There is a gap between the “old States” and the “new States”
- ✓ EUomo encourages and support patient groups in the new member States.
- ✓ Estonia has formed the first patient group with our help and we ask the GA to accept them as a member of EUomo.

**Proposed actions:**

4.1 Encourage and subsidize EUomo’s growth in eastern Europe. We admit that this is not an easy task.
4.2 Prove best method of expansion by pilots (see above Estonia)
4.3 EUomo will organize their next GA 2017 in Vienna, combined with a workshop and translation in three languages. Patients living in Eastern EU countries will be encouraged and financially supported to attend.

**Goal 5: Develop EUomo organizations, staff and funding.**

**Current situation:**

- LOC strategy developed
- Statutes and bye laws restructured
- Sustainability ensured by 3 year contracts
- EPAD events were organized and will be repeated when appropriate
- New website launched
- Newsletter published

**Proposed actions:**

5.1 Develop patient experts such as through the EUPATI training program and others e.g. the LSE programs in HTA for patient organizations. Use any training programs nationally, wherever language considerations allow for Europa Uomo activists to further improve their expertise.

5.2 Communications

- Improve external visibility by sensitizing the mass media.
- Develop Facebook page – all board members could contribute one item per month.
- Take professional advice with a view to installing a document handling system for Board members and have in place by autumn 2016.
- Consider having a more frequent number of slimmer Newsletters – say 6 per annum by eliminating special editions. This requires a more active participation of all member associations which should provide at least four articles per calendar year and duly distributed over the same calendar year.
- Review value of Bulletin and Digest by end 2016 and terminate if not justified.
- Member event reports should also be considered for the website.
- Twitter could be used as a repository of interesting articles gleaned from journals, on-line publications, newspapers etc. Test the possibility of a Europa Uomo Twitter account by the end of 2016.
- Establish a continuous, open, transparent line of communication from a bottom up to a top down information strategy.
- A precise business plan would be advisable for the further development of the Newsletter, Website and Social Media.
Goal 6: Support a coordinated European research program with patient advocate representation.

This goal is divided into 4 component parts in order to ease the description of a concept that addresses the sequence of the necessary work steps.

a. Obtain the support of EU Parliament and EU Commission for coordinated research in Europe
b. Obtain the support of EU Parliament and EU Commission for the registration and reporting of all trials in Europe
c. Representation of EUomo in EMA work groups/commissions such as the Committee for Medicinal Products for Human Use (CHMP), the Committee for Advanced Therapies (CAT), the Clinical Trial Facilitation Group, etc.
d. The organization of coordinated prostate cancer research for faster and better results with patient representation

Current situation:

✓ Parliamentary support has been achieved with the research funding program Horizon 2020, however this is but the first modest step towards the coordination of research (at least 3 independent organizations are required from different EU countries)
✓ This has been achieved but the EUDraCT register of clinical trials is only in English. [link]
✓ EUomo has representatives in EMA in different committees and working groups. The reports of those work groups are available on the EMA website.

Proposed actions:

6.1 EUomo continues to send representatives to meetings and apply for membership in EMA and other organizations.
6.2 These representatives will defend the patient interests and communicate EUomo goals.
6.3 EUomo will work together with EAU and other organizations to develop and support concepts for coordinated research.
6.4 EUomo requests from all companies producing prostate cancer relevant pharmaceutics and medical devices the participation of patient representatives in the design of trials and studies.
In order to ensure effective representation of Europa Uomo at meetings and on committees of external organisations a group of representatives has been formed to be known as the Liaison Officers Club (LOC). This memorandum sets out the terms which shall apply to the appointment, removal and deployment of these Liaison Officers.

