## THE SELECTION PROCESS

Independent research on drugs has been supported in Italy by the Institute for Research and Health Care through the selection process of research projects. The process involves the evaluation of the clinical and scientific aspects of the proposals, as well as the economic feasibility of the research. The evaluation is carried out by a committee of experts who have a wide range of expertise in various fields of medicine and research. The evaluation process is designed to ensure that the research is of high scientific quality and has the potential to contribute to the advancement of medicine and healthcare.

## GENERAL RULES FOR THE 2006 CALL FOR PROPOSALS

When submitting a letter of intent to the 2006 AIFA program on independent research on drugs, the following information was required:

- **Project Title and Description:** A brief description of the project, including the objectives, methods, and expected outcomes.
- **Principal Investigator:** Information about the principal investigator, including their qualifications and experience.
- **Research Team:** Information about the team involved in the project, including their roles and responsibilities.
- **Research Plan:** A detailed plan of the research, including the timeline and budget.
- **Research Environment:** Information about the research environment, including the facilities and resources available.
- **Funding Requirements:** Details of the funding requirements, including the amount of funding needed and the sources of funding.

The assessment of projects is based on the following criteria:

- **Scientific Validity:** The scientific merit and feasibility of the project.
- **Relevance of the Expected Results:** The relevance of the expected results for the clinical practice and the NHS.
- **Feasibility:** The feasibility of the project, including the availability of resources and the capability of the research team.
- **Innovation:** The degree of innovation and the potential for new insights.
- **Institutional Engagement:** The level of institutional engagement in the project.
- **Public vs. Private Sector Engagement:** The balance between public and private sector engagement.

Letters of intent were submitted by 30 September 2006, and AIFA funded projects in area 1 up to a maximum of 300,000 Euro for each proposals (the cost of therapies reimbursable and limitations of use within the NHS; AIFA funded projects in area 2 and area 3 were considered as part of a double blind preparation team members). The evaluation of the project was based on the following criteria:

- **Scientific Merit:** The scientific merit of the project, including the methodology and the potential for new insights.
- **Relevance of the Expected Results:** The relevance of the expected results for the clinical practice and the NHS.
- **Feasibility:** The feasibility of the project, including the availability of resources and the capability of the research team.
- **Innovation:** The degree of innovation and the potential for new insights.
- **Institutional Engagement:** The level of institutional engagement in the project.
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- **Innovation:** The degree of innovation and the potential for new insights.
- **Institutional Engagement:** The level of institutional engagement in the project.
- **Public vs. Private Sector Engagement:** The balance between public and private sector engagement.
An innovative aspect of the program is represented by the way of funding independent research: an ad hoc fund was set up, requiring pharmaceutical companies to contribute 5% of their yearly expenditure devoted to promotional initiatives (e.g., seminars, workshops, etc.) aimed at physicians. Around 40 million Euro is available each year for funding the research program and the other activities supported by this fund: independent drug information and the reimbursement of orphan drugs, and “life saving” drugs, not yet marketed.

With the help of an independent scientific committee (Committee for Research and Development, R&D), specific research areas are identified. The role of the R&D Committee is to support AIFA in identifying research areas for the call for proposals, conducting the first phase of the selection process, and supervising the implementation of the projects.

For the 2005 call for proposals, out of the 402 letters of intent originally submitted, 101 were admitted to the second phase of the evaluation (study sessions), and 54 studies were funded (Table 1). All funded studies are currently underway.

The R&D Committee is currently defining the research topics to be included in the next call for proposals, due in August 2007. Hearings with different scientific and health institutions have taken place and an ad hoc web site was opened to receive suggestions from individual researchers, learned societies, patient associations, research groups, etc.

The experience from 2005 to date

The promotion of independent research on drugs represents one of the strategic actions assigned to the Italian Medicines Agency (AIFA) by legislation. The general aim of this program is to support clinical research on drugs, as an element of transfer of the knowledge acquired in clinical practice to the healthcare sector (NHS), and where commercial support is insufficient.

There is not only a concern for patient populations normally excluded by clinical studies—e.g., children, pregnant women and the elderly. There is also an effort to gather more information on research issues less explored in commercial research, such as clinically relevant and patient-related efficacy of drugs, including the assessment of clinical strategies, and long-term follow-up on efficacy and safety of therapies.

AIFA set up the program on independent research in 2005, and two call for proposals (2005 and 2006) have already been held. The 2005 call for proposals aimed at investigating research activities in public (e.g., NHS, universities) and not-for-profit organisations (e.g., no-profit foundations, patient associations, research groups) and research on drugs included in the treatment of rare diseases.

Area 1. Orphan drugs for the treatment of rare diseases and drugs for non-responders.

Area 2. Head-to-head comparison of drugs and therapeutic strategies.

Area 3. Strategies to improve the appropriateness of drug use and pharmacoepidemiology studies.

Lack of support in the areas of orphan drugs generally stems from the limited segment of patient populations involved. Comparative studies, especially between generics and original, and strategies aiming at providing effective and independent information to NHS and patients also suffer from a considerable degree of neglect.
An innovative aspect of the program is represented by the way of funding independent research: an ad hoc fund was set up, requiring pharmaceutical companies to contribute 5% of their yearly expenditure devoted to promotional initiatives (e.g., seminars, workshops, etc.) aimed at physicians. Around 40 million Euro is available each year for funding the research program and the other activities supported by this fund: independent drug information and the reimbursement of orphan drugs, and “life saving” drugs, not yet marketed.

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For the 2005 call for proposals, out of the 402 letters of intent (LOI) previously submitted, 40% were admitted to the second phase of the evaluation (study sessions), and 25% of them were funded (Table 1). A total of 54 studies were supported by the Scientific Committee in 2005.

For the 2006 call for proposals, out of the 413 LOI submitted, 85% were admitted to the study sessions, and 46% of them were funded. The R&D Committee is currently defining the research topics to be included in the next call for proposals, due in August 2007. Hearings with different scientific and health institutions have taken place and an ad hoc web site was opened to receive suggestions from individual researchers, learned societies, patient associations, research groups, etc.
An innovative aspect of the program is represented by the way of funding independent research: an ad hoc fund was set up, requiring pharmaceutical companies to contribute 5% of their yearly expenditure devoted to promotional initiatives (e.g., seminars, workshops, etc.) aimed at physicians. Around 40 million Euro is available each year for funding the research program and the other activities supported by this fund: independent drug information and the reimbursement of orphan drugs, and “life saving” drugs, not yet marketed.

With the help of an independent scientific committee (Committee for Research and Development, R&D), specific research areas are identified. The role of the R&D Committee is to support AIFA in identifying research areas for the call for proposals, conducting the first phase of the selection process, and supervising the implementation of the projects.

### The Experience from 2005 to Date

#### Background

The promotion of independent research on drugs represents one of the strategic tasks assigned to the Italian Medicines Agency (AIFA) by legislation. The general aim of the program is to support clinical research on drugs, as well as research on the thoroughness of the National Health Service (NHS), and when necessary to support it in an efficient manner.

There is not, in any case, a single project but a network of projects coordinated by clinical doctors and hospitals, such as physicians and pharmaceutical researchers. This is a network to obtain more information on research issues less explored in commercial research, such as clinically relevant endpoints, relative efficacy of drugs (including the assessment of clinical severity), and long-term follow-up and safety of treatments.

AIFA set up the program on independent research in 2005, and two call for proposals (2005 and 2006) have already been launched. The call for proposals is aimed at investigators working in public (e.g., NHS, universities, etc.) or non-profit organisations (e.g., scientific foundations, patient associations, etc.). The first two years, three main areas of drug research were included in the program:

- **Area 1.** Orphan drugs for the treatment of rare diseases and drugs for non-responders.
- **Area 2.** Head-to-head comparison of drugs and therapeutic strategies.
- **Area 3.** Strategies to improve the appropriateness of drug use and pharmacoepidemiology studies.

Lack of support in the area of rare diseases generally stems from the limited segment of patient populations involved. Comparative studies, especially when generics are included, also suffer from a considerable degree of neglect.

#### The AIFA Fund

An innovative aspect of the program is represented by the way of funding independent research: an ad hoc fund was set up, requiring pharmaceutical companies to contribute 5% of their yearly expenditure devoted to promotional initiatives (e.g., seminars, workshops, etc.) aimed at physicians. Around 40 million Euro is available each year for funding the research program and the other activities supported by this fund: independent drug information and the reimbursement of orphan drugs, and “life saving” drugs, not yet marketed.

With the help of an independent scientific committee (Committee for Research and Development, R&D), specific research areas are identified. The role of the R&D Committee is to support AIFA in identifying research areas for the call for proposals, conducting the first phase of the selection process, and supervising the implementation of the projects.

