Transparency: Working with Patient Groups -Theory into practice

Paul Woods



Industry support for increased transparency

Necessary for company and industry reputation

Leaders get positive publicity

Responding to critical commentaries on our activities

Let's base the debate on facts

Compliance with code and regulatory requirements

> now and in the future

Working with patient groups -Roche

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Working with patient groups



Roche is proud of its history of working with patient groups. The company wishes to ensure that collaborations reflect common values of integrity, maintenance of independence, respect, equity, transparency and mutual benefit. These values act as guiding principles for the guidelines.

Patient groups are increasingly important partners for Roche. We share an interest in helping patients

understand and manage their disease, including having timely and equitable access to the treatment they need. Roche is able to contribute a range of skills, expertise and knowledge which might enhance the patient organisation's activities.

Patient groups are important in helping Roche to gain a greater understanding of what it is like to live with a disease, the challenges facing patients and their families and the role that drug therapies play in the management of the disease. They also provide the company with an insight on how to support healthcare professionals who in turn support patients.

Roche has established a set of guidelines which should underlie the relationship between Roche and any patient group. Any agency working with patient groups on behalf of Roche must also follow these guidelines.

Through implementing these guidelines, Roche will move to a role as a true partner working in collaboration with the patient group, where the patient group knows explicitly what it can expect from Roche.

In 2008 Roche provided support to > a range of patient group organisations, globally.

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Related Links

- > List of Sponsored Patient Groups
- > Products
- > Stakeholder Dialogue
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 Working with Patient Groups Positions

- Corporate Principles
- Corporate Principles

Working with patient groups -Roche

8 http://www.roche.com/corporate_responsibility/patients/patient-groups/patient-groups-list.htm Global Web Site Roche Worldwide Deutsch Site Map Contact + Text Size -Roche Home About Roche Products Corporate Responsibility Research & Development Media Investors Careers Q Corporate Responsibility > Patients > Patient Groups > Sponsored Patient Groups Sponsored Patient Groups In 2008 Roche provided support to a range of patient group organisations, globally: Select division: Please select: Please select: . . Activity Recipient A.P.A.T. (Assistance to transplanted Collaboration to provide patient support (campaigns, world Argentina Pharma patients) kidney day, disease awareness, bioequivalence comparisons, patient conferences) A.R.S.I. (R.A patients) Administration, educational material, patient supportive Argentina Pharma activities ACIAPO (Association of Integral Breast cancer awareness campaigns, free mammography Argentina Pharma Assistance for Oncology Patients) Argentina Pharma Adolescentes x la Vida (Teens for Life) Integral adherence support to new/on Fuzeon patients Argentina Pharma Apostar a la Vida (Bet for Life) Educational grants APPANER (PRO Partnership help for Support to adherence & education for CF patients and their Argentina Pharma parents of CF Children) families Argentina Pharma Fundación Pacientes de Cancer de Community Awareness Activities during November Pulmón, (Lung Cancer Patients Foundation) Fundación Principios (Principle Argentina Pharma Collaboration to stimulate disease awareness (chronic kidney Foundation) disease) for patients and their relatives Argentina Pharma Fundación Sosten (Support Awareness activities Foundation) HUESPED Foundation Argentina Institution dedicated to inform and educate about AIDS, Pharma helping the inquirer, doctors and patients Argentina Pharma IBIS Foundation for Research on HIV / Support to ARV treatment adherence AIDS Argentina Pharma Linformas Argentina (Lymphomas Collaboration to run awareness campaigns to NHL patients Argentina) and patient relatives MACMA (Breast Cancer Patients Educational grants Argentina Pharma Movement) Australia Pharma All About Acne Core support for education about acne: Support to produce All About Acne DVD for schools program Part-industry sponsorship for 'Parliamentary Friends of Australia Pharma Arthritis Australia Arthritis' launch; educational booklet for consumers; and website upgrade



Working with patient groups -Roche

Roche Position on Working with Patient Groups

Interactions with Patient Groups - Integrity and Transparency

Pharmaceutical companies are increasingly partnering with patient groups on projects ranging from disease awareness campaigns to clinical trial design and implementation. Different stakeholders, e.g. governments, the public and the media, are calling for integrity and transparency in terms of how the industry interacts with these groups, including the provision of financial and in-kind support. Roche understands and fully supports the request. for integrity and the need for public transparency and consistently high standards of conduct in any interaction with patient groups.

