

Annexe 1

COMP Report to the European Commission in Relation to Article 10 of Regulation 141/2000 on Orphan Medicinal Products

Statistics on Orphan Designations for COMP Report

Figure 1: Prevalence Range of Designated Orphan Conditions - April 2005

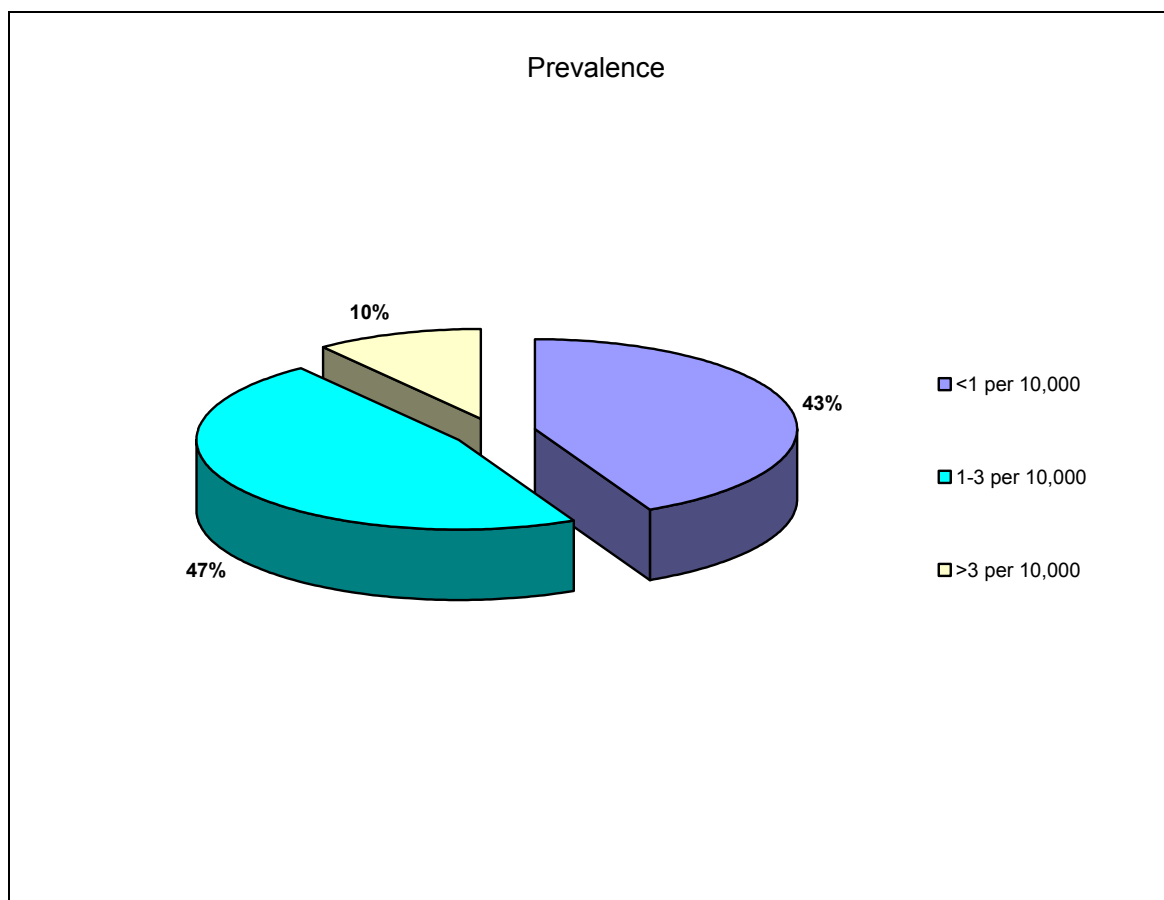


Figure 2: Overview of Orphan Designation Procedures - Outcomes
April 2005

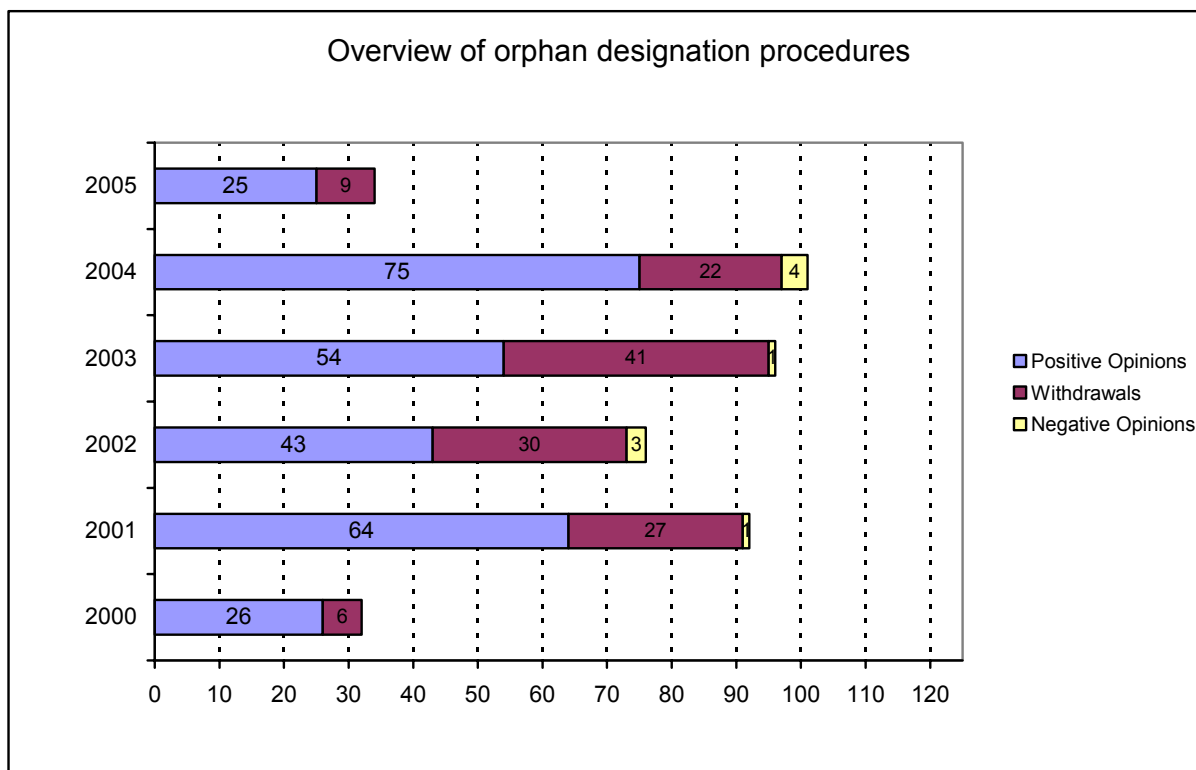
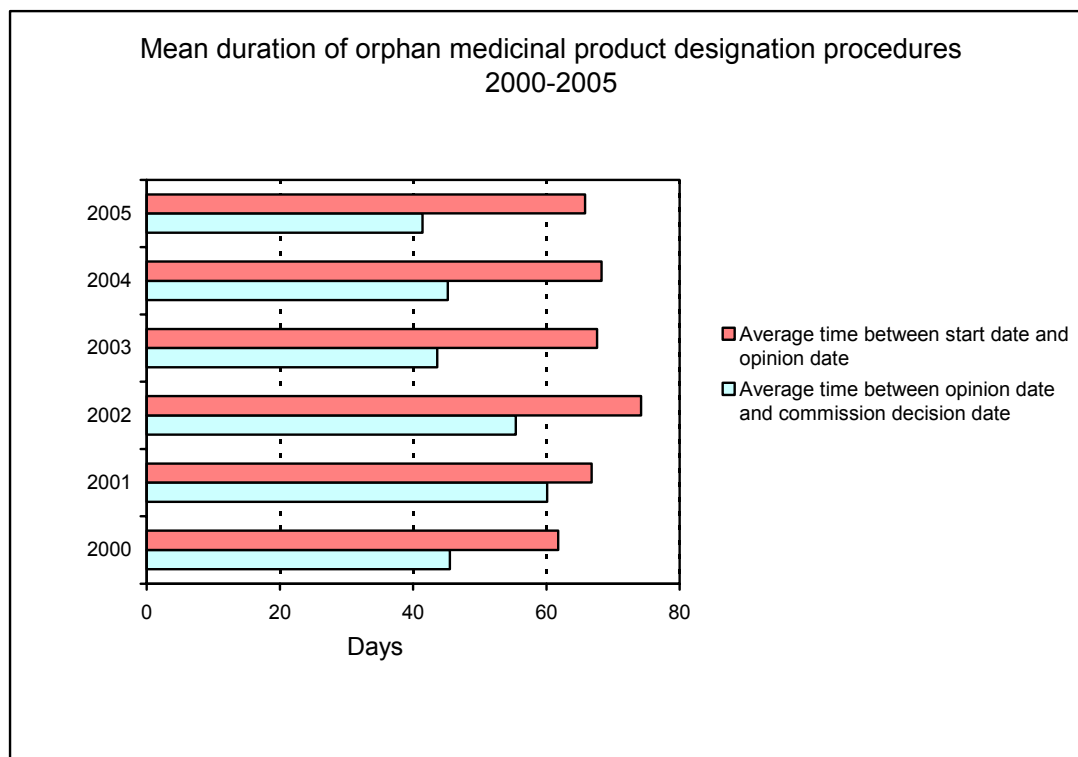