### Table 1. Summary of the Italian Program for Independent Research on Drugs

<table>
<thead>
<tr>
<th>Area</th>
<th>Call for Proposals 2005</th>
<th>Letters of Intent</th>
<th>Study Protocol</th>
<th>Letters of Intent</th>
<th>Study Protocol</th>
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<tbody>
<tr>
<td>Area 1: Orphan drugs</td>
<td>150</td>
<td>31</td>
<td>20</td>
<td>184</td>
<td>38</td>
</tr>
<tr>
<td>Area 2: Head to head comparison of drugs</td>
<td>80</td>
<td>25</td>
<td>13</td>
<td>121</td>
<td>24</td>
</tr>
<tr>
<td>Area 3: Pharmacovigilance and appropriateness</td>
<td>172</td>
<td>45</td>
<td>21</td>
<td>149</td>
<td>37</td>
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<tr>
<td>Total</td>
<td>402</td>
<td>101</td>
<td>54</td>
<td>454</td>
<td>99</td>
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</table>

The 2006 call for proposals has now been concluded (synthesis of the documents presented in Appendix 1). All 161 letters of intent, 98 were admitted to the study sessions and 71 were funded.

The R&D Committee is currently defining the research topics to be covered in the next call for proposals, due in August 2007. Hearings with different scientific and health institutions have taken place and an ad hoc website was opened to receive suggestions from individual researchers, non-profit organizations, patient associations, research groups, etc.
The promotion of independent research on drugs represents one of the strategic tasks assigned to the Italian Medicines Agency (AIFA) by legislation. The general aim of the Agency is to support clinical research on drugs, even areas of interest for the National Health Service (NHS), and where conventional support is too minimal or nonexistent.

There is not only a concern for patient populations normally unrepresented by clinical studies on efficacy and safety, such as children, pregnant women and the elderly. There is also a need to obtain more information on research issues less explored in commercial research, such as clinical use in emergency situations, non-commercial drugs, and the limited segment of patient populations involved. Comparative studies, especially when generics are included, and strategies aimed at promoting independent research on drugs in areas of interest for the NHS and where commercial support is normally insufficient.

AIFA set up the program on independent research in 2005, and the call for proposals (2005 and 2006) have already been launched. The call for proposals is aimed at investigators working in public institutions (e.g., NHS, universities, etc.) or non-profit organisations (e.g., scientific foundations, patient associations, etc.). For the first two years, three main areas of drug research were included in the program:

1. Strategies to improve the appropriateness of orphan drugs for the treatment of rare diseases (Area 1)
2. Head to head comparison of drugs (Area 2)
3. Risk-benefit assessment of drugs (Area 3: Pharmacovigilance)

An innovative aspect of the program is represented by the way of funding independent research: an ad hoc fund set up by AIFA is used to reimburse pharmaceutical companies for 10% of their preclinical expenditure directed to independent research. The program on independent research on drugs was approved by the Istituto Superiore di Sanità (ISS) (www.iss.it) and the scientific community. The promotion of independent research on drugs is considered an important tool for the implementation of the projects.

The call for proposals has now been concluded (application form: www.aifa.gov.it), and 61 letters of intent (25% of the total) have been submitted. Of these, 101 were admitted to the second phase of the selection process (2006 call), and 54 studies were funded (Table 1). All funded studies are currently underway. Around 40 session participants have attended the study sessions, and 51 were funded.

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1. Strategies to improve the appropriateness of orphan drugs for the treatment of rare diseases (Area 1)
2. Head to head comparison of drugs (Area 2)
3. Risk-benefit assessment of drugs (Area 3: Pharmacovigilance)

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Table 1: The Experience from 2005 to Date

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<td>2005</td>
<td>101</td>
<td>54</td>
<td>36</td>
<td>18</td>
</tr>
<tr>
<td>2006</td>
<td>101</td>
<td>54</td>
<td>36</td>
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AIFA set up the program on independent research in 2005, and two call for proposals (2005 and 2006) have already been launched. The call for proposals is aimed at providing independent information on drug use and pharmacoepidemiology studies. AIFA invited researchers, learned societies, patient associations, research groups, etc. to submit projects. The 2005 call for proposals has now been concluded (a synthesis of the content is presented in Appendix 1). Out of 454 letters of intent, 99 were admitted to the study sessions and 51 were funded. The 2006 call for proposals has now been concluded (a synthesis of the content is presented in Appendix 1). Out of 454 letters of intent, 99 were admitted to the study sessions and 51 were funded.

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THE SELECTION PROCESS

The evaluation of the study protocols involved the organisation of independent study sessions, involving more than 20 experts (half from Italian institutions and half from abroad). The evaluation procedure mirrors the accredited standards of internationally recognised scientific institutions. The assessment of projects is based on the following criteria:

- Potential impact on the regulatory activity of AIFA
- Scientific validity, in order to select projects with the highest scientific merit;
- Relevance of the expected results for the clinical practice within the NHS;
- Potential interest for the life cycle in health in collaboration with Regional Health Authorities. AIFA aims at protecting patients’ health, improving the quality of the healthcare system and reducing costs and unnecessary duplication of the drug development process. The support of innovation is essential in order to ensure a research-based pharmaceutical market.

The evaluation procedure involves the organisation of independent study sessions, involving more than 20 experts. The evaluation of the letters of intent had been completed (or by 30 November 2006). If a multinational study was proposed, it should have a multilingual protocol and be performed in the Italian portion. Letters of intent were submitted by 30 September 2006, and not to a specific project, taking into account that funding did not exceed 500,000 Euro and that the antigens to be used could not be produced in the same area or topic. Principal investigators of projects funded in the 2005 program might provide financial support to a project funded in the 2006 program.

The assessment of projects is based on the following criteria:

- Financial support to the 2006 AIFA program for independent research on drugs, the following information was required:

- The objective and the rationale of the study or programme:
- The scientific validity of the proposed study or programme:
- The potential impact of the study or programme on the regulatory activities of AIFA:
- The relevance of the expected results for the clinical practice within the NHS:
- Any other information that could demonstrate how the project was linked to the Italian portion.

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- The potential impact of the study or programme on the regulatory activities of AIFA:
- The relevance of the expected results for the clinical practice within the NHS:
- Any other information that could demonstrate how the project was linked to the Italian portion.
The Italian Medicines Agency (AIFA) is a governmental organisation responsible for the promotion of research, drug expenditure governance, and the promotion of appropriate drug use. AIFA activities include, among the others, marketing and the promotion of appropriate drug use; the assessment of the risk-benefit ratio associated with Regional Health Authorities. AIFA aims at protecting public health through the continuous assessment of the risk-benefit ratio associated with Regional Health Authorities.

The AIFA annual photo contest with the theme “Research” was launched in 2005 and was distributed accordingly. Hundreds of images were submitted in 2006 for AIFA’s second annual photo contest with the theme “Research”. The Agency selected the winners (some of them shown here) while the remaining images were published on the AIFA website (www.agenziafarmaco.it).

To view more contest submissions and learn how to enter the 2007 competition, click on www.agenziafarmaco.it.

The Agency selected the winners (some of them shown here) while the remaining images were published on the AIFA website (www.agenziafarmaco.it).

In order to use available resources on important though neglected areas of interest, AIFA aims at protecting public health through the continuous assessment of the risk-benefit ratio associated with Regional Health Authorities. AIFA aims at protecting public health through the continuous assessment of the risk-benefit ratio associated with Regional Health Authorities. AIFA aims at protecting public health through the continuous assessment of the risk-benefit ratio associated with Regional Health Authorities. AIFA aims at protecting public health through the continuous assessment of the risk-benefit ratio associated with Regional Health Authorities.
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When submitting a letter of intent to the 2006 AIFA program on independent research on drugs, the following information was required: (see Box 2). Two written comments were obtained for each study protocol. Investigators admitted to the second phase of the evaluation procedure had to present a full study protocol.\n\nIn order to guarantee independence in the evaluation procedure, no R&D Committee members were included in the study sessions. Letters of intent were not accepted if the content was considered duplicated, by the R&D Committee. The following topics were considered for the 2006 program: (in order of the interest given by the final ranking report)\nA. Lack of commercial interest for the objectives of the study, due to the limited availability of the drug in the NHS;\nB. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nC. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nD. Lack of commercial interest for the objectives of the study, due to the limited availability of the drug in the NHS;\nE. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nF. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nG. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nH. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nI. 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The assessment of projects is based on the following criteria:

1. Scientific validity, in order to select projects with high clinical relevance for the clinical practice (topic 1) that might provide financial support to an entire area or topic, taking into account that funding did not exceed 500,000 Euro and that reimbursement was considered equivalