

European
Haemophilia
Consortium

Annual Report
2012



Message from the President



The year 2012 was a year of consolidation, improved organisation and solid achievement for the European Haemophilia Consortium (EHC) as we began the journey toward a more professional and decisive organisation.

Haemophilia care in Europe will face many challenges and opportunities in the coming years. We have a tremendous disparity in the availability of treatment and comprehensive care throughout Europe. The EHC data collected during the year demonstrated a per capita FVIII use variation in Europe from 0.1 IU per capita in Armenia to 8.5 IU per capita in Sweden, and within EU countries a 17-fold difference between Sweden and Romania at 0.5 IU per capita.

Despite the widely accepted comprehensive care model, in many countries there are major disparities in access to different components of comprehensive care, including social and psychological support, pain management, genetics and physiotherapy.

Exciting opportunities exist for the availability of new and potentially better factor therapy via longer-acting factor concentrates and the availability of these new products in the future. In addition, more biosimilar factor products create a real possibility for improving access to care on an economic basis for many countries, improving choice and providing a greater range of therapeutic options for many countries and people with haemophilia.

Real barriers exist, however. The requirements of the European Medicines Agency (EMA) Guidelines for Clinical Trials for Factor Concentrates and the European Orphan Drug Legislation may result in a significant delay in the availability of these new products in Europe. We also face the prospect of a possible monopoly situation in the supply of longer-acting factors if market exclusivity is granted to one company. During 2012, the EHC – with the active involvement of our Medical Advisory Group (MAG) – started to engage on these critical issues with Members of the European Parliament (MEPs) and with the EMA. We will do everything we can to ensure that the future prospect of access to more effective treatments for some is transformed into effective access to improved treatment for all. We want to see access to better treatment for people with haemophilia in all European countries.

Our Round Tables grew significantly in profile and importance due to the fact that two of the three Round Tables in 2012 were held in the European Parliament. This trend has now been established and will continue. This gives us more access to key MEPs and increases the profile of the Round Tables and of haemophilia in the European Parliament.

Our Annual Conference in 2012 in Prague was very successful due in part to the fact that we are now proactively planning the events and the programmes on a timelier basis.

Our data collection was greatly improved by the detailed data collection we did on every aspect of comprehensive care in 35 European countries. The response was much greater than for the previous survey in 2009, when 19 countries responded, and demonstrated that our National Member Organisations realised the utility of the data from the previous survey. At the end of 2012 we submitted the data to the journal *Haemophilia* for publication.

Work on the European Haemophilia Network (EUHANET) project element on establishing a system for the classification of haemophilia treatment centres in Europe continued under the auspices of EHC. This is an important milestone as EHC will be fully involved in the establishment of a system for the classification of centres in Europe, which may eventually lead to clarity regarding the services provided in each country, assist in better organisation of care and perhaps by external audit, also assist in establishing a quality system for centres.

In terms of the organisation, we came a long way in 2012. The challenges facing haemophilia care in Europe and haemophilia patient organisations are large and complex. The EHC cannot solve all problems and deal with all challenges but we can prioritise actions and policies that will have the greatest impact on the greatest number of people with haemophilia and on national organisations. Our proactive work with the EMA, our data collection, our Round Tables in the European Parliament are all designed to deal with these challenges. Our advocacy support for countries (including Latvia and Poland in 2012) and our increased engagement with NMOs demonstrate our commitment to assist NMOs to develop the capacity to better advocate nationally.

The EHC is a small organisation with limited resources. To have the maximum impact, we must plan what we do carefully and target resources accordingly. In 2012, we took a major step toward professionalism by hiring Amanda Bok as Senior Policy Officer and by year-end as CEO. The EHC now has a CEO and an additional part-time staff member. This is a good beginning. Working with the small staff team, the Steering Committee and our Medical Advisory Group, we will redouble our efforts to ensure that the EHC continues to develop strategically and to represent our National Member Organisations. We made a good beginning in 2012 and we look forward to achieving even more in 2013.

EHC Activities

Round Table of Stakeholders

The European Haemophilia Consortium (EHC) held three successful Round Tables in 2012, which attracted close to 125 participants, including Members of the European Parliament (MEPs), the European Commission, the European Medicines Agency (EMA), patient groups, clinicians and industry as well as active participation from almost a dozen of the EHC's National Member Organisations (NMOs).



Patrick Thomenius of the Swedish Haemophilia Society gives his presentation.