Figure 3: Timelines for Orphan Medicinal Product Designation Procedures – April 2005



Statistics on Protocol Assistance for COMP Report

Figure 4: Number of Protocol Assistance Requests, Oral Explanations and Pre-submission Meetings: 2001-2004

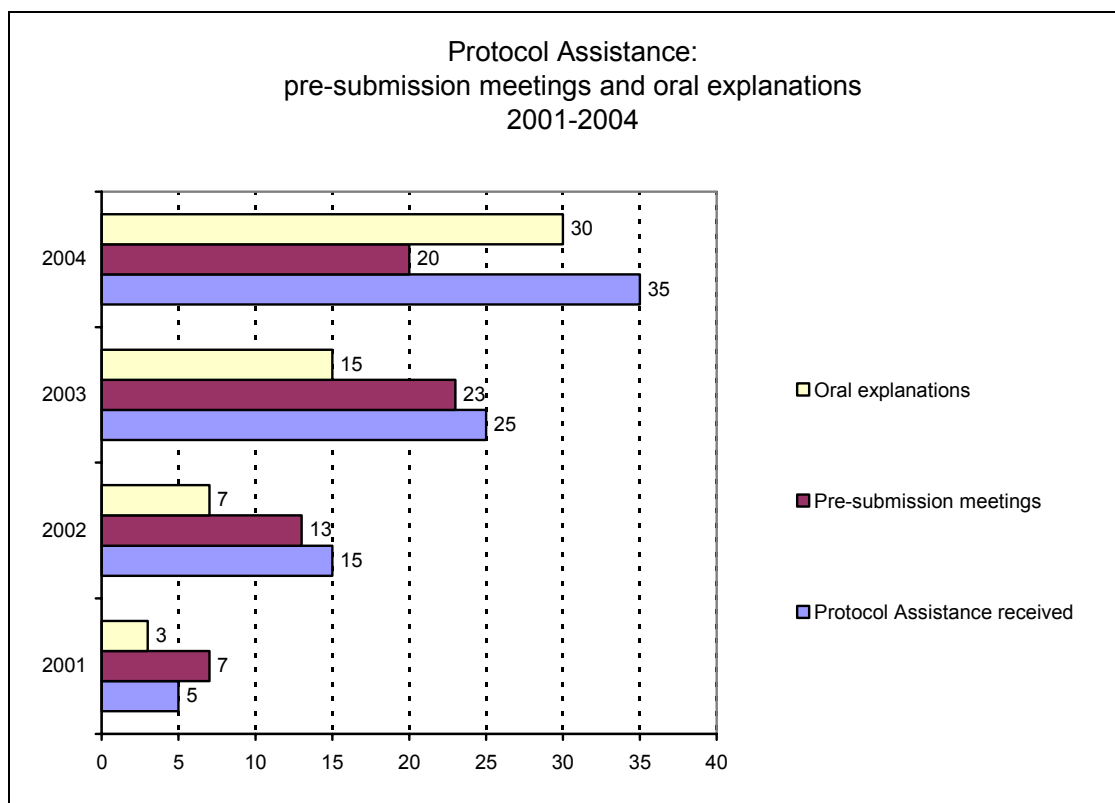


Figure 5a: Timelines for Protocol Assistance and Follow-up Procedures: 2001-2004

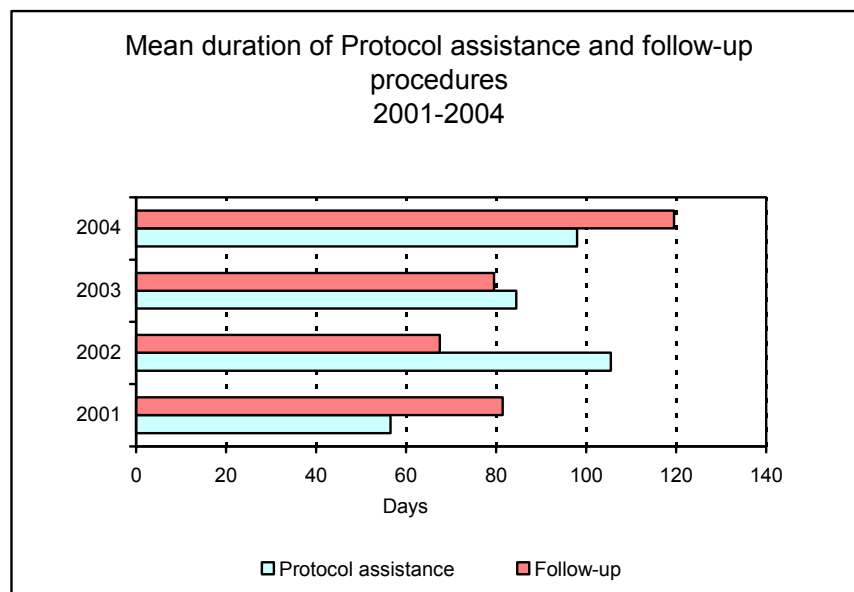


Figure 5b: Mean Duration of Protocol Assistance and Follow-up Procedures: 2001-2004

