

New SME Office:

how can EMEA support biotechnology companies?

SwedenBIO Annual General Meeting

Workshop on IP and Clinical Trials

1 June 2006

Agenda

- Introduction
- Survey of SME Stakeholders
- Role of SME Office
- SME Regulation and Incentives
- SME Definition

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Objective of SME Incentives

- To promote innovation and the development of new medicinal products by SMEs



Legal Background

- Article 70.2 of Regulation 726/2004 of 31 March 2004 introduced a provision for financial and administrative assistance for SMEs
- Implementing Regulation (EC) No 2049/2005 adopted on 15 December 2005



Scope

- Medicinal Products for Human Use
- Medicinal Products for Veterinary Use
- Not for medical devices



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Activities to prepare for Regulation

- Survey of Pharmaceutical Industry: expectations/needs circulated through stakeholder organisations in September 2005
- 1st meeting with representatives of stakeholder organisations held on 17 November 2005



Survey of SME Stakeholders

- **Circulated on 16 September 2005**

- **Sent to the following organisations:**
 - **Emerging Biopharmaceutical Enterprises (EBE) EFPIA**
 - **The European Association for Bioindustries (EuropaBio)**
 - **Euopharm SMC**
 - **European Generic Medicines Association (EGA)**
 - **Association of the European Self-Medication Industry (AESGP)**
 - **International Plasma Fractionation Association (EPFA)**
 - **European Animal Health Industry (IFAH-Europe)**
 - **Association of Veterinary Consultants (AVC)**
 - **European Group for Generic Veterinary Products (EGGVP)**
 - **European Federation of Associations of Health Product Manufactures (EHPM)**

- **Deadline for response: 28 October 2005**

Survey of SME Stakeholders

SME office

1. Administrative assistance
2. Procedural assistance
3. Other issues

Workshop/Trainings

7. Topics

User Guide & Communication

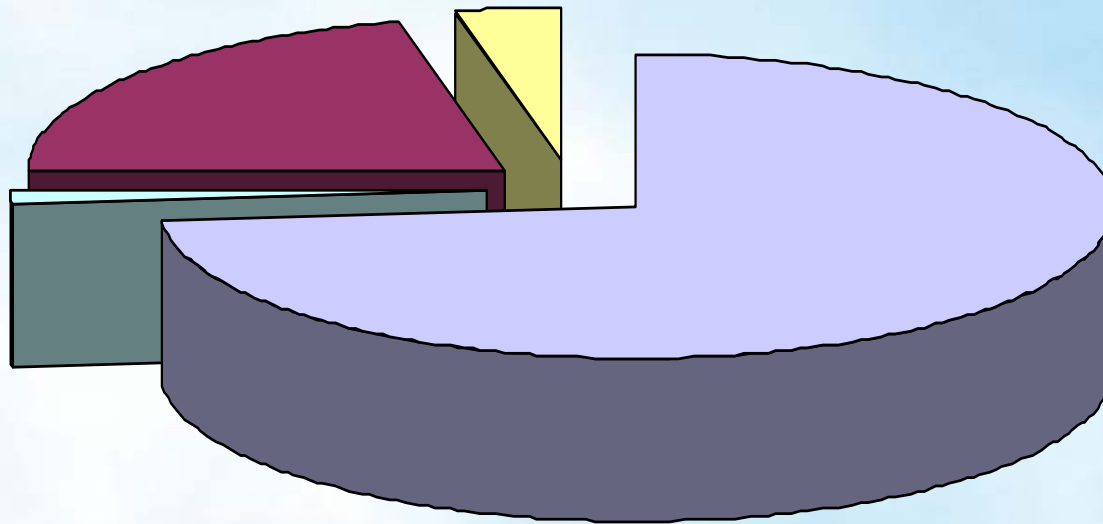
4. Topics
5. Distribution
6. Other information