Roche

Values added by Patient Groups

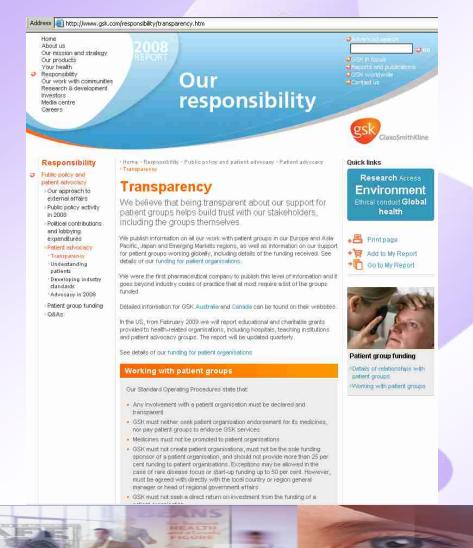
Patient groups provide patients with support and information on how to live with their disease or condition, represent patient views and campaign for change on Issues that affect patients' lives. Some carry out vital research into the causes and potential treatments for specific conditions. Patient groups play also a crucial role by sefeguarding the rights of patients. Patient groups offer Roche valuable insights that influence our work around the world and across therapeutic areas - from drug development through regulatory approval and reimbursement into product launch and marketing.

Roche's Vision and Position

Roche's commitment to patients is demonstrated in many ways throughout the Roche Group and is fundamental to what we believe to be Roche's most significant contribution to society: to create, produce and market innovative solutions of high quality for unmet medical needs. Hence, Roche and patient groups share a common vision to improve patient's access to innovative treatments and services. Roche is convinced that an open dialogue and transparent exchange of information among all the stakeholders in the healthcare community is vital to advancing access and healthcare delivery to patients. Building and sustaining relationships with patient groups is an efficient way for Roche to come up to its patient commitment and its commitment and responsibility to society as a whole.

Roche works with a wide range of patient groups in a variety of different disease areas, such as encology, virology, inflammatory diseases, metabolic diseases and diseases of the central nervous system as well as in the area of disgnostics technologies. Our idea of innovation in healthcare centers on patient needs and benefits. Best placed to identify patients' needs are the patients themselves supported by their doctors, families or carests. Therefore, patient groups are important partners for Roche. Interacting with patient groups enables Roche to learn about unmet patient needs; such valuable information will guide us in the development of new medicines. Our raim is to support the volo of patients and to foster a constructive Roche Working with patient groups: Good practice guidelines

Working with patient groups – GSK



Working with patient groups

Our Standard Operating Procedures state that:

- Any involvement with a patient organisation must be declared and transparent
- GSK must neither seek patient organisation endorsement for its medicines, nor pay patient groups to endorse GSK services
- Medicines must not be promoted to patient organisations.
- GSK must not create patient organisations, must not be the sole funding sponsor of a patient organisation, and should not provide more than 25 per cent funding to patient organisations. Exceptions may be allowed in the case of rare disease focus or start-up funding up to 50 per cent. However, must be agreed with directly with the local country or region general manager or head of regional government affairs.
- GSK must not seek a direct return on investment from the funding of a patient organisation
- Any information on GSK pipeline compounds must be factual and nonpromotional and provided to patient organisations as part of a scientific dialogue
- It is acceptable for GSK clinical trials or medical personnel to work with patient organisations to ensure optimal clinical trial recruitment, and to consult them on clinical trial design and protocols
- GSK must not directly sponsor patient organisation representatives to attend medical congresses, conterences and other healthcare professional events. Exceptions include where the representative is invited to speak at the conference or where the medical congress has a specific workstream designed for patients. GSK may sponsor representatives to attend nonmedical congresses
- GSK may pay a modest honorarium or speaker fee to the patient organisation that an advisory board member or speaker represents.
- Any third party working for GSK on a given project must be fully transparent about this relationship when interacting with a patient group on the project.

Working with patient groups -**GSK**



Responsibility

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US groups

: Q&As

Patient group funding

Patient groups provide people with support and information on how to live with their disease, represent patient views and campaign for change on issues that affect patients' and carers lives. Some also carry out vital research into the causes and potential treatments for specific conditions.