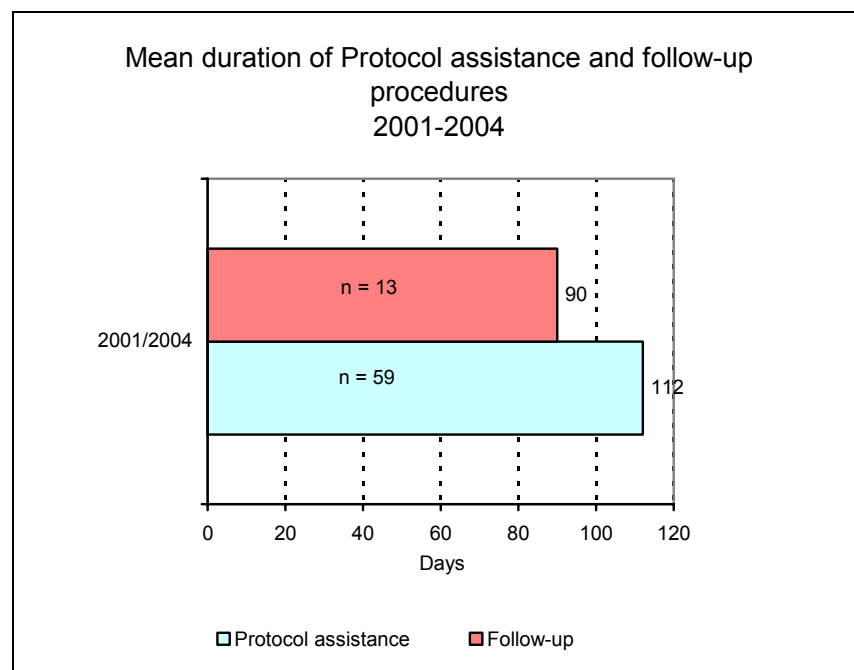


Figure 6: Number of Protocol Assistance finalised per year:
2001-2004

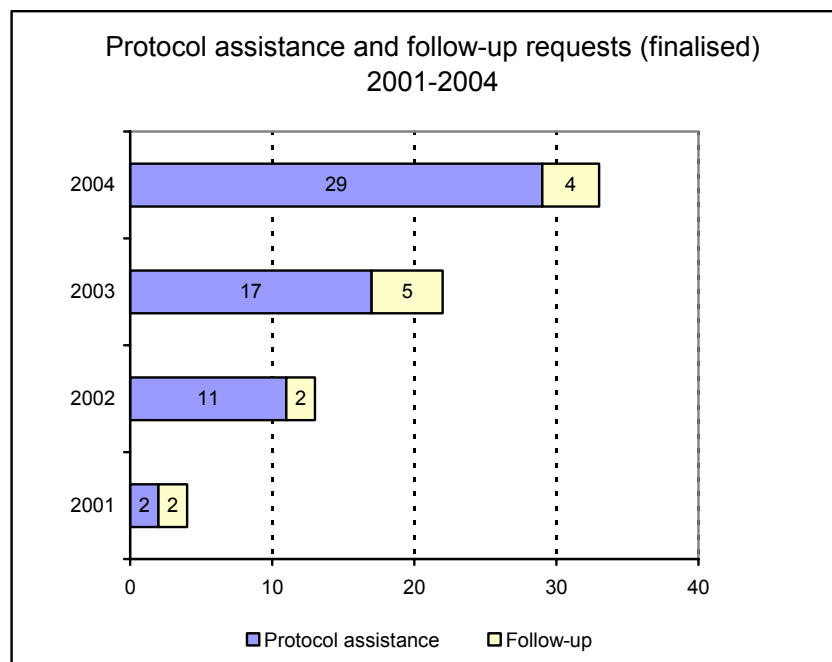


Figure 7a: Distribution of Protocol Assistance Requests by ATC code
2001-2004

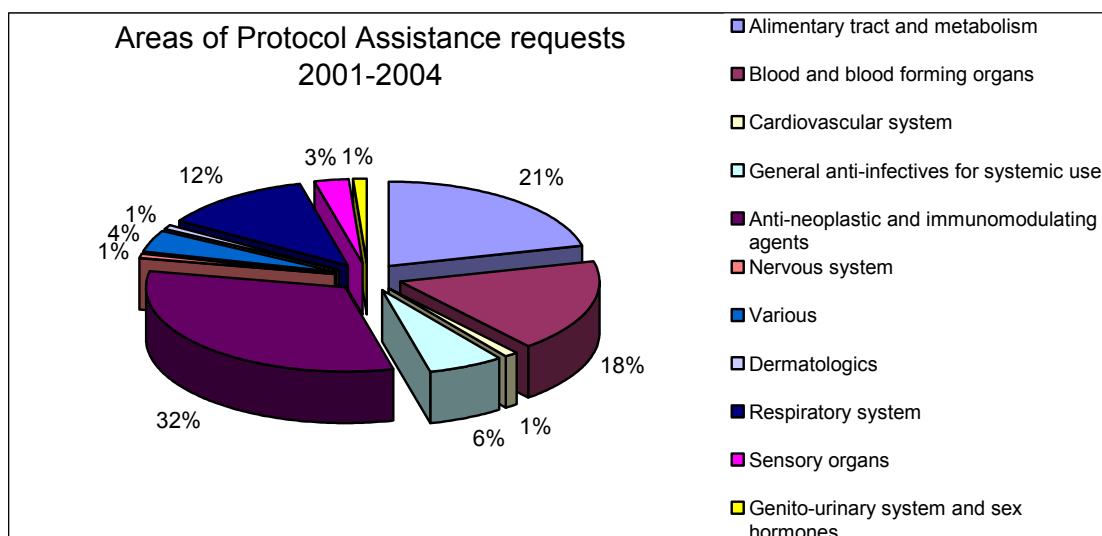


Figure 7b: Main ATC categories of Protocol Assistance Requests
2001-2004

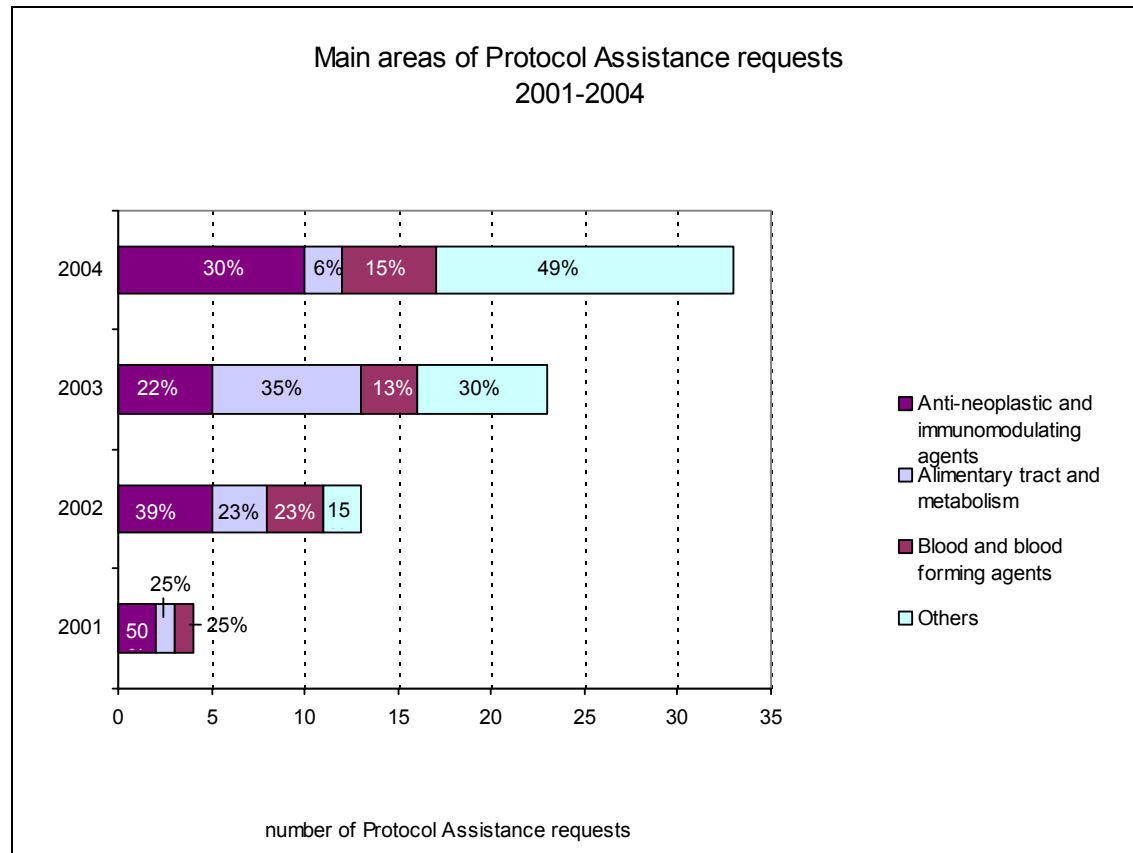