Other

8. Other interested organisations
9. Other comments

Response to Survey

- 56 individual companies
- 3 stakeholder organisations



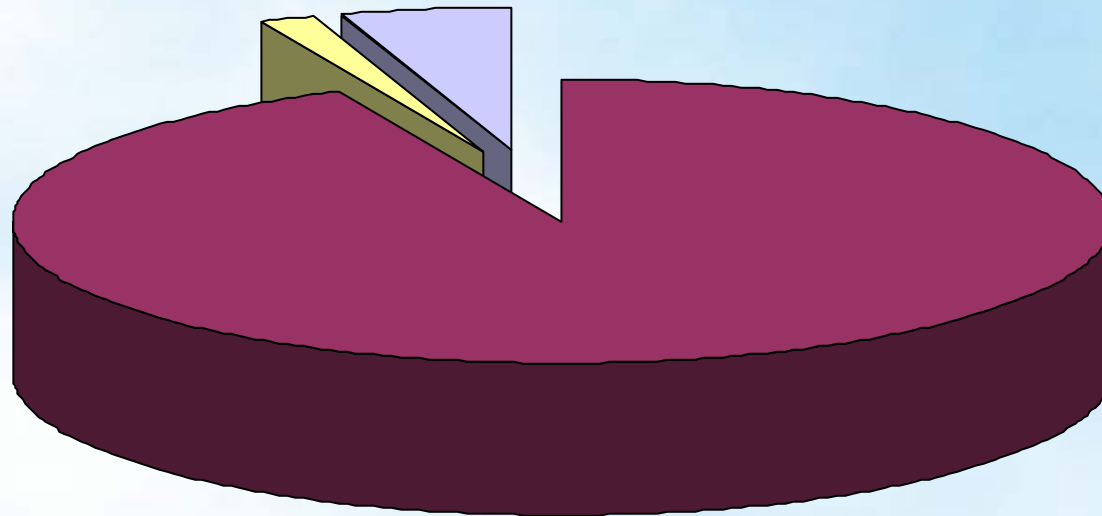
□ Human med product

□ Vet med product

□ Herbal med product

□ CRO

Responses to Survey



■ EU Member States ■ Norway ■ Switzerland

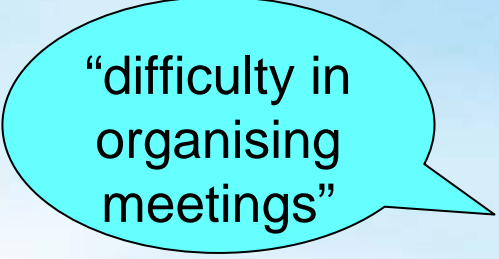
Feedback on Administrative & Procedural difficulties

- 40 out of 59 responders raised administrative issues
- 40 out of 59 responders raised procedural issues

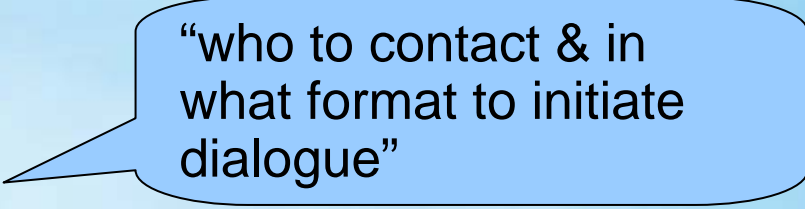
- Problems faced or anticipated in following areas:
 - Contact with EMEA
 - Regulatory issues
 - Clinical Trials
 - Scientific Advice
 - Translations
 - Fees
 - Electronic Submissions
 - Other (compassionate use, herbals, pharmacovigilance, funding R&D, pricing & reimbursement)

Contact with EMEA

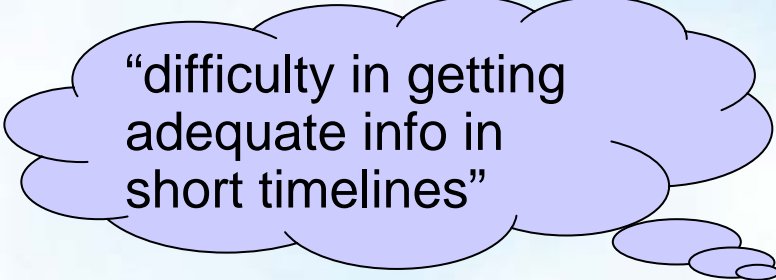
Comments:



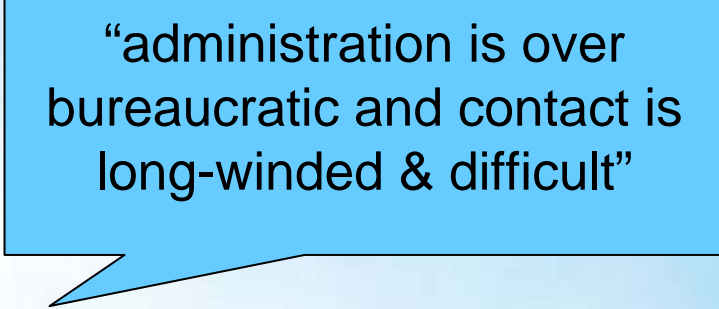
“difficulty in organising meetings”



“who to contact & in what format to initiate dialogue”



“difficulty in getting adequate info in short timelines”



“administration is over bureaucratic and contact is long-winded & difficult”

Suggestions included:

- need point of reference for practical advice
- introduce “buddy system” where advice can be obtained on any issue throughout development
- in-depth discussion after meetings/hearings

Regulatory Issues

Comments:

“SMEs have difficulties entering EU system due to administrative burden”

“volume of literature & complexity of guidelines is challenging”

Suggestions included:

- identification of key dates in development
- procedural advice on “potential pitfalls”
- practical hints, assistance filling in forms/preparing CTD
- preparation of pre-sub meetings

Clinical Trials

“necessary to use
CROs in
respective
countries”

“Directive prevents
research and adds
enormous costs &
time delays to
initiating research”

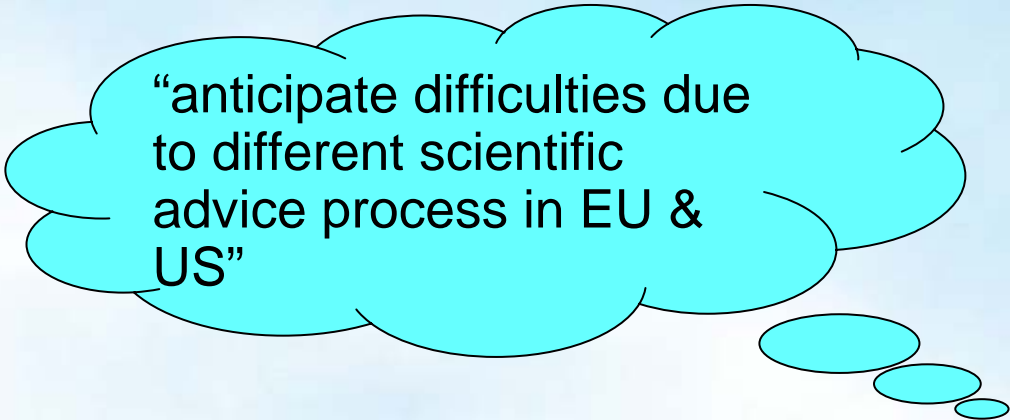
“difficulties in applying
for clinical trials in
other Member States”

Suggestions included:

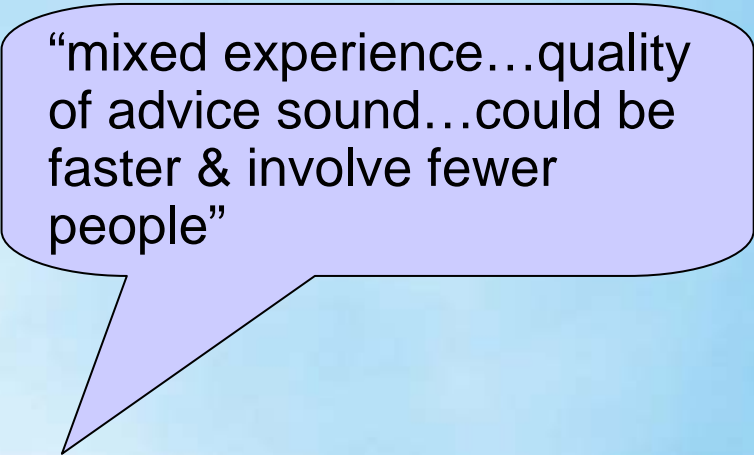
- assistance needed from SME Office on clinical trial conduct in EU countries
- need contact in National Competent Authorities to clarify requirements

Scientific Advice

Comments:



“anticipate difficulties due to different scientific advice process in EU & US”



“mixed experience...quality of advice sound...could be faster & involve fewer people”

Suggestions included :

- enhanced advice – “protocol assistance”
- advice at key milestones in product lifecycle
- informal way of bridging gap between clinical phase & MAA phase
- assistance on simple issues that do not warrant scientific advice procedure

Translations

Comments:

“ensuring
quality in
statutory
timelines”

“translation procedure
is very heavy and costly”

“difficulties to find
translation offices
competent in
EU languages”

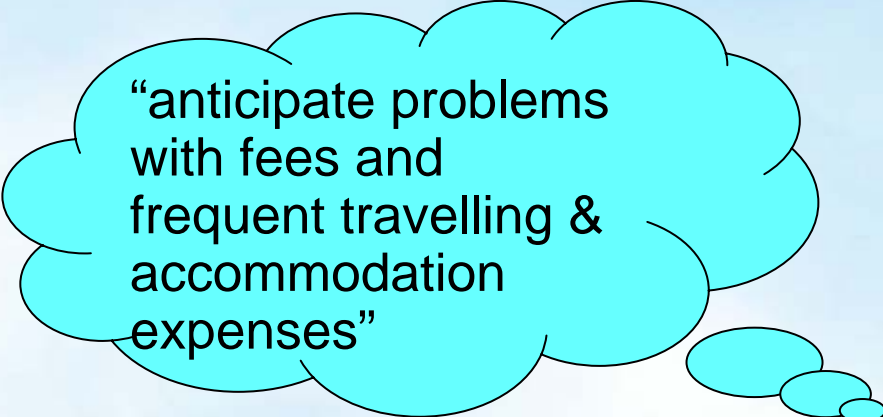
“difficulties in
orphan translations”

Suggestions included:

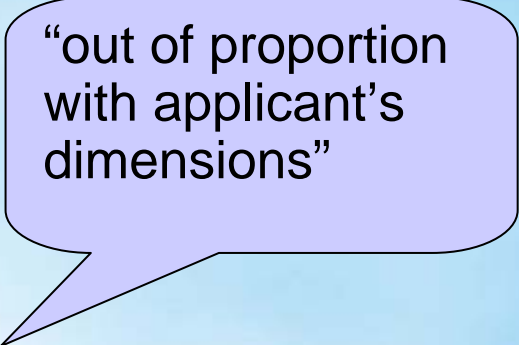
- assistance needed
- “support at low cost”.. “should be free”
- co-ordination of linguistic review post-opinion

Fees

Comments:



“anticipate problems with fees and frequent travelling & accommodation expenses”



“out of proportion with applicant’s dimensions”

Suggestions included:

- fee reductions for all procedures
- informal contacts by phone, e-mail, videoconference
- SME & orphan sponsor to accumulate incentives e.g fee reduction & deferral for MAA

Electronic Submissions

Comments:

“anticipate e-CTD submission as challenge + resource intensive in terms of timing/software”

“cost of software & entire process, including life-cycle management can be prohibitive for SMEs”

Suggestions included :

- advice on requirements
- funding should be considered for companies who develop IT technology & adapt to new requirements
- avoid costs of printing/binding/shipping

Conclusions from Survey

- Excellent response – Thank you!
- Detailed feedback addressed to relevant sectors in EMEA
- Aim to tailor SME service to meet needs
- Further feedback required in future

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- **Role of SME Office**
- SME Regulation and Incentives
- SME Definition

SME Office

- Advise applicants on administrative and procedural issues
- Facilitate communication
- Organise workshop/training sessions

SME Office

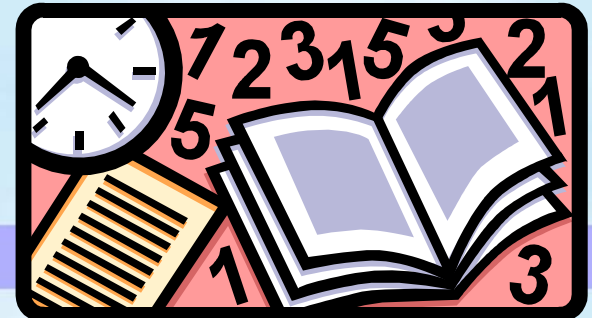
- A dedicated structure within the Agency Secretariat
 - Two full-time staff + representatives in all relevant sectors
 - A cross-Agency activity
- A single interface ('One stop shop')

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- Activities to prepare for Regulation
- **SME Regulation and Incentives**
- SME Office

Incentives for SMEs

- Administrative and procedural assistance
- Fee reductions
- Fee exemptions for certain administrative services
- Deferral of fee for application for marketing authorisation or inspection
- Conditional fee exemption
- Translation of product information



Fee Reductions

- 90% reduction on :
 - scientific advice
 - inspections
 - scientific services
 - Maximum residue limits (veterinary medicines)

- 100% 'waiver' on administrative services (except for parallel distribution)

Fee Reductions for orphans

If SME + Orphan status :

=> 100% 'reduction' on :

- scientific advice/protocol assistance
- scientific services

Fee deferrals

*Granting of the
Marketing Authorisation*

Marketing Authorisation Application
+
Inspections (pre-authorisation)

Post-authorisation

TIME



***Payment deferred until
the end of the
marketing authorisation
procedure***



Conditional Fee Exemption



IF scientific advice used:

***=> Payment only in case of success
(Marketing Authorisation Granted)***

Example

	<i>Standard application non-SME</i>	Standard application SME	
Scientific Advice	<i>70 000 EUR</i>	7 000 EUR (-90%)	} <i>Payment deferred until the end of the procedure</i>
Inspection	<i>17 000 EUR</i>	1 700 EUR (-90%)	
Marketing Authorisation Application	<i>232 000 EUR</i>	232 000 EUR if success 0 EUR (-100%) if failure	
Total	<i>320 000 EUR</i>	241 000 EUR if success (-25%) 8 700 EUR if failure (-97%)	

Translations

EMA provides for the translations of:

- SPC
- Conditions on supply/use
- Labelling/package leaflet
- (MRL statement)

SME User Guide

- EMEA will publish detailed guide on administrative/procedural aspects
- Guide will reference existing national provisions for SMEs



Training/Workshops

- EMEA will organise a series of training sessions /workshops for SMEs
- Depending on topic may be organised in the margins of expert meetings at EMEA or in sessions at external conferences/symposia
- Feedback received from survey useful in identifying topics of interest

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Assignment of SME Status

- Applicant must be established in the Community
- Meet SME criteria defined in Recommendation 2003/361/EC
- Submit information necessary to demonstrate compliance with the criteria

Definition of SME

- 1996 first common definition of SME adopted by Commission
- 6 May 2003 new recommendation (2003/361/EC)
- entered into force 1 January 2005
- will be applied by EMEA