**Liaison Officer**

- A Liaison Officer is an official representative of Europa Uomo.
- The nomination or removal of each Liaison Officer must be approved by the Board by formal decision.
- A Liaison Officer will represent Europa Uomo where needed and act according to its goals.
- A Liaison shall provide the Coordinator with information concerning the outcome of meetings attended by means of a formal Liaison Officer’s Report. Where applicable and feasible the official minutes of the meeting attended shall be attached to the Liaison Officer’s Report.
- The Liaison Officer’s Report shall be submitted within 30 days of attendance at the meeting.
- Board members are LOCs by the reason of being a Board member.
- When asked, by the Coordinator, to attend a meeting a Liaison Officer is free to accept or decline the invitation.
- A Liaison Officer shall not take positions or bind Europa Uomo without a mandate given by the Coordinator or a Board member.
- Liaison Officers may be invited, on an ad hoc basis to Board meetings (or portions thereof) and where so invited this will be indicated on the agenda

**Coordinator**

The Liaison Officer Coordinator shall be a Board member appointed by the Board. The functions of the Coordinator are:

- To coordinate the efforts of individual Liaison Officers.
- To provide the Board and Europa Uomo members with information concerning the outcome of the meetings attended.
- To bring to the Board the important matters and decisions to be made by it.
- To provide Europa Uomo with information about the costs incurred vs benefits of representation.
- To decide which reports will be distributed to the membership by the secretariat or otherwise by means of the website or newsletter.

**Invitations**

An invitation for attendance at a meeting can come from different sources and arrive at different destinations e.g.:
• Sent to the secretariat
• Sent to the Chairman
• Send to a Board member, *ex-officio or former Board member*
• Send to a personal address

If an invitation is received and requires official representation from Europa Uomo the following rules apply:

• The invitation is sent to the secretariat (this enables a central record to be maintained)
• The secretariat sends this to the Coordinator (or the secretary in absence of)
• The Coordinator will assess the request and decide whether or not anybody should attend and, if so, who should attend based on the following criteria (not in any specific order):
  o Scientific skill level (if the meeting appears to require it)
  o Language skills
  o Any prior relationship with the organisation(s) hosting the meeting which might be beneficial
  o Travel costs
  o When a long term commitment is required the Coordinator will seek to appoint a Liaison Officer who will be available as required
  o Personal preferences of the Liaison Officer concerned.

**Costs and fees**

• The cost of transport, accommodation and meals will be paid by the host/sponsor of the conference or by Europa Uomo.
• If there is a royalty or fee, this must be paid to Europa Uomo and not to the attendee.

**Scope of the above described rules**

• These rules only apply when the meeting is attended as a representative of EUOMO.
• It is accepted that Board members or LOCs may receive invitation to attend or speak in their own right or as representing their home organization. The above rules do not apply to such invitations.
• It is possible that a board member or LOC attend in their own right or represents their own home organization and EUOMO in the same meeting. In this case the above described rules apply.

**Changes to the above described rules**

The Board will evaluate the operation of these rules and the reports and make changes if needed in the light of experience.
## Addendum 1: Liaison Officer’s Meeting Report

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### Meeting topics
-  

### Comments from LOC

### Actions needed from Europa Uomo

### A.O.B.

### Cost incurred by Europa Uomo for attendance at this meeting


Activities Europa Uomo (June 2015 – May 2016)

L. Denis
Press Conference: ‘Launch of PerMed’s Strategic research and Innovation Agenda (SRIA) on Personalised Medicine
Brussels, Belgium
02.06.15

J. Dowling
European Medicines Agency: PCWP meeting and PCWP/HCPWP joint meeting
London, United Kingdom
03-04.06.15

Board meeting Europa Uomo (19.06.15)
Europa Uomo Seminar (19-20.06.15)
Europa Uomo General Assembly (20-21.06.15)
Board meeting Europa Uomo (21.06.15)
Warsaw, Poland
19-21.06.15

A. Vancauwenbergh
Meeting L. Fidanidis (office MEP De Backer) European Parliament
Brussels, Belgium
30.06.15

J. Dowling
Health Research Authority EU Taskforce Group meeting on ‘EU guidelines on summaries of clinical trial results for laypersons’
London, UK
06.07.15

A. Deschamps, J. Dowling, K. Mastris
Visit Secretariat Antwerp
Antwerp, Belgium
08.07.15

G. Feick
Foundation of Federal Association of Cancer Patient Support Organizations in Germany
Germany
18.07.15

G. Feick
Support the US All Trials registered and all results reported campaign
http://www.alltrials.net
25.07.2015

K. Mastris
Pan-European Steering Committee meeting: “Continuing momentum for Every Moment Matters”
London, UK
28.07.15

C. Arnold, A. Deschamps, J. Dowling, K. Mastris
Conference Call (Google Hangouts/Skype)
24.08.15

J. Dowling
Health Research Authority EU Taskforce Group meeting on ‘EU guidelines on summaries of clinical trial results for laypersons’
London, UK
26.08.15

Online Europa Uomo Board meeting (conference call)
02.09.15

A. Deschamps
Egan-Roche Workshop
Basel, Switzerland
02-03.09.15

K. Mastris
Expert Group on Cancer Control meeting
Meeting De Lorenzo (ECPC), Knox (Europa Donna) and Costa (ESO)
Luxembourg, Luxembourg
14-16.09.15

European Prostate Awareness Day 2015: ‘Increasing Male Life Expectancy’ (16/9)
Informal meeting on LOC’s (16.09)
Board meeting EUomo (17.09)
Brussels, Belgium
16-17.09.15
C. Arnold, K. Mastris
Virtual advisory board meeting: ‘2015 Patient and Caregiver mCRPC Symptoms Survey: Results and Implication’ (Bayer)
18.09.15

C. Arnold, E. Büchler, E. Kumhofer, K. Mastris
18th ECCO - 40th ESMO congress (+ booth)
Press Event: ‘Results from the International Prostate Cancer Symptoms Survey’ (Bayer) (Mastris/Arnold)
MenWhoSpeakUp Campaign (Mastris)
1st WE CAN (Workgroup of European Cancer Patient’s Network) meeting (Mastris)
ECCO Patient Advisory Committee (PAC) meeting (Mastris)
Vienna, Austria
25-28.09.15

L. Denis
Klaus Meier Annual Award – European Society of Oncology Pharmacists
Vienna, Austria
27.09.15

J. Dowling
Health Research Authority EU Taskforce Group meeting on ‘EU guidelines on summaries of clinical trial results for laypersons’
London, UK
30.09.15

L. Denis, A. Deschamps, B. Dourcy-Belle-Rose, A. Vancauwenbergh
ProstaatKankerStichting Donateursdag (1st meeting GA EUomo 2016)
Ede, The Netherlands
13-14.10.15

ESO conference ‘Personalised Approach to PCa Management’ (12.11.15)
7th European Multidisciplinary Meeting on Urological Cancers (EMUC) (12-15.11.15)
Europa Uomo Board meeting (14.11.2015)
Barcelona, Spain
11-15.11.15

L. Denis
ExtraOrdinary General Assembly European Cancer Patient Coalition (ECPC)
Brussels, Belgium
27.11.15

K. Mastris
**3i Pathways 3rd Stand Alone meeting 2015**  
Berlin, Germany  
28-29.11.15

L. Denis  
**Grote commissie Lionne Venderbos: ‘Active surveillance for prostate cancer: quality of life and risk stratification’**  
Rotterdam, the Netherlands  
02.12.15

A. Deschamps, J. Dowling, K. Mastris  
**Preparatory meeting Review Day February 2016**  
London, UK  
04.01.16

A. Deschamps  
**Prostate cancer European Roundtable (International Centre for Parliamentary Studies)**  
Brussels, Belgium  
26.01.16

E. Büchler, R. Damm, L. Denis, B. Dourcy-Belle-Rose, M. Duncan, C. Waller  
**3rd ESO Conference on Active Surveillance for low risk Prostate Cancer**  
Milan, Italy  
12-13.02.16

A. Deschamps  
**Joint PCWP-HCP meeting (EMA)**  
London, UK  
08-09.03.16

**31st EAU annual congress (11-15.03.2016)**  
**3rd ESO Prostate Cancer Observatory:** Innovation and care in the next 12 months (11.03.16)  
**Europa Uomo Review Strategy meeting** (11.03.16)  
**Europa Uomo Board meeting** (11 & 12.03.2016)  
**Abstract Poster Session 8:** ‘Correlation between stage shift and differences in mortality between the two Study arms of the ERSPC’ (L. Denis, 12.03.16)  
**Europa Uomo Scientific presentations** (13 & 14.03.2016)  
Munich, Germany  
10-15.03.16

K. Mastris,  
**ESO Telephone Conference Masterclass Milan 24-26.06.16**
G. Feick, M. Duncan, M. Lippuner, R. Wotton
1st Telephone Conference Working Group EUomo Action Plan
29.03.16

G. Feick, M. Duncan, M. Lippuner, R. Wotton
2nd Telephone Conference Working Group EUomo Action Plan
08.04.16

Europa Uomo Board meeting
Amsterdam, The Netherlands
27.04.16

K. Mastris
ECCO Patient Advisory Committee
Brussels, Belgium
04.05.16

K. Mastris, G. Feick
International Consortium for Health Outcomes Measurements (ICHOM) 2016 meeting
London, United Kingdom
16-17.05.16

K. Mastris
‘As One for Patients’: Global Patient Advocacy Group Summit (Merck)
Darmstadt, Germany
18.05.16

L. Denis, B. Dourcy-Belle-Rose
3rd European Conference of Oncology Pharmacy: ‘Unity in Diversity’
Dubrovnik, Croatia
19-21.05.16

K. Mastris
Speak Up Campaign & Review meeting (Bayer)
Berlin, Germany
20.05.16

K. Mastris, L. Denis
General Assembly European Cancer Patient Coalition (ECPC)
Brussels, Belgium
03-05.06.16
EUROPA UOMO COMMUNICATIONS

Preface

It is a great pity that shortage of time has unfortunately precluded any discussion of this important paper on Communications, as excellent initiatives like the present Strategy Plan need a carefully thought out communications programme to assure its merited success. This aspect is discussed in some detail in the present document. I am speaking on the basis of a long experience in promotional activities and also as a journalist in Italy.

Introduction to the document

Europa Uomo was set up in 2003 by 3 forward-looking colleagues: Dr Alberto Costa (Italy), Prof. Louis Denis (Belgium) and Tom Hudson (The Republic of Ireland). They rapidly managed to increase the number of national member associations to 10 (Austria, Belgium, Finland, France, Germany, Republic of Ireland, Italy, Sweden, The Netherlands and the United Kingdom), established a 7 man Board, why not 10? which wrote the initial Statutes, established its offices in Antwerp and assigned the various administrative responsibilities with the election of the chairman, the general secretary and the treasurer. Mainly thanks to Prof. Louis Denis and Dr Alberto Costa, it quickly acquired two important initial sponsors such as ESO and OCA. Meetings were nevertheless dominated mainly by organizational and administrative matters.

However, though E.Uomo has successfully grown to now number 23 national association members, little has otherwise changed. The Board has remained composed of the original 7 members and therefore excludes most member associations from the activities proposed by the Board, and the majority of member associations have limited say in the life of this important and ambitious European advocacy group whose principal objective may be summarized as “A world in which no man suffers or dies from prostate cancer”.

The limited co-operation of non Board member organisations is highlighted by the limited co-participation of most associations in the development of the Newsletter, which acts also as a kind of visiting card reporting on Europa Uomo’s ambitious and praiseworthy objectives and activities, as well as progress in medical achievements. The quarterly Newsletter is ideally named “Did You Know?”. Another common shortcoming is the difficulty in carrying out interesting comparative statistical studies of great utility which often require even three reminders to be completed, and lastly, an occasional absence at the annual general assemblies.

The limited expertise in communications was clearly evidenced by two disappointing meetings with members of the European Parliament, which led to no hoped for developments or support, as well as the lasting and complete financial dependence on the generosity of the sponsors, which naturally limits our endeavours due to the need to keep within our budget. This could easily lead to our being acquired, taken over or annihilated by a larger international association with similar goals. Thanks mainly to Prof Louis Denis and our Treasurer, Christian Arnold, at present we have a three year financial commitment by our sponsors, but it would be most opportune to use this time to raise the visibility of E.Uomo by means of a clear-cut
Communications Strategy in order to be seen more as a very useful business partner with similar goals to those of our sponsors. Though financially speaking the immediate future seems quite stable, we must be beware of ongoing Spending Reviews in European countries. In Italy, for example, waiting times for clinical visits are now often enormous and some visits are no longer free even for pensioners.

The Project Committee

A Project Committee composed of Gunter Feick, the undersigned, Max Lippuner and Roger Wotton has produced the draft of a Strategy Plan for approval at the forthcoming GA, which is well introduced by our deputy chairman, André Deschamps. Its first goal is to push for the introduction of early and periodic screening in all represented European countries. Early Detection will surely favour survival, the quality of life of all patients and undoubtedly lead to financial saving by the national public health care systems. It is in fact estimated that the greater part of deaths from prostate cancer are in fact caused by late detection. According to figures kindly provided by our Swedish colleagues, late detection accounts for 5 out of every 6 deaths. The contents of such invitations would surely prove an ideal way to introduce the male population, often unaware of the possible existence of such a predicament, to the personal assistance assured by the 23 national Europa Uomo associations.

This calls for a further carefully prepared and organized third encounter with members of the European Parliament and the European Commission. Ongoing controversy and debate regarding the future use of PSA screening is pointless as, if abandoned, it will definitely be replaced by another probably more accurate form of screening, which may have added values including, for example, the prompt indication as to whether the prostate cancer is dormant or aggressive. In the latter case surgery is more likely to be the best solution. Closer relations with Europa Donna may therefore be advisable, especially in Latin countries where men are more hesitant to broach the problem of the possibility of having a prostate cancer, whereas the women are usually more practical-minded.

As mentioned above, such posted screening invitations could prove an excellent way to promote Europa Uomo as the Patients’ Advocacy Group in each member country, to which potential patients could address themselves in order to decide on what to do, and establish a lasting contact with the same advocacy group which would surely prove of great help, especially from psychological and visibility viewpoints.

However such praiseworthy endeavours will be insufficient to change the limited evaluation of our efforts to assist prostate cancer patients, also bearing in mind that prostate cancer is second only to cardiovascular problems for the premature death of members of the male population.

Based on my own personal experience in the communications world, the quickest and most successful way to improve external visibility is by sensitizing the mass media. Here Tackle in the UK has been most successful, and as a result they are often consulted by the British political and medical authorities. I am at present evaluating how this may be achieved at international level, possibly by means of a public recognition of the existence of such Health Care initiatives in each member country and, for example, a system of awards at both national and
international levels. Any Suggestions would be most appreciated in the hope of being able to achieve this ambitious objective in the near future.

**Substitute top-down management by a bottom-up one**

This leaves unchanged one important organizational aspect which will greatly help to favour a more active participation of all member associations, while remembering to respect present budget limits. That is to replace the present “top-down management style” by a “bottom-up one”. This could be achieved by inviting other member associations to appoint a colleague to participate in the work of the Project Committee which, thanks to Gunter Feick, is very parsimonious with regard to expenses and encounters are mostly effected by phone call sessions followed by informative emails, and the same colleague could be the second member at each annual assembly, and some time could, on that occasion, be dedicated to the Project Committee, which is a body also already foreseen in our Statutes. The creation of the team of LOCs (Liaison Officers) seemed an excellent way to favour more involvement of most national associations. Unfortunately, at least for the time being, its membership is mostly limited to the same national associations which are already represented on the Board. A pity !

**The Newsletter & the Website**

Lastly, we come to the Newsletter which, together with the Website, gives a detailed account of our objectives and activities. Our deputy chairman, André Deschamps, would like us to produce 6 maybe slimmer issues of the Newsletter per year instead of only 4. However this calls for a much more active participation by all member associations which should therefore be required to produce during the course of each calendar year at least 4 articles, reports or brief studies to appear in the various issues of the Newsletter.

Nancy Verbrugghe who runs our website is most anxious not only to include the texts of each Newsletter on the Website, but also to favour the distribution of such news, piece by piece, through the social media such as Facebook. Sweden, for example, has succeeded in developing ongoing communications with Facebook which has enlarged its already commendable direct membership of about 10,000, by a further 12,000.

The effective and lasting success of the Newsletter will greatly depend on its contents, distribution and, consequently, its notoriety. See the attached Italian categorized mailing list which numbers more than 2,000 addressees (see below).

Other publications such as The Bulletin Board and The Prostate Digest, which are principally for internal distribution, are periodically produced and distributed by our secretary John Dowling. They are nonetheless part of Communications.

Having said all the above, our continued success will very much depend on your active and enthusiastic participation in our Communications Programme for the common good, and hopefully lead to a considerable drop in deaths which, at the moment, are chiefly the result of late detection.