Figure 8: Scope of Requests for Protocol Assistance
2001-2004

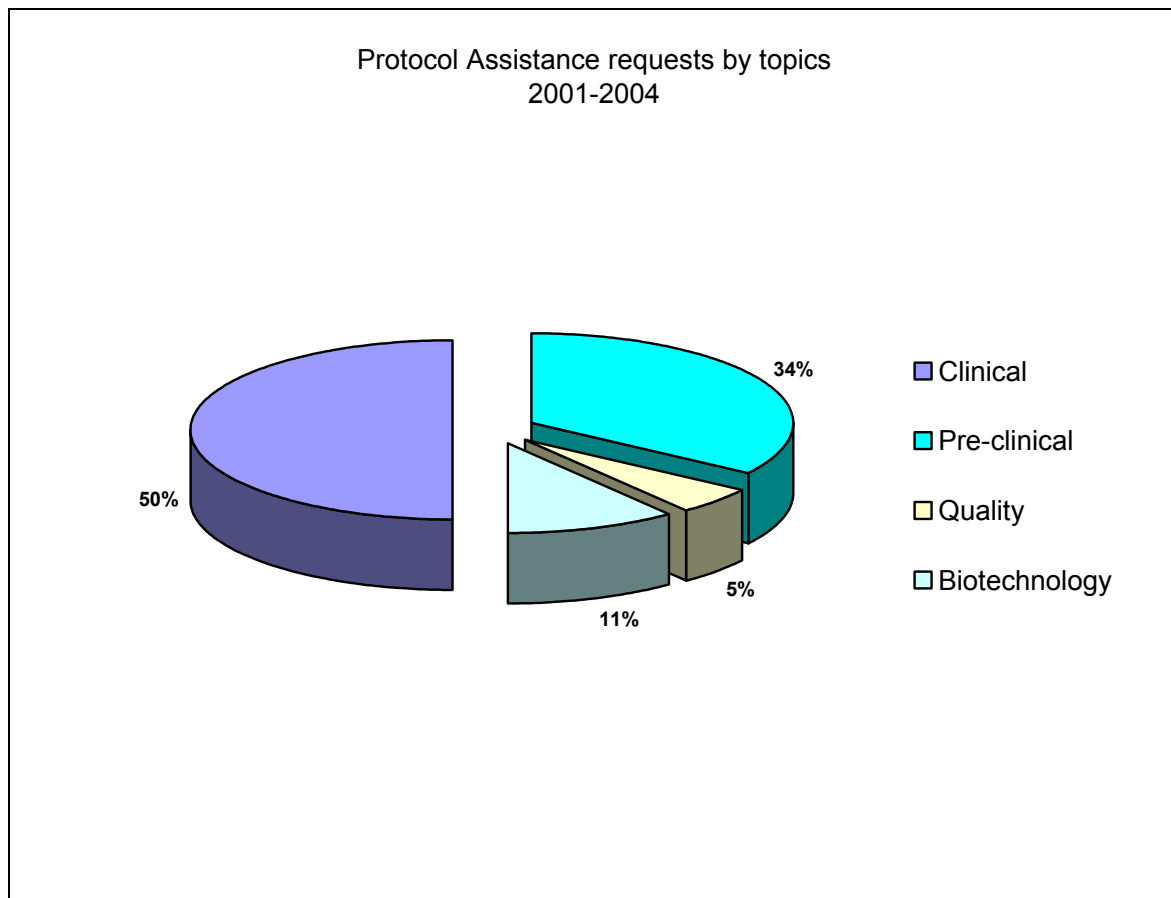


Figure 9: Requests for Protocol Assistance by Clinical Trial Phase
2001-2004

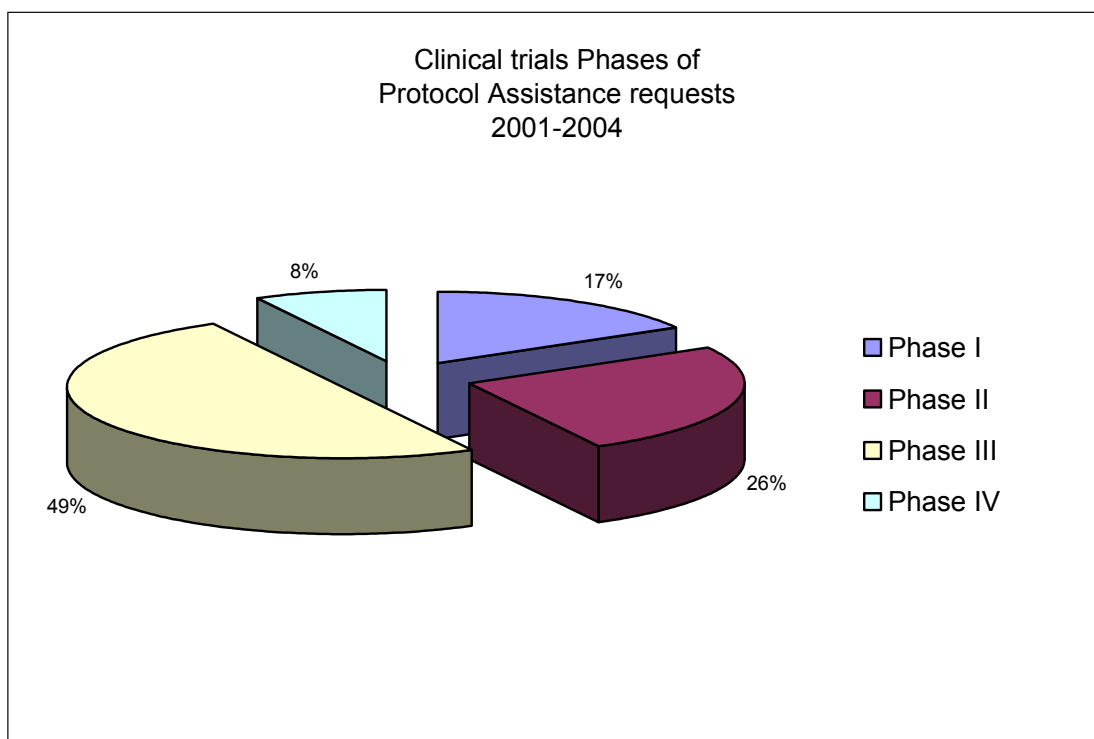


Figure 10: Protocol Assistance Requests - Type of products
2001-2004

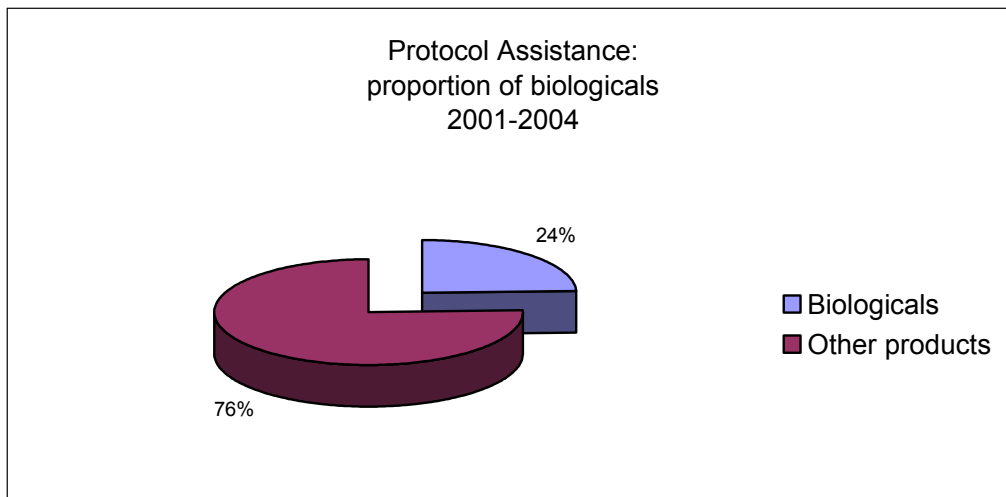


Figure 11: Protocol Assistance Requests - Proportion of Emerging Therapies: 2001-2004

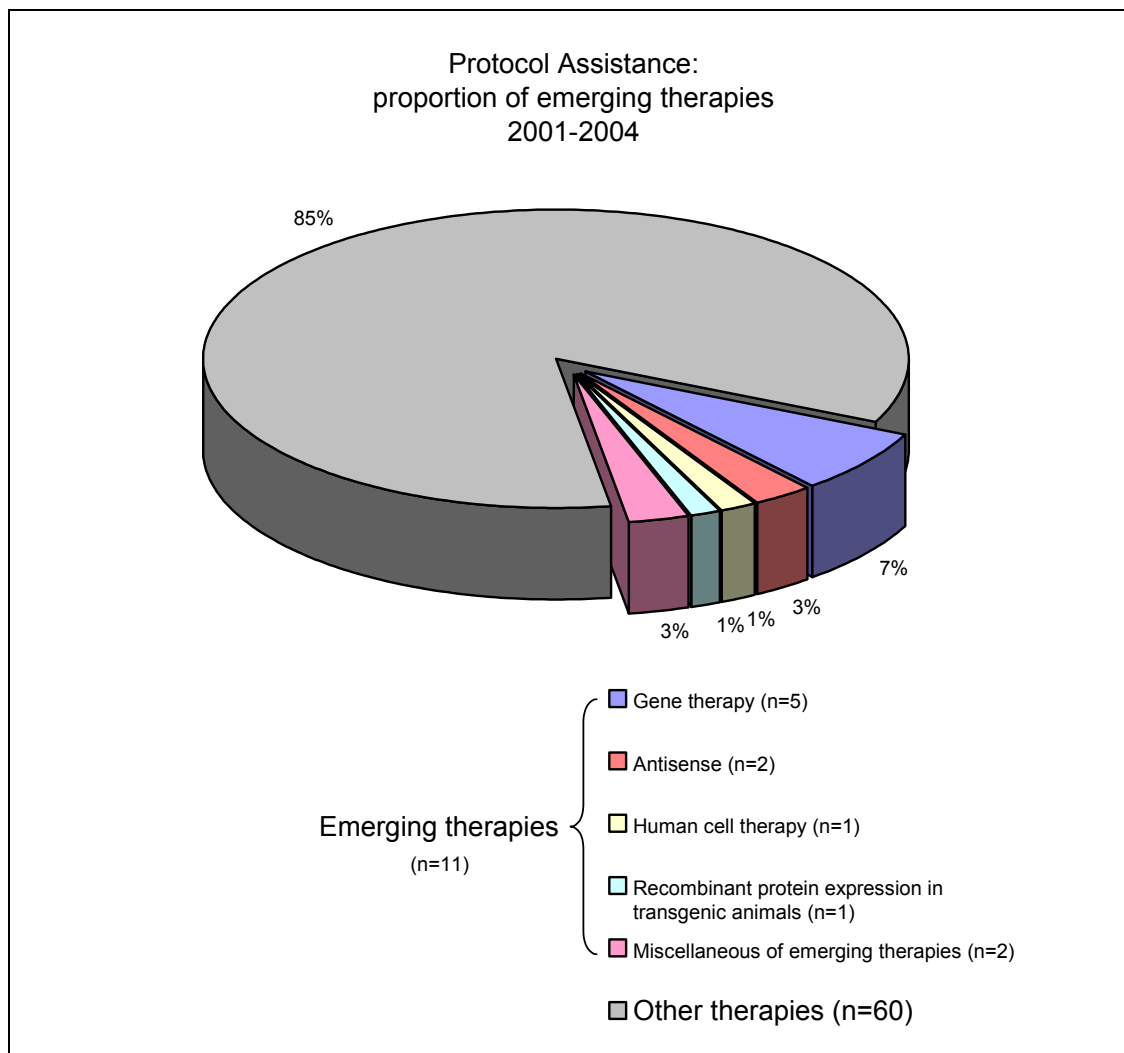


Figure 12: Overview of Fee Reductions Granted to Orphan Medicinal Products – Status (April 2005)

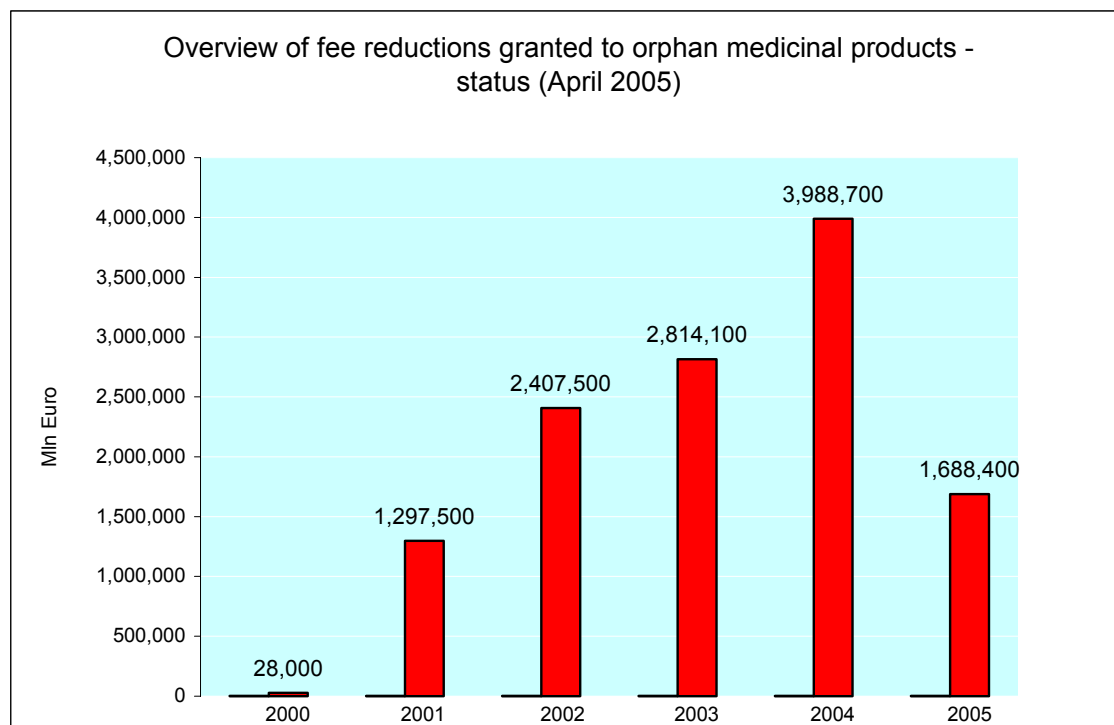


Figure 13: Paeditric Use of Orphan Medicinal Products (April 2005)

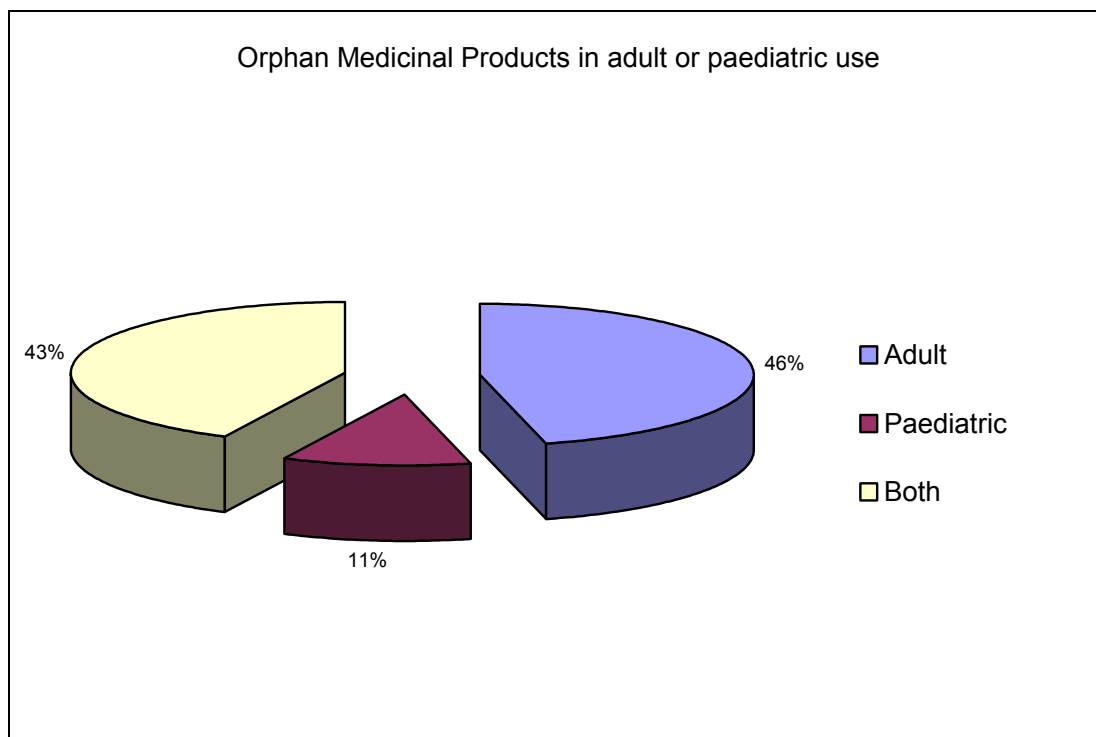
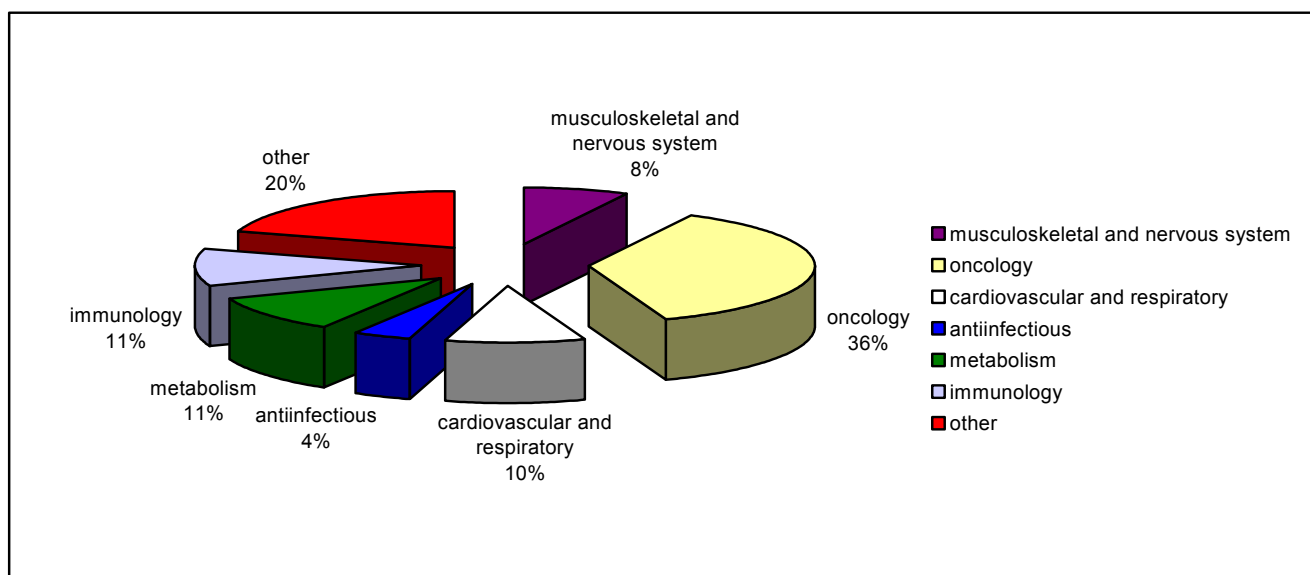