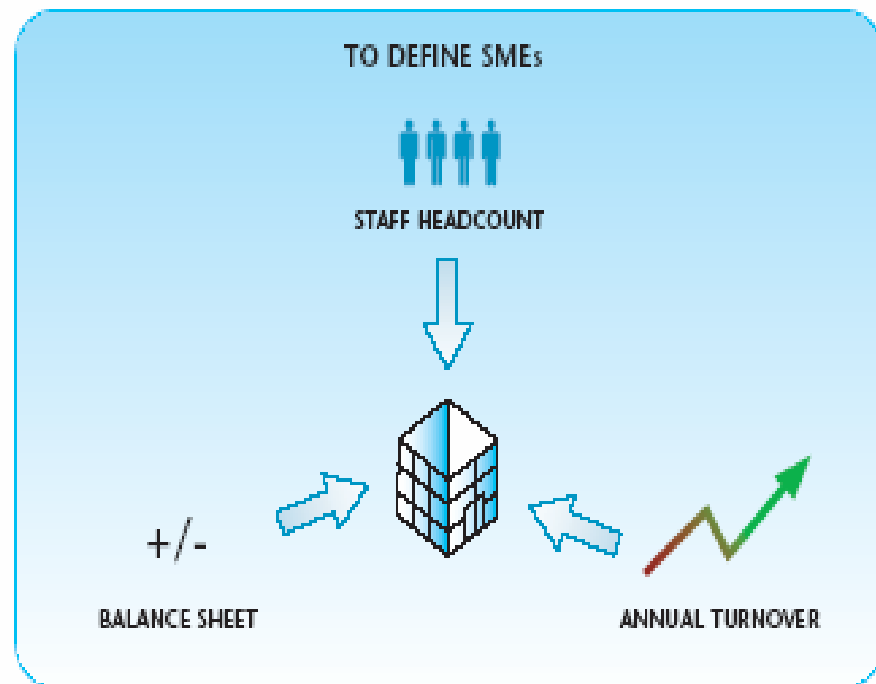
Definition of SME

Enterprise:

- any entity engaged in an economic activity irrespective of its legal form

New thresholds based on:

- Staff headcount
- Annual turnover
- Annual balance sheet



Different Categories of Enterprises Defined

- Autonomous: completely independent or have one or more minority partnerships (each < 25 %) with other enterprises
- Partner: holding of no more than 50 % with other companies
- Linked: enterprises which form a group through direct or indirect control of the majority voting rights of an enterprise by another or through the ability to exercise a dominant influence on an enterprise



Definition of SME

THE NEW THRESHOLDS (Art. 2)

Enterprise category	Headcount: Annual Work Unit (AWU)	Annual turnover	or	Annual balance sheet total
Medium-sized	< 250	≤ €50 million (In 1996 € 40 million)	or	≤ €43 million (In 1996 € 27 million)
Small	< 50	≤ €10 million (In 1996 € 7 million)	or	≤ €10 million (In 1996 €5 million)
Micro	< 10	≤ €2 million (previously not defined)	or	≤ €2 million (previously not defined)

User Guide and Model Declaration on the New SME Definition

- Published by the European Commission
- Available at the following web-address:

http://europa.eu.int/comm/enterprise/enterprise_policy/sme_definition/index_en.htm



How to apply for SME status

- Complete SME Declaration form on EMEA web-site:
<http://www.emea.eu.int/SME/SMEapplication.htm>
- Submit signed original + electronic copy to SME Office together with:
 - most recent annual accounts (audited if possible);
 - details of ownership of company
 - proof of establishment in an EEA country
- EMEA will issue an EMEA-SME number
- SME status valid for 2 years

..the first SMEs....

- 51 companies assigned SME status
- 17 under review
- 2 withdrawn
- Majority human, 3 vet, 1 consultant
- 26% micro, 33% small, 41% medium-sized

Type of company:

- 25% biotechnology
- 35% biopharmaceutical
- 40% pharmaceutical

..experience so far....

Financial/administrative assistance:

- 5 SME companies in scientific advice
- 3 submitted MAAs
- 5 received regulatory assistance

Thank you for your attention

E-mail queries: smeoffice@emea.eu.int

For more information visit EMEA Web-site:

<http://www.emea.eu.int/SME/SMEoverview.htm>