The first Round Table, "Economics and Health Outcomes in Haemophilia," was held in March and focused in particular on the Swedish Health Technology Assessment (HTA) Report and its importance as a new European standard and model in a changing economic climate.

The second Round Table was held in June in the European Parliament and addressed "Clinical Trials." Held at a time when novel, potentially historic new treatment products came into latter stages of development, it attracted more than 50 participants, including many MEPs, and set the stage for a critical advocacy campaign.



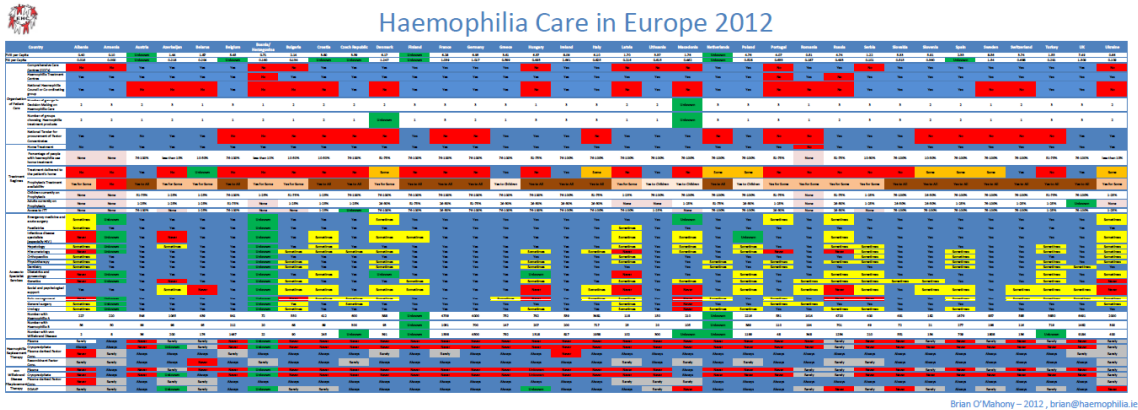
More than 50 people attended the Round Table hosted by Nessa Childers MEP in the European Parliament on the topic on Clinical Trials.



Hosted by Miroslav Mikolasik MEP and Nessa Childers MEP, the event attracted 40 people.

The third Round Table was held in October in the European Parliament and featured the "Results of an EHC Survey of 35 European Countries," which unveiled critical scientific data regarding Europe-wide adherence to the Principles of Haemophilia Care.

Data Collection and Analysis



In 2012, the European Haemophilia Consortium (EHC) followed up and expanded on the 2009 Survey of Haemophilia Care in 19 European Countries. It reached more countries and included more in-depth questions. The 2012 survey was completed by 35 of the 43 EHC National Member Organisations, including the 19 countries that had responded to the previous survey in 2009. The 2012 data gave us a detailed picture of the current situation in relation to treatment and care in these 35 countries. There are major disparities in relation to access to replacement therapy and access to the various elements comprising comprehensive care. The data will be an invaluable advocacy tool for National Member Organisations who seek to initiate, improve or maintain treatment or care in their country as it gives them a direct basis for comparison with other European countries.

Haemophilia The Official Journal of the World Federation of Hemophilia
European Association for Haemophilia and Allied Disorders and the Hemostasis & Thrombosis Research Society

Haemophilia (2013), 1-9 DOI: 10.1111/hae.12125

ORIGINAL ARTICLE

Haemophilia care in Europe – a survey of 35 countries

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Summary: A questionnaire was circulated in 2012 to national haemophilia patient organizations in Europe affiliated to the European Haemophilia Consortium (EHC) and the World Federation of Hemophilia (WFH) to seek information about the organization of haemophilia care and treatment available at a national level. The 35 responses received highlighted major differences in the availability of treatment and care. There was a wide range in factor VIII consumption with usage ranging from 0.20 IU per capita in Armenia to 5.56 IU per capita in Sweden (median IU per capita). The decrease in health budgets in many countries was not matched by decreases in use of FVIII per capita. In the 19 countries that responded to the previous survey, there was a significant improvement in access to prophylaxis and home treatment.

Keywords: Organisation, Specialist Care, Treatment

An article on the survey has been published in 'Haemophilia'

EUHANET

Building on the success of EUHASS, in 2012 the European Haemophilia Consortium (EHC) partnered again with the University of Sheffield and four other organisations on the European Haemophilia Network (EUHANET) project, a three-year project supported by the European Commission to standardise and certify the delivery of haemophilia care throughout Europe.