Figure 14: Distribution of Orphan Designations by ATC code (April 2005)



Development plans of Orphan Sponsors - Responses

In March 2005 EMEA Questionnaire on Status of Development sent to 259 sponsors.

On 26 April 2005, 170 responses had been received.

Figure 15: Response to EMEA Survey of Orphan Sponsors on Status of Development (April 2005)

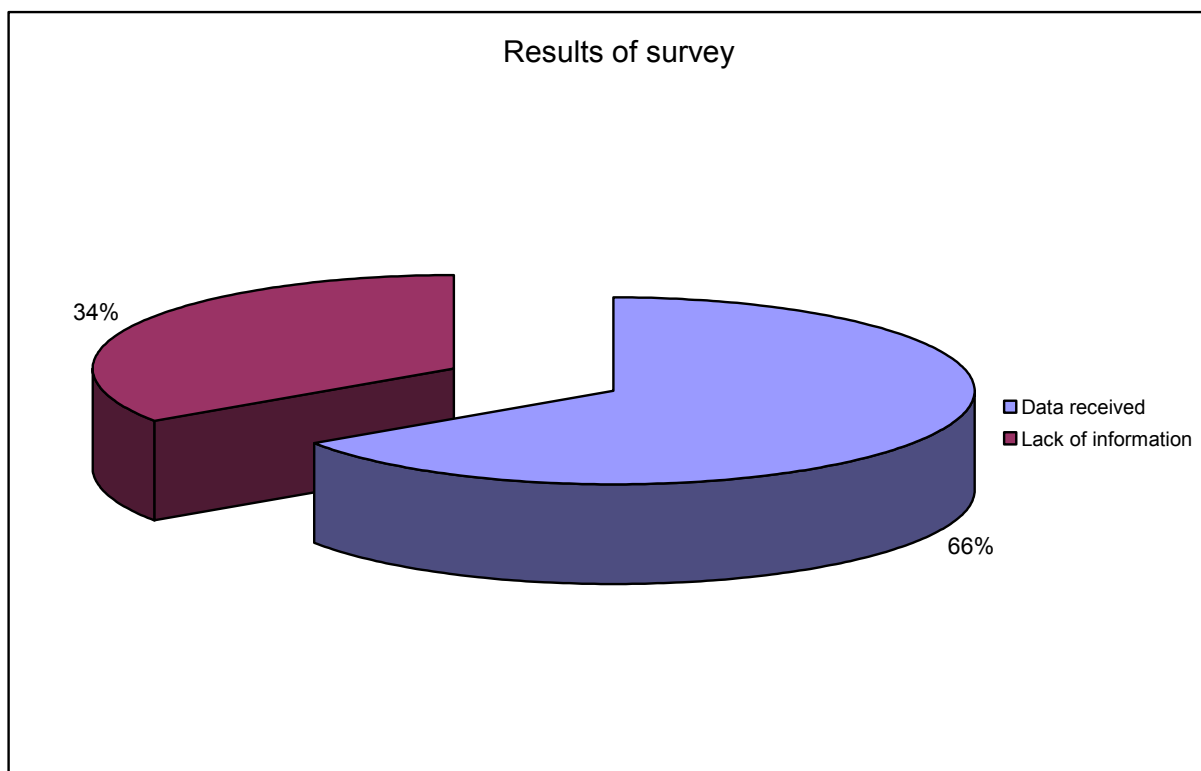


Figure 16: Status of Development of Orphan Sponsors (April 2005)

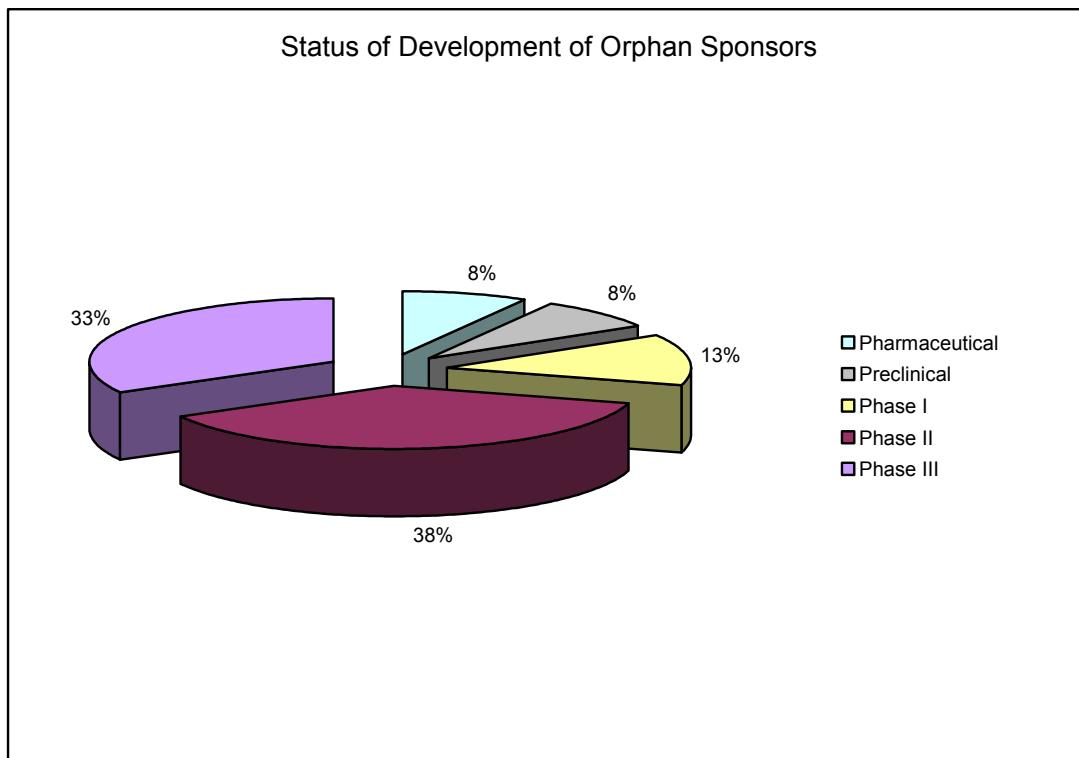


Figure 17: Status of Compassionate Use Programmes of Orphan Sponsors (April 2005)