We work with a wide range of patient groups in a variety of different disease areas, such as cancer, asthma, diabetes and multiple sclerosis. Our interest in patient advocacy is about understanding patient needs and their illness. Our aim is to support the voice of patients and to foster a constructive healthcare debate for all stakeholders'. GSK and patient groups share a vision to improve patient's access to effective treatments and services.

We are committed to working with patient groups at the highest levels of transparency and ethical standards. Key principles of our work with patient groups are trust and mutual respect. We enter into relationships committed to sustaining a long-term working relationship, which also reinforces the credibility and independence of patient groups.

Global principles for working with patient groups

- · The independence of patient groups, of their political judgement and of their activities shall be assured.
- In all co-operative matters, transparency is vital
- Any joint policies undertaken between patient groups and GSK shall be based. on mutual respect and trust
- . We shall refrain from using undue influence to promote specific medicines or services
- . In any working with patient groups we will always comply with local laws/governance.

+ Home - Responsibility - Public policy and patient advocacy - Patient group funding **Ouick links**

Research Access Environment Ethical conduct Global health



In the community What we do *Find out more about our work in the community

Address 🗿 http://www.gsk.com/responsibility/patient-groups/european-patient-organisations.htm



Home + Responsibility + Public policy and patient advocacy + Patient group funding Pan European drouns

Patient group funding

During 2008, we provided financial support to the following pan European patient

Alzheimei: Europe Eurordis, European Organisation for Rare Diseases Europa Donna: European AIDS Treatment Group European Cancer Patient Coalition European Cervical Cancer Association European Coalition of Positive People European Federation of Allergy and Airways Diseases Patients Associations European Federation of Neurological Associational European Headache Alliance European Institute of Women's Health European Multiple Scierosis Platform European Parkinson's Disease Association European Patients' Forum Global Alliance of Mental Illness Advocacy Networks - Europe Genetic Interest Group Institute for Neuroaeanthocytosis International Diabetes Federation - Europe International Osteoporosis Foundation Pulmonary Hypertension Association - Europe Find out more about the groups we supported in 2006 and 2007

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Working with patient groups – GSK

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Patient group funding

European Patients' Forum (EPF)

The vision of EPF is to ensure that the European patient voice is at the centre of heathroare. EPF works as a catalyst for advocating a strong European patient voice; enabling patient groups to join forces and develop alliances. They work with like-minded stakeholders and with the EU institutions.

We have supported this organisation since 2005.

During 2008:

- . We gave an unrestricted grant of 640,000 to support their activities
- We also gave EPF two honorana of 6500 to support the attendance of the Director General at GSK's European Health Advisory Board meetings
- In addition we gave an educational grant of €40,000 to support EPF's annual Conference planned for December 2009

Our support represents 13:49 per cent of their overall income

During 2007:

- . We gave an unresticted grant of €40,000 to help them with their activities
- We gave an educational grant of €36,250 to help support EPF's 2007 spring conference (second payment)
- We gave an educational grant of €50,000 to support EPF's spring conference planned for April 2008.
- We also gave EPF two honoraria of \$500 to support the attendance of the Director General at GSK's European Health Advisory Board meetings.

Our support represented 25.3 per cent of their income overall.

In 2006

- We provided €35,000 as an unrestricted grant to help support their activities.
- We gave an additional unrestricted grant of €36,250 to support EPF's spring conference planned for 2007.
- We also gave EPF an honorarium of €500 to support the attendance of the Director General at GSIN's European Health Advisory Board meeting.
- Our support represented 17 per cent of their income overall.



In the community What we do Find out more about our work in the community

Working with patient groups – GSK USA

litp://us.gsk.com/docs-pdf/responsibility/gsk-grants-1q2009.pdf

e a Copy 🚔 🤮 🖓 Search 🖑 It Select 📷 🔍 + 🚺 💀 😕 🥬 🕞 💀 🗁 Grants & Charitable Contributions to US Based Healthcare Organizations 1st Quarter 2009 Project Description tion Name Amos Acquired Immunodeficiency Syndrome Action Incorporated -Acquired Immunodeficiency Syndrome Action Baltimore Community Forums \$10,000 Baltimore ACVP/STP Coalition for Veterinary Pathology Fellows Veterinary Pathology Training Program \$63,77 ACVP/STP Coalition for Veterinary Pathology Fellows Veterinary Pathology Training Program \$53,949 \$63,828 ACVP/STP Coalition for Veterinary Pathology Fellows Veterinary Pathology Training Program Albany Medical College 10th Annual Human Immunodeficiency Virus Clinical Care Symposium \$5,000 Alex's Lemonade Stand Foundation Lemon Ball 2009 Platinum Sponsorship \$10,000 2009 Research Roundtable Membership \$50,000 Alzheimer Association American Academy of Continiung Medical Education \$50,000 American Conference for the Treatment of Human Immunodeficiency Virus Educating Physicians in Their Communities: Immunization Education \$20,000 American Academy of Pediatrics - Georgia Chapter 37th Annual Conference Session - Interactive Case Studies in Asthma American Academy of Physician Assistants \$6,500 \$40,000 American Association for Cancer Research 2009 Annual Meeting - Clinical Scholars Award American Association for Cancer Research 2009 Annual Meeting - Elion Award \$60,000 American Association for the Study of Liver Disease New Challenges - New Solutions Campaign \$100,000 Cardiovascular Disease Risk in Patients with Type 2 Diabetes: A Call to Action for the American Association of Clinical Endocrinologists \$129,859 Endocrinologist Coaches vs. Cancer: 11th Annual Tourney Tip-Off Breakfast & 6th Annual Basketball Gala \$30,000 American Cancer Society - Pennsylvania Division \$1,000 American Chemical Society - Division of Organic Chemistry Support 41st National Organic Chemistry Symposium American College of Chest Physicians American College of Chest Physicians - 2009 Sleep Medicine \$15,000 American College of Neuropsychopharmacology 2009 Corporate Supporting Fee \$50,000 Continuing Education Sessions. \$10,500 American Dental Hygienists Association Annual Scientific Meeting of the Headache Cooperative of the Pacific \$20.000 American Headache Society Neurology Resident Curriculum \$25,000 American Headache Society American Headache Society \$20,000 Online Headache Education Program American Pharmacists Association 2009 Annual Meeting Educational Session: Migraine American Pharmacists Association \$20,500 Management: A Head Start for Pharmacists

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Working with Patient groups Novartis

a) http://www.corporatecitizenship.novartis.com/patients/patient-partnership/patient-groups.shtml

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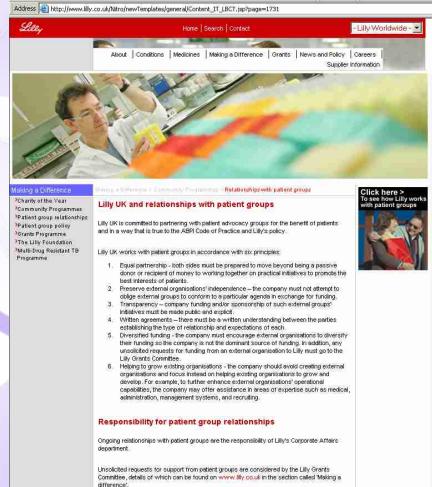
🕅 Read our position on Patient group interaction and support >

Working with Patient groups Novartis

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E Austria		
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Alzheimer	r Angehörige u	und Betrevende
AMA - Au	strian Myelomi	a Association
Angehoer	ige Demenz	
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Austrian 1	Fransplant Spo	orts Federation (ATSF)
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Die Knos	pe Breast Can	cer Group
Dritter Wi	ener Alzheime	ertag für Patienten und Angehörige
GHZ Eiser	nstadt Alzheim	ièr
Help 4 yo	u company (A	ktiv mit Rheuma)
Hilfe zur S	Selbsthilfe für	seelische Gesundheit



Working with Patient groups Lilly UK





Working with Patient groups Lilly UK

Staring + Difference > Commonly Figurement - Patient Group Funding

Descriptions of Lilly's patient group relationships

Lilly UK is committed to partnering with patient advocacy groups for the benefit of patients and in a way that is true to the ABPI Code of Practice and Lilly's policy.

Lilly UK has agreed with patient advocacy groups that it will make public the scope of our partnerships in the UK in order to increase transparency. This includes stating the amount of funding that Lilly provides.

Cancerbackup

Lilly has provided a grant to Cancerbackup to help the organisation raise public awareness of cancer and campaign for improved access to information and better services for people with cancer.

Lilly funding in 2007 was £17,000, which represents 0.4% of Cancerbackup's overall income.

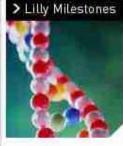
Depression Alliance

Lilly in partnership with Boehringer Ingelheim provided a core partnership unrestricted donation to Depression Alliance, toward enabling Depression Alliance to allocate capacity toward information sharing and advising on activities to improve the health outcomes of individuals with depression. In addition, Lilly and Boehringer Ingelheim commissioned Depression Alliance to provide advice and input into the "Now We're Talking!" disease awareness campaign that aimed to raise awareness of the need for increased support for healthcare professionals in primary care, toward delivering enhanced care for people with depression.

Lilly and Boehringer Ingelheim funding to Depression Alliance in 2007 was $\pm 20,000$, which represents 11.5% of its total 2007 budget.

> Lilly Clinical Trial Registry





Working with Patient groups Lilly US

Address a https://www.lillygrantoffice.com/grant_registry.jsp Lilly Grant Office HOME GRANT GRANT REQUEST INITIATE GRANT LILLY GRANT INTERNATIONAL FAQs GUIDELINES PROCESS REQUEST REGISTRY REGISTRY **Contact the Lilly Grant Office** by email: Lilly Grant Registry grantinfo@lillygrantoffice.com Disclosure of Grants and Contributions Funded by Grant Registry Lilly Report Click here to view the Lilly has for many years provided funding in the form of grant registry report. educational grants and charitable contributions to support 6 medical education, patient education, and other worthy activities that we believe increase healthcare knowledge and Grant Registry improve patient care. As a business that exists to serve FAOs patients, we believe in being transparent and open regarding Click here to view our educational and charitable giving. That is why we are Frequently Asked making this online public disclosure of Lilly grants and charitable Questions about the contributions to healthcare-related organizations in the U.S.* Grant Registry, \odot In the United States, Lilly has two sources of grants or charitable contributions that are documented on this website: Download a Brochure Click here to download The U.S. Affiliate Lilly Grant Office (LGO) evaluates the majority of the requests the Company receives for grants the latest version of in the United States. our print brochure. \bigcirc The Lilly Research Laboratories (LRL) Grant Office evaluates the majority of the requests from international organizations and some requests from U.S. agencies that operate internationally. · For programs outside the U.S. and US possessions that are specific to the originating country, Lilly local offices are tasked with reviewing the majority of educational grant and charitable contribution requests.

Working with Patient groups AstraZeneca

Address 🕘 http://www.astrazeneca.com/responsibility/community-support/patient-group-support?itemId=5212120&nav=yes



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ome Responsibility Community support

Patient group support

Staying in touch with changing needs is vital to our aim of making the most meaningful difference we can to patient health.

We talk continuously to physicians and patient groups and organisations to understand what they need and want. This includes working with, and supporting, patient groups and organisations who represent the particular demands of specific health issues, as well as discussing with healthcare professionals the broader range of disease challenges they and their patients face.

Our ongoing aim is to ensure that all of our relationships with patient groups and other healthcare organisations continue to be based on transparency, trust and a shared objective to improve the lives of patients. Our new Global <u>Community Support Policy</u>, launched in January 2009 reinforces that commitment.

In line with the respective UK ABPI and Swedish pharmaceutical industry association (LIF) codes of practice requirement to do so, we make public all our relationships with patient groups in the UK (through our website, <u>AstraZeneca.co uk</u>) and in Sweden (through LIF's external website <u>LIF se</u>). In line with the requirements of the EFPIA code, we now also report which patient groups in Europe we support (see below).

During 2008, in the absence of any external requirement to do so, AstraZeneca in the US disclosed their contributions to non-profit organisations in the US, including patient groups and other healthcare organisations, and their grants in support of independent medical education. Current information is available on our <u>US website</u> and this will be updated on a biannual basis.

We also collect and publish information about interactions between AstraZeneca's global therapy area teams and patient groups (see below).

Beyond this, we are continuing to develop a global framework for consistent management and capture all of our support to patient groups and other healthcare organisations worldwide. Completion of this work and publication of this information, including the nature of the relationship and the associated financial commitments, was planned for 2008 but the continued re-organisation and re-structuring within the Company during the year caused some delay. However, we are now on track to start delivering this in 2009.

PATIENT GROUP SUPPORT - EUROPE

- + Austria
- Belgium
- Bulgaria



More about our people

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Working with Patient groups AstraZeneca

PATIENT GROUP SUPPORT - EUROPE

O Austria

Patient Group	Nature of Support & Purpose
HPE Österreich	Healthcare Awareness Publications and Events
Lungenunion	Healthcare Awareness Publications and Events
Pro Mente Salzburg	Provision of Education & Training

Belgium

Patient Group	Nature of Support & Purpose
Europa Donna Luxembourg	Provision of Education & Training
Crohn & Colitis	Unrestricted use grant
European Patients Forum (EPF)	Unrestricted use grant
Vlaamse diabetes Vereniging - Flemish Association of Diabetes	Unrestricted use grant

O Bulgaria

Patient Group	Nature of Support & Purpose
Асоциация на Пациентите с Онкологични Заболявания - АПОЗ, София - Association of Patients with oncology diseases - Sofia	Healthcare Awareness Project Support
Българска Асоциация на Онкоболните и Сподвижници - БАОС, Варна - Bulgarian Association of oncology patients and their supporters - Varna	Healthcare Awareness Project Support
Сдружение на Жените с Онкологични Заболявания - СЖОЗ, Пазарджик Association of Women with oncology diseases - Pazardjik	Healthcare Awareness Project Support
Асоциация на Пациентите с Онкологични Заболавация, АПОЗ София,	Provision of Education & Training

AstraZeneca: Global Policies

- @G

Address 🔕 http://grouppolicies.astrazeneca.net/community-support/support-to-patient-groups.asp

ome	Home 🕐 Community Support, Including Product Donations and Patient Group Support 🔸 Support To Patient Groups And Other Healthcare Organisations	Search
nti-bribery and Anti- orruption	Support to Patient Groups and other Healthcare Organisations	Advanced search
inethics communications community Support, including Product onations and Patient roup Support Community Support Support To Patient Groups	Our support to <u>patient and upper</u> and other <u>beathcare organisations</u> must always comply with relevant legal and regulatory requirements and applicable international and national codes, as well as our own international and national <u>standards</u> . Across all of our activities, the following principles must always apply: > Our support, whether through financial or in-kind assistance, must always be based on transparency, trust and a shared objective to improve patient healthcare. > The independence of such groups and their activities must always be respected.	Other useful links AZ Community Databas ISMO Pharma Code Standards for Global Tr interactions with Patient Groups UK Community Support Policy
And Other Healthcare Organisations	> We must not request the promotion of a particular prescription-only medicine by patient groups.	Contacts
Product Donations ata Protection and rivacy egal and Intellectual roperty	> The arrangements for events and hospitality involving patient groups will be governed by standards similar to those in place for healthcare professionals. Where applicable, public disclosure of support for patient groups and other healthcare organisations must be done locally in accordance with the relevant external regulations, applicable codes and local Company policy commitments.	Global Compliance Rhiannon Rowsell
eople roviding Information bout Our Products	All support to patient groups and other healthcare organisations, whether or not publicly disclosed at a local level, must be documented by a written agreement and registered on the AstraZeneca Global Community Database.	
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no Sponsor	Content Owner: Paul Woods, updated: 05 Jan 2009 Contact: David Robinson	

Into practice - Some points for discussion?

What information to provide

- Different national requirements
- Different company interpretations and positions
- Europe: meaning of
 - 'short description of of the nature of the support'
 - '(any) financial support and/or significant indirect/non-financial support'
- Uncertain future requirements

Accounting systems

- May require significant redesigns of international processes and IS
- Systems need to cover other sectors eg HCP support

Large organisations

Easy to miss an item of support

Commercially sensitive? Private data

Is there any justification for withholding any information? Eg interactions concerning development projects

Into practice - Some points for discussion?

'Reasonable' event venues and hospitality

- Can our criteria for HCP meetings be directly applied to patient group interactions?
- Can we provide any support if a patient group chooses an exotic location for their meeting?

Payments for work done

- Groups and/or individuals
- Fair market value

Written agreements

Some patient groups have their own agreement templates

• We "shall not request, nor shall patient organisations undertake the promotion of a particular prescription-only medicine"

- What does promotion mean in this context?
- Influence on patient group activities of recent ECJ ruling on advertising definition

Dear Signatory: I'd like to provide a prize for the local diabetes support group draw. OK?