Home page of EUHANET

EHC Conference

Held in October in Prague, Czech Republic, the European Haemophilia Consortium (EHC) Conference attracted close to 300 participants and was widely considered a success. It featured a wide-ranging scientific program and more than 20 speakers on topics ranging from:

- Inhibitors
- Orthopaedics and physiotherapy
- Life stages and haemophilia
- Prophylaxis
- Minimising bleeding episodes in haemophilia
- Similarities and differences between haemophilia A and B
- Understanding health outcomes focusing on haemophilia
- Haemophilia in Europe



Logo of the EHC-conference

The event organisation was outsourced and professionalised, and the date for all future conferences was set for the first weekend of October.

WFH World Congress



The EHC stand at the WFH Congress.

The Steering Committee and National Member Organisations of the European Haemophilia Consortium (EHC) participated in the World Congress of the World Federation of Hemophilia (WFH) in Paris in July. For the first time, the EHC had a stand, which allowed the organisation to showcase its mission, objectives and activities, and to raise its profile with participants from outside of Europe. The EHC information was provided in

Russian, French, Italian, Spanish, German and Dutch.

Advocacy

Given the economic strains on Europe, 2012 continued to be a challenging year for many National Member Organisations (NMOs). The European Haemophilia Consortium (EHC) provided targeted, country-specific advocacy support to half a dozen NMOs through country missions, government meetings, strategic letter-writing campaigns and interviews with the press. It provided support

*Brian O'Mahony and the
Minister of Health of Latvia.*



in areas of national tenders, procurement systems and the adequate supply of factor concentrates in hospitals.



On a policy level, and following from its June Round Table on “Clinical Trials,” the European Haemophilia Consortium (EHC) launched a strategic campaign

with the European Medicines Agency (EMA) regarding its Guidelines on Clinical Investigation of Recombinant and Human Plasma-Derived Factor VIII and FIX Products. The objective of the campaign was both to seek derogation from the new paediatric requirements as well as to advocate for the inapplicability of orphan drug status for new, longer-acting products. The EHC’s actions began in 2012 with a strategic and targeted letter-writing campaign with the EMA, EUCERD and Members of the European Parliament.

Communications

Newsletters and Public Policy Reports

In addition to its three annual newsletters, the European Haemophilia Consortium (EHC) also published 12 monthly reports focused specifically on EU policies and developments. These EU-focused reports provided an analysis of current and upcoming policies and negotiations with the objective of keeping National Member Organisations and the Medical Advisory Group abreast of relevant EU-related developments.



Russian translation



In order to meet the needs of its large Russian-speaking membership, the European Haemophilia Consortium (EHC) continued and completed the Russian translation of its website and many relevant publications.

Katia Krichkevitch, responsible for Russian translation, and Steffan Hartwig, web administrator at the EHC stand

Internal Structure

Changes to Staff and Leadership

The Steering Committee of the European Haemophilia Consortium (EHC) saw a change of composition with the departure of Uwe Schlenkrich from Germany, who stepped down for health reasons, and the co-option of Chris James from the United Kingdom and Radoslaw Kaczmarek from Poland. Alain Weill was elected as President of the World Federation of Hemophilia (WFH) and thereby transitioned from full Steering Committee member to ex-officio member.

The EHC brought in a Chief Executive Officer in December with the mandate to professionalise the organisation, both internally and externally, and to help the organisation grow in a new direction.



*Uwe Schlenkrich,
SC Member since 2007*

*Chris James, former
CEO of the UK
Haemophilia Society*

*Radek Kaczmarek,
member of the
board of the Polish
Haemophilia
Society*

*Alain Weill, elected
President of the
WFH*

*Amanda Bok, CEO of the
EHC*

EU Public Policy and Relations



In 2006, the European Haemophilia Consortium (EHC) started working with external EU public policy consultants. In 2012, the EHC began to work with Rohde Public Policy to continue the work of the Round Tables, to produce EU Policy newsletters for National Member Organisations and to assist with setting up the advocacy program with EU institutions and Members of the European Parliament.

Partners and Volunteers

The European Haemophilia Consortium (EHC) is grateful for the valuable support of its partners and volunteers. Special thanks go to:

Volunteers:



Declan Noone, for his contribution to the 35 European Country Survey.



Katja Kirchkevitch, for her Russian translation of the website and other EHC materials.



Steffen Hartwig, for supporting the EHC's website as its administrator.



Uwe Schlenkrich, for his news updates and daily contribution to the EHC's website.

Medical Advisory Group:



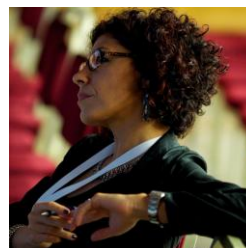
Prof Angelika Batorova, Professor and Medical Director at the National Haemophilia Center, University Hospital, Bratislava



*Dr Gabriele Calizzani
EHC Steering Committee Representative*



Prof Paul Giangrande, Consultant haematologist at the Oxford University Hospitals NHS Trust and Director of the Oxford Haemophilia Centre



Prof Flora Peyvandi, Associate Professor of Internal Medicine at the University of Milan



*Prof Alessandro Gringeri,
Associate Professor of
Internal Medicine at the
University of Milan,
Council Member of the
Interdepartmental
Centre of Pharmaco-
economics and Outcome
Research of the
University of Milan*



*Prof Wolfgang
Schramm,
Head of Department of
Haemostasis and
Transfusion Medicine
at the University
Hospital of Munich*

Steering Committee Members:



*Brian O'Mahony,
President*



*Jordan Nedevski,
Vice-President Finance*



Gabriele Calizzani



Chris James



Radoslaw Kaczmarek



Gabor Varga

Donors

The European Haemophilia Consortium (EHC) is grateful for the generous support of its donors:

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From Nature for Life



Financial Report

The year 2012 was a positive and productive one for the European Haemophilia Consortium (EHC) in terms of its finances and its financial management.

The final 2012 figures show significantly higher turnover for the organisation than that of earlier years and the end of year income exceeded the EHC's budgeted expectations. The financial result of the Annual Conference in Prague also exceeded original expectations and contributed significantly to our general budget. The additional income over budget was dedicated to securing a new professional staff resource that started as Senior Policy Officer in September and became Chief Executive Officer in December.

In 2012 the EHC introduced strong new financial policy rules and regulations, and revised the financial governance rules for the EHC Steering Committee (SC), staff and volunteers. To ensure financial transparency, the EHC introduced and rolled out monthly financial reports to the SC. The EHC also committed to conducting a voluntary and external audit in accordance with Belgian Audit Standards on an annual basis, beginning in 2012 (attached in this report).

In further efforts to increase transparency and clarity, in 2012 the EHC developed new and more detailed budget lines for 2013. For this reason and on an exceptional basis as the EHC transitions into a new budget presentation structure, the 2012 actuals and 2013/2014 budgets are presented separately. Similarly, in 2012 for the last time the financial reporting for the EU Project, EUHANET, is presented separately from the overall EHC budget. This too, shall be merged from 2013 onwards.

Finally, in efforts to stabilise the EHC's financial income, in 2012 we revised our financial support policy and introduced the Corporate Giving Program, effective as of 2013, in order to secure a small but critical amount of unrestricted funding that could be applied towards the sustainability of our organisation and our programmes.



Jordan Nedevski
Vice President Finance

European Haemophilia Consortium

Financial Report 2012

		2012 Finals	2012 Budget
Income			
1	NMO Membership	8,370	8,400
2	Corporate Sponsorship Round Tables	132,000	130,000
3	EHC Annual Conference	59,500	40,000
4	EU Projects	19,792	
5	Specific Projects	17,825	15,000
6	Office Sublet IPOPI	3,740	4,080
7	Bank Interest	718	500
8	Miscellaneous	17,415	
9	Extraordinary income	80,000	
10	TOTAL	339,361	197,980
Expenditure			
1	Steering Committee Travel Costs	15,328	15,000
2	SC Meetings	14,473	10,000
3	Communication Costs	1,311	4,000
4	Office and Staff Executive Staff	25,430	
5	Staff Wages	47,212	45,000
6	Rent and Utilities	7,200	7,200
7	Office Equipment	3,298	1,000
8	Communication Costs	1,633	2,000
9	Professional Services Legal and Other Services	2,920	12,000
10	Accounting	4,003	
11	Audit	2,094	
12	EHC Promotion	107	
13	Website	1,649	
14	Publications	309	
15	Translation	0	
16	Round Tables Consultant	51,418	50,000
17	Venue and Travel	22,524	22,000
18	EU Projects	0	
19	Data Collection Project	4,594	5,000
20	EHC Conference	1,144	
21	Specific Projects	0	15,000
22	Insurance	776	600
23	Membership Fees	350	1,500
24	Bank Charges	295	500
25	Other Costs	217	
26	Miscellaneous	17,415	5,000
27	Written off debts	80,000	
	TOTAL	305,701	195,800
	Surplus	33,660	2,180

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**Report of the Auditor to the Members
of the council committee of the ASBL**

Consortium Européen de l'Hémophilie
0887.106.966

Rue du Marché aux Herbes 105/14
1000 Brussels

Financial Statements at 31 December 2012

We have audited the accompanying financial statements showing a balance sheet total of 197.093€ and an excess of income over expenditure of 33.660€ which have been prepared under the accrual accounting method.