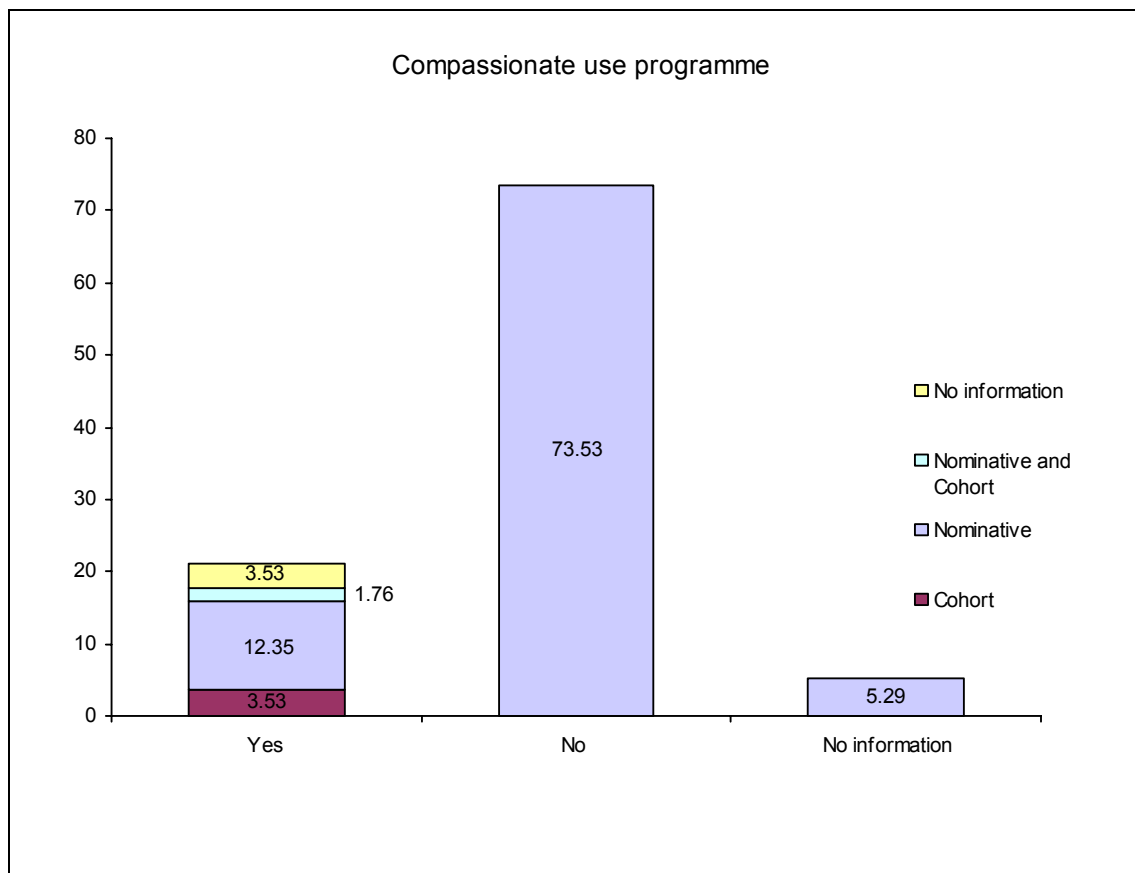


Figure 18: Planned Requests for Protocol Assistance (April 2005)

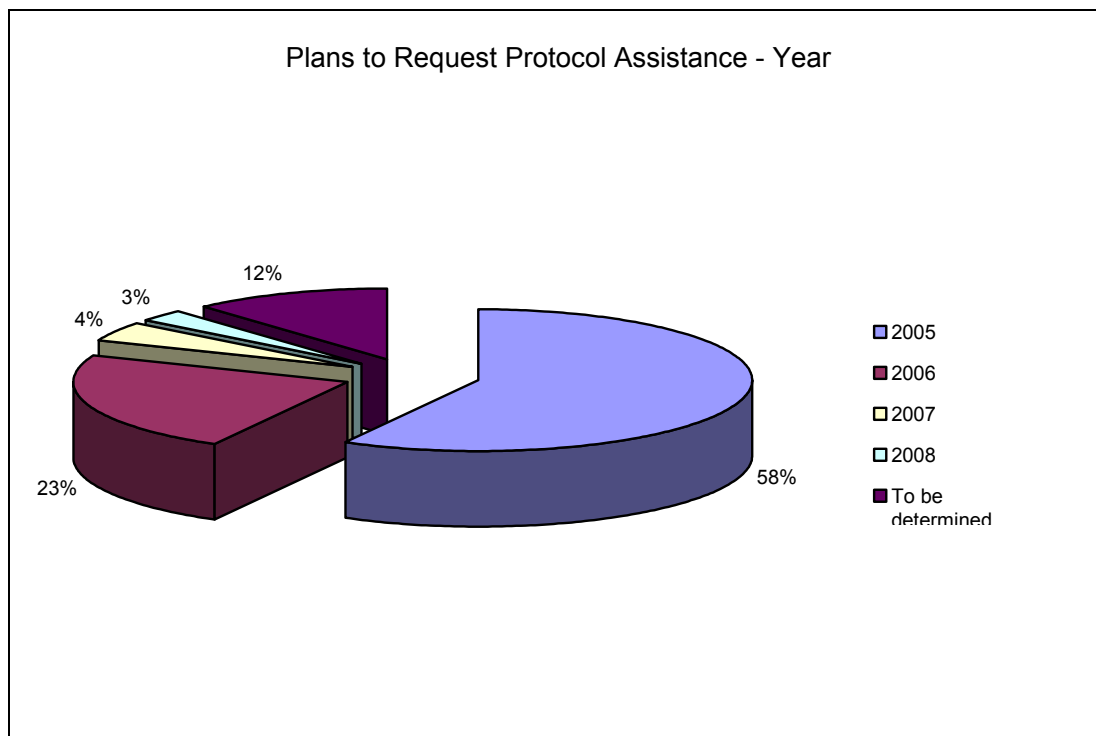
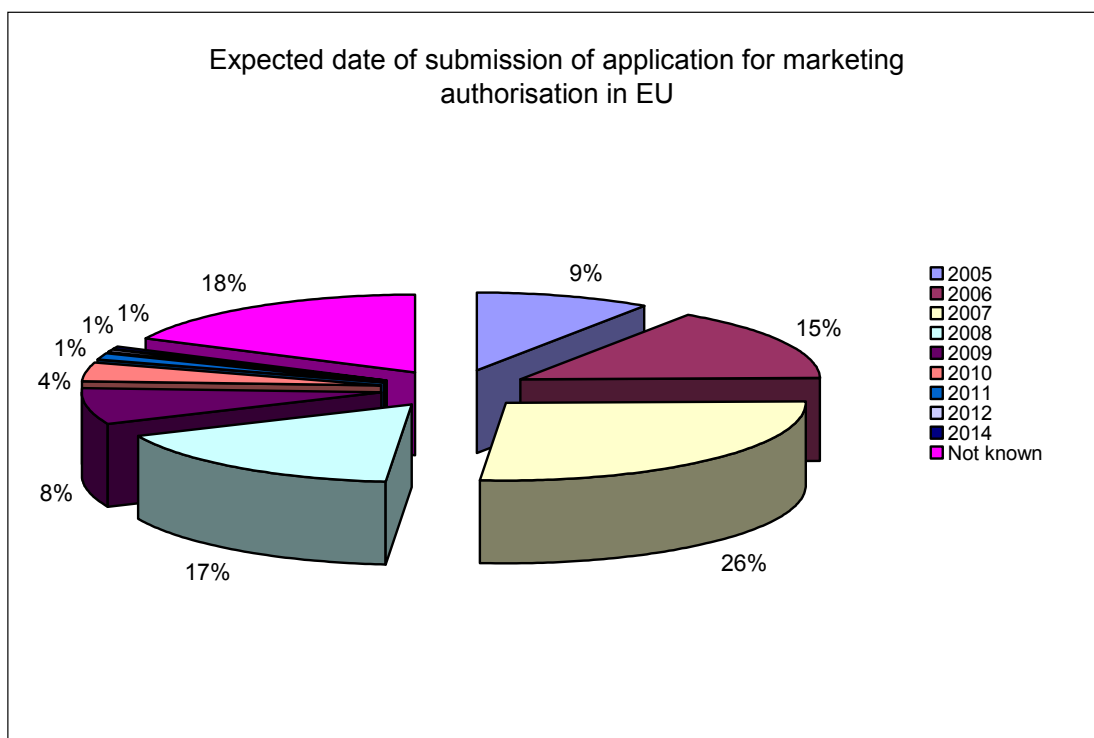
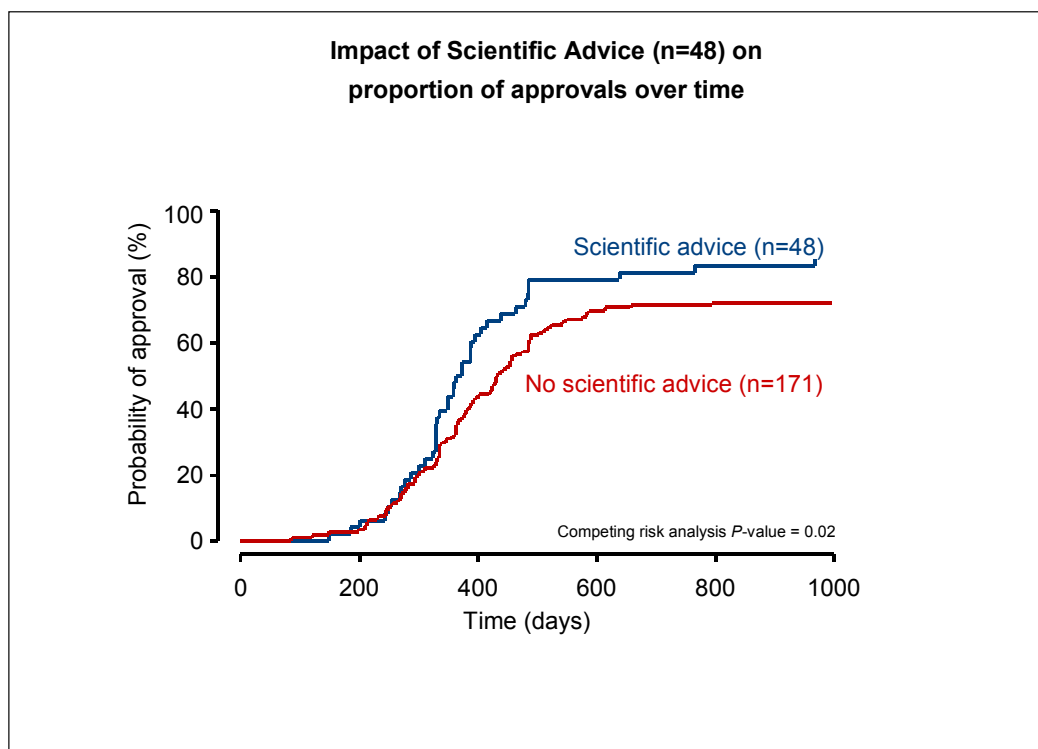