Malcolm Galloway Duncan
June 2016
The Italian Mailing

Categories

1) Members equipped with Internet addresses
2) Specialized medical experts
3) Important personalities
4) The Scientific Committee
5) Foundations & Charity Organisations
6) Medical research institutes
7) Local and national medical authorities
8) Actual and potential sponsors
9) Italian and European politicians
10) Italian hospitals specializing in prostate cancer care such as Multidisciplinary Centres & Prostate Cancer Units

The present Italian mailing surpasses 2,000 addresses
CODE OF PRACTICE BETWEEN PATIENTS’ ORGANISATIONS\(^1\) AND THE HEALTHCARE INDUSTRY\(^2\)

PREAMBLE

We fully appreciate and support that our European healthcare systems stand for social equity and solidarity. We maintain that access to limited resources is governed by principles of equality. In a democratic society, patients’ organisations play an increasingly important role. Their work is extremely varied depending on local need, but generally can be divided into two broad categories:

- Raising awareness and advocacy about diseases and health policy issues and how to best maintain health
- Providing support for patients, their families and carers, building capacity within their membership, setting up self help/support groups and sensitising society to equitable sharing of healthcare.

Our governments in Europe are committed to protecting the health of their citizens based on social solidarity, irrespective of age, race, gender, domicile and socio-economic status. This is intended to ensure equality in healthcare and to support the laudable goal of “health for all”.

Increasingly as our populations age in Europe and more and more high-tech treatment becomes available; society will be faced with difficult decisions on how finite resources are fairly allocated within healthcare systems and budgets. Patients’ organisations along with other stakeholders need to be involved in those debates to ensure that policy decisions and actions are fully transparent and adopted in a consensual manner.

Many interests and stakeholders interact in our health systems. Patients’ organisations have the role to ensure that the patients’ voice is heard at all levels of decision making, implementation and monitoring of policies and actions that concern health and healthcare and that the existing system achieves the best outcome for society. Patients’ organisations have an interest in interacting and communicating with these different stakeholders, including industry, in the interest of their patients. Good communication will embrace trust, integrity, honesty and openness.

The valuable and serious work of patients’ groups and the service they provide needs to be recognised, valued and supported. However, most groups are struggling to find sufficient,

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\(^1\) Patient organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or carers represent a majority of members in governing bodies.

\(^2\) The healthcare industry is defined as commercial manufacturers of healthcare products, devices and services, including distributors and wholesalers.
diversified resources, to fulfil their mission and objectives and remain independent, whether funding comes from corporate or public sources.

Funding support for European activities is difficult to obtain. It very much depends on the organisation raising its own financial resources and relying largely on volunteers to carry out the workload. Credibility, transparency and democracy are the most treasured assets of patients’ organisations.

Every group aims to be in a position to carry out its work based on the support of purely altruistic charitable contributions. However, there are hardly any non-commercial sources prepared to fund patients’ groups at a European level. This poses an ongoing challenge to European patients’ groups: the need to develop a strategy which will balance corporate funding with a maximum from other sources.

We owe it to our members and patients across Europe, who have placed their trust in us, to act in a fully democratic, independent and transparent manner, according to the highest standards of good governance. We derive our legitimacy from our membership, our statutes and our democratically elected boards, many of whom are patients, carers or survivors who volunteer their time and expertise.

Patients’ organisations are keen to work in a constructive manner together with all stakeholders to ensure that the credibility of patients’ groups is safeguarded.

For this reason, patient organisations (see list below) have developed the following transparent and robust Code of Good Practice to guide the relations between patient organisations and the industry (including their representatives and consultants). We encourage all patient organisations to adopt this Code when engaging in a dialogue, working partnership, joint initiative, and/or when accepting support from any funding source. We expect all signatories to adhere to this Code which may be revised over time as circumstances demand. This Code does not intend to cover every possible funding opportunity or relationship, but rather to define a set of basic principles and recommendations.

1. RECOMMENDATIONS

We invite patient organisations to adhere to the following recommendations and develop their own Code of Practice along these guiding principles:

1.1 Funding of patient organisation activities
A patient organisation should only accept funds for activities that are consistent with its mission and objectives. Patients organisations that receive funding from any source, including industry or governmental bodies, should at all times remain open, honest and transparent concerning the amounts and sources of such funding. Public documents of patient organisations, e.g.
annual reports and websites, should clearly illustrate such information and be fully accessible. For transparency sake, funders should also receive public acknowledgement for their support.Acknowledgement should be attributed to the funding person or organisation itself, but not to a specific product or project. In line with the EMEA criteria\(^3\), organisations should indicate the percentage of the overall income that each funder (individual person, government organisations, industry, etc) represents.

1.2 **Core funding**
Funds for core activities should always be received on an unconditional basis. To avoid undue reliance on any particular company, such funds should be balanced and diversified as much as possible to avoid conflicts of interest and guarantee independence.

1.3 **Project funding**
Funds or sponsorships for projects can only be accepted without any conditions imposed on the design and conduct of the project, guaranteeing full independence of the patient organisation. Any ensuing publication will be the property of the patient organisation(s) and findings may not be used or quoted by the funder without the explicit permission of the patient organisation(s) involved. No information in relation to the project should ever be used to promote the use of any specific product or business of the funder.

1.4 **Funding of patient organisation events**
Patients’ organisations may accept funds, sponsorship or assistance in kind for their own specific events. Funding should ideally come from more than one source, though it is recognised that this will not always be possible.

Sponsors should not exercise any control over the programme content or choice of speakers at patient organisations’ events.

1.5 **Funding of communication activities**
Patient organisations should mention the names of the sponsors supporting their website or electronic materials. Sponsor logo size and the space dedicated to the mention of the company on the website should be modest in size to avoid being perceived as an advertisement. If logos need to be displayed, their size should be restricted and fully implement national/European legislation\(^4\) into consideration.

1.6 **Involvement with industry sourced websites, publications or leaflets.**
Patient organisations should not be funded for activities aimed at promoting the use\(^5\) of any specific product and/or service. They may contribute to the production of material that relates to the management of a specific condition but should make all best efforts to ensure that no


\(^5\) Any use, including compassionate use of the product, not formally marketed.
specific product or other treatment can be perceived to be recommended by the patient organisation.

2. PATIENTS ORGANISATIONS’ INVOLVEMENT IN ACTIVITIES OF THE INDUSTRY OR OTHER FUNDERS

Regarding activities relating to a healthcare product, device or service, marketed or distributed by the healthcare industry /or still under development, the following measures are highly recommended:

2.1 Promotional activities related to approved prescription medicines

All promotional activities related to approved Rx (prescription) medicines are not permitted within the current EU legislation and respective industry codes of ethics. Patient organisations must ensure that none of their activities can possibly be associated with promotional activities. Genuine interaction/cooperation (e.g. satellite symposiums) is encouraged, provided this is in no way promotional. Patient organisations should be mindful of potential conflicts and unintended consequences and ensure that they strictly adhere to their own independent patient-centred agenda.

Patient organisations should develop a list of the types of activities that can be considered promotional and therefore might cause a conflict of interest and be against the law. The list should include the following:

- Disseminating unbalanced, non-validated or partial information about a product/service which is produced, marketed or provided by a company, whether it funds your organisation or not.

- Being quoted in the company’s corporate communication in favour of, or against a product.

- Participating as speaker/participant in a company event for the launch of a pharmaceutical product (see below §2.4).

- Participating in an ad hoc meeting sponsored by a single company to inform patients on their products. (See below §2.4).

- Agreeing that a company displays/disseminates a patient organisation’s own materials on the company’s exhibition stand at any commercial or trade exhibition or scientific conference.
- Appearing in promotional materials for a certain product of the company (e.g. booklets about a specific medicine) or to testify as a “consumer” of that medicine. Contact information to patient organisations can be included in a separate section.

Patient organisations should develop a full list of the types of activities that could be considered promotional under their national legislation.

2.2 Industry press releases
- Patient organisations and their representatives must be vigilant and refuse to be quoted in industry press releases that relate to a marketed product or a product under development.

- If a patient organisation feels the need to communicate to the media about a product, it should issue its own press release which is clearly independent of industry.

- If a company quotes a patient organisation’s opinion or refers to the organisation’s own communication materials (magazines, publications, web site etc.) without the organisation’s written permission, it is important to object to the company by registered letter with a copy to the company’s national industry association.

2.3 Training organised by industry or a group of companies
If commercial sponsors offer to provide patient organisations with training and capacity building programmes, either about general themes such as “Diseases and the Media”, “Management of a NGO”, or on more product related themes such as “Drug Regulatory Process”, “Cost/effectiveness studies for pricing and reimbursement”, or “How to lobby”, patient organisations must be aware that not all themes are neutral. Some programmes may influence the patient organisation’s or its representatives’ way of thinking. The following check points can help to decide whether to participate in such training programmes:

- The programme is sponsored by several companies, instead of a single one.

- Patient organisations/representatives have been involved in the preparatory phase of the training programme.

At all times it is preferable to find an equivalent programme run by other NGOs or academic institutions and ask the company to sponsor the patient organisation’s participation.

2.4 Participation in conferences or seminars held by industry
- If a patient organisation/representative participates in an industry launch/promotion of a product, no photo must be taken or released without prior authorisation from the

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person/s involved. For clarity and to avoid future complications, it is recommended to make arrangements in writing before the event.

- If a patient organisation/representative participates in an ad hoc meeting sponsored by a single company to inform patients about their products, the former should insist that multiple sources of information from independent third parties are involved to ensure that the information is more balanced. Information meetings without independent experts present could be considered as an infringement of the Pharmaceutical Advertising Directive\(^7\).

2.5 **Guidance for individual compensation**

There are several situations where industry may propose honoraria to a patient organisation’s volunteers or staff members:

- Participation in a meeting or conference organised by the company itself.
- Participation in a meeting or conference organised by a third party.
- Reviewing industry materials, leaflets, protocols etc.
- Consultancy on industry policy, advisory committees etc.

This is current practice for health care professionals. Patient organisations should be considered on an equal basis, and therefore can also receive honoraria for similar circumstances. Patient organisations’ internal policies and agreements should be fully transparent.

2.6 **Involvement in industry-source web sites or other material (DVDs, printed material, etc)**

Patient organisations should refrain from contributing to industry web sites.\(^8\)

2.7 **Disease awareness campaigns by industry**

Disease awareness campaigns can be considered as an indirect form of advertising in some EU countries and therefore against the legislation. Although such campaigns may benefit some patients or the general public, it is unwise of patient organisations to be associated unless the campaign has the backing of the public health authority.

Patient organisations must ensure that any such campaign is not only an industry initiative, but responds to a well characterised public health need, that is agreed and supported by the national and/or European public health authorities.

2.7.1 **Disease awareness campaigns by patient organisations**

When conducting their own disease awareness campaigns, patient organisations must ensure that any information regarding a commercial product mentioned by them must be based on the

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\(^7\) Link to Pharmaceutical Advertising Directive

\(^8\) However, any health-related information that a patient organisation provides on its own website or in its printed materials should be free from any commercial advertising. This should also be stated in the information. The accuracy of the information should be checked by an advisory board that is independent from the commercial interests of the company.
Summary of Product Characteristics (SmPC) or another commercially independent and validated source. This information can be made available by the patient organisation, provided the following conditions are observed:

- Clear statement of how the information was arrived at
- Mention of the validated source of information
- Mention of health professionals / independent experts who have been consulted
- Identification of the Editorial Board who has control, responsibility and oversight
- The patient organisation has a Transparency Policy in place, disclosing funders,

### 2.7.2 Within industry’s editorial responsibility

Commercial organisations wishing to mention the name of a patient organisation should seek prior written authorisation from the latter.

### Conclusion

This document is intended as guidance to help and encourage patient organisations to develop their Code of Practice. It is a dynamic document and will be updated as necessary. Other areas of collaboration between patient organisations and industry need to be addressed (e.g. clinical trials) for which guidance will be developed in a separate document.

Date: 1 June 2009

**Patient organisations endorsing this Code: *  
European Cancer Patient Coalition (ECPC)*  
European Aids Treatment Group (EATG) *  
GAT  
 RETT Syndrome  
 Myeloma Euronet  
 European Organisation for Rare Diseases (EURORDIS) *  
 Alzheimer Europe (AE)  
 European Patient Forum (EPF) *  
 International Diabetes Federation - European Region  
 Lupus Europe

*Patient organisations involved in developing the Code
Thanks to our sponsors

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