This report forms a whole with the audited financial statements and may not be published.

The Council's officers are responsible for the preparation of financial statements. It is our responsibility to form an independent opinion, based on our audit, on those statements and to report our opinion to you.

We conducted our audit in accordance with Belgian Auditing Standards. An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosures in the financial statements. It also includes an assessment of the significant estimates and judgements made by the officers in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Council's circumstances, consistently applied and adequately disclosed.

We planned and performed our audit so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement. In forming our opinion we also evaluated the overall adequacy of the presentation of information in the financial statements.

The financial statements give in our opinion – on the bases of the accrual accounting method – a true and fair view of the state of the Council's affairs as at 31 December 2012 and of its excess of income over expenditure for the year then ended.

Limal, June 21st 2013

Stéphane Rosier
Certified Public Auditor



**Balance
Exercice 2012**

EUR

01/01/2012 - 31/12/2012

Entire outline

<u>FIXED ASSETS</u>		20/28	1.461,70
III. Tangible assets (note III)		22/27	111,70
C. Furniture and vehicles		24	111,70
1. Fully owned by the association		241	111,70
241000 COMPUTER EQUIPMENT			335,02
241009 DEPRECIATION /COMPUTER EQUIPMENT			(223,32)
IV. Financial assets (note IV and V)		28	1.350,00
C. Other financial assets		284/8	1.350,00
2. Amounts receivable and cash guarantees		285/8	1.350,00
288000 CASH GUARANTEES			1.350,00
<u>CURRENT ASSETS</u>		29/58	195.631,38
VII. Amounts receivable within one year		40/41	67.700,82
A. Trade debtors		40	(14.760,00)
400000 CUSTOMERS			1.740,00
404000 INCOME RECEIVABLE			63.500,00
409000 AMOUNTS WRITTEN OFF			(80.000,00)
B. Others amounts receivable		41	82.460,82
411200 C/A V.A.T. ADMINISTRATION			2.460,82
416000 SUNDRY AMOUNTS			80.000,00
IX. Cash at bank and in hand		54/58	67.405,59
550000 KBC 736-0015727-77 (SIGHT ACCOUNT)			1.629,01
550001 KBC 746-0011961-78 (SAVING ACCOUNT)			36.594,93
550002 KBC 746-0001443-54 (COMPTE EPARGNE EUHAN			29.081,38
550003 KBC 736-002608-76 (COMPTE A VUE EUHANET)			100,27
X. Deferred charges and accrued income (note VII)		490/1	60.524,97
490000 DEFERRED CHARGES			1.024,97
491000 ACCRUED INCOME			59.500,00
Total assets			197.093,08

**Balance
 Exercice 2012**

EUR		01/01/2012 - 31/12/2012	Entire outline
SOCIAL FUNDS		10/15	86.035,15
I. Associative funds		10	9.419,96
B. Permanent means		101	9.419,96
101100 PERMANENTLY FUNDS IN CASH			9.419,96
V. Accumulated profits		140	76.615,19
140000 ACCUMULATED PROFITS (LOSSES -)			76.615,19
AMOUNTS PAYABLE		17/49	111.057,93
IX. Amounts payable within one year (note X)		42/48	16.918,92
C. Trade debts		44	8.030,31
1. Suppliers		440/4	8.030,31
440000 SUPPLIERS			(3.622,36)
444000 INVOICES TO BE RECEIVED			11.652,67
E. Taxes; remunerations and social security		45	8.888,61
1. Taxes		450/3	1.579,48
451800 VAT TO BE PAID /REGULARIZATIONS			14,75
453000 TAXES WITHHELD			1.564,73
2. Remunerations and social security		454/9	7.309,13
454000 SOCIAL SECURITY CONTRIBUTIONS			1.589,67
455000 REMUNERATIONS TO BE PAID			(22,78)
456000 HOLIDAY PAY			5.742,24
X. Accrued charges and deferred income		492/3	94.139,01
492000 ACCRUED CHARGES			1.001,63
493000 DEFERRED INCOME			63.500,00
493010 DEFERRED INCOME - EUHANET			29.637,38
Total liabilities			197.093,08

**Balance
Exercice 2012**

EUR 01/01/2012 - 31/12/2012 Entire outline

INCOME STATEMENT		
I. Operating income	70/74	260.692,58
A. Turnover (note XII;A)	70	349,00
700300 OTHER		349,00
D. Contributions; donations; legacies and subsidies (note XII;B)	73	231.671,97
730000 NMO MEMBERSHIP FEES		8.370,00
730010 SPONSORSHIP EHC/OTHER		121.000,00
730020 ROUND TABLE MEMBERSHIP		11.000,00
730030 RESTRICTED GRANTS		17.825,43
730040 EHC ANNUAL CONFERENCE		73.476,54
E. Other operating income	74	28.671,61
740000 OTHER OPERATING INCOME		3.740,00
740010 EUHANET PROJECT		4.775,02
740020 EUHASS PROJECT		19.791,87
743900 SOCIAL WITHHOLDING TAXES REFUND		364,72
II. Operating charges	60/64	(307.325,70)
B. Services and other goods	61	(180.939,39)
610100 OFFICE RENT		(7.200,00)
612130 POSTAGE		(308,92)
612140 MOBILE COSTS		(1.673,11)
612150 TELEPHONE AND INTERNET COSTS		(1.569,77)
612300 OFFICE EQUIPMENT		(1.347,92)
613100 FIRE INSURANCE (BUILDING)		(1.034,79)
613212 ACCOUNTANCY FEES		(6.097,13)
613216 CONSLUTANCY		(16.078,89)
613410 TRAVEL COSTS		(12.580,65)
613490 SC MEETING		(13.178,31)
613500 MEMBERSHIP FEES		(339,50)
613900 ROUND TABLE - INTEREL FEES		(69.495,39)
613910 ROUND TABLE - EXPENSES		(19.334,79)
613920 CONTINGENCY		(14.796,26)
614000 PROMOTION		(5.697,74)
614010 PROMOTION - PUBLICATION		(837,00)
615090 EU PROJECT VARIOUS EXPENSES		(4.775,02)
615100 SPECIFIC PROJECT		(4.594,20)
C. Remuneration; social security costs and pensions (note XII;C2)	62	(46.252,72)
620200 GROSS SALARIES BELGIUM		(35.431,13)
621200 O.N.S.S. CONTRIBUTIONS		(7.679,78)
623000 OTHER PERSONNEL CHARGES		(1.046,88)
623200 EXPENSES REFUND EMPLOYEES		(943,45)
623900 MEAL VOUCHERS		(1.040,16)
625000 PROVISION PECULE DE VACANCES		(5.742,24)
625010 REPRISE PROVISION PECULE DE VACANCES (-)		5.630,92
D. Depreciation of and other amounts written off formations expenses; intangible and tangible fixed assets (-)	630	(111,66)
630200 DEPRECIATION OF TANG. FIX. ASS		(111,66)
E. Amounts written off stocks; contracts in progress and trade debtors (appropriations -; write-backs +)	631/4	(80.000,00)
634000 AM. WRITTEN OFF TRADE DEBT -1		(80.000,00)

Balance
Exercice 2012

EUR		01/01/2012 - 31/12/2012		Entire outline	
G. Other operating charges (-)	640/8				(21,93)
643105 WITHHOLDING TAXES /INTERESTS			(21,93)		
III. Operating profit	70/64				
Operating loss	64/70				(46.633,12)
IV. Financial income	75				740,04
B. Income from current assets	751				728,39
751000 FIN INCOME FROM CURRENT ASSETS			728,39		
C. Other financial income (note XIII; A)	752/9				11,65
754000 EXCHANGE DIFFERENCES			11,65		
V. Financial charges (-)	65				(446,77)
C. Other financial charges	652/9				(446,77)
654000 EXCHANGE DIFFERENCE			(50,30)		
654010 PAYMENT DIFFERENCES			(27,86)		
657000 BANK CHARGES			(290,92)		
657200 OTHERS FINANCIAL COSTS			(77,69)		
VI. Profit on ordinary activities	70/65				
Loss on ordinary activities	65/70				(46.339,85)
VII. Extraordinary income	76				80.000,00
E. Other extraordinary income (note XIV; A)	764/9				80.000,00
764000 OTHERS EXTRAORDINARY INCOME			80.000,00		
IX. Profit for the period	70/66				33.660,15
Loss for the period	66/70				