Figure 19: Planned Applications for Marketing Authorisation for Designated Orphan Medicinal Products (April 2005)



Impact of Scientific Advice/Protocol Assistance

Figure 20: Impact of Scientific Advice/Protocol Assistance on the Proportion of Approvals Over Time (2004)



Orphan Applications – Product Classification

Figure 21: Type of Medicinal Products Subject of an Application for Orphan Designation (2000-2004)

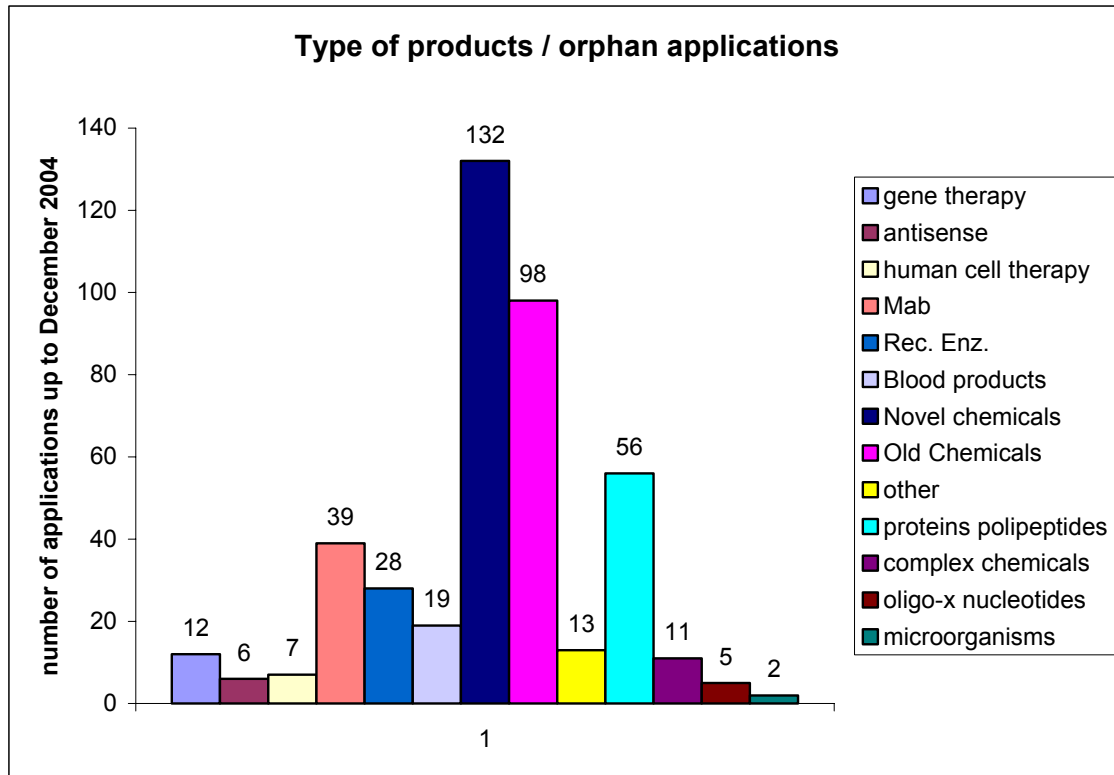


Figure 22: Percentage of Designation Applications for Biotech Products (2000-2004)

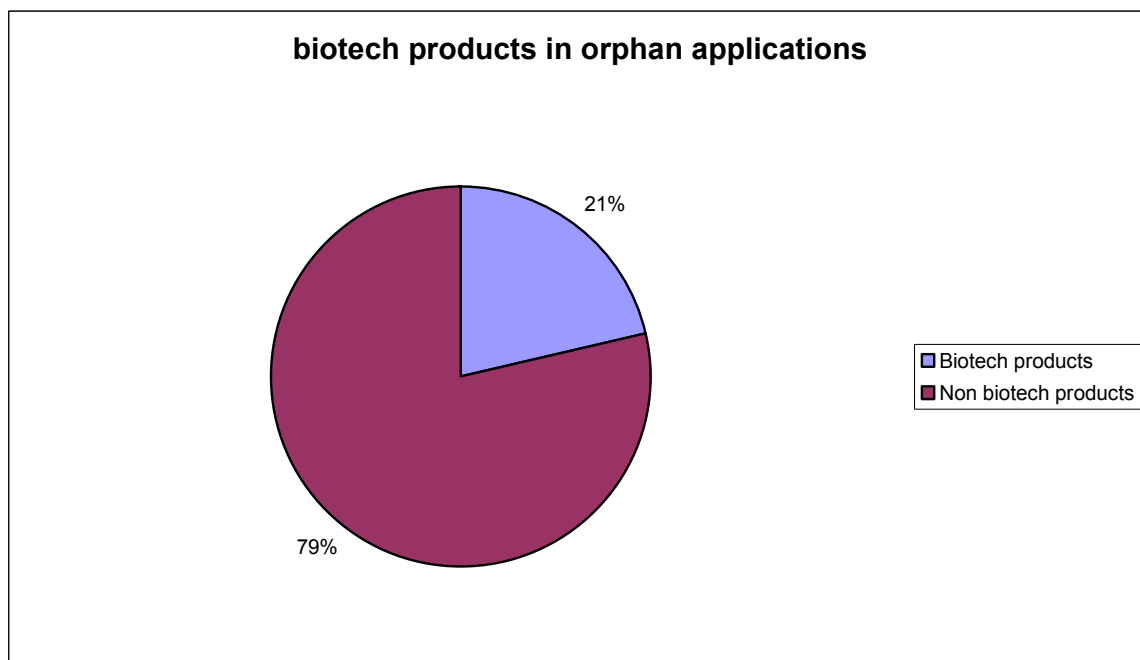


Figure 23: Percentage of Designation Applications for Innovative/Novel Medicinal Products (2000-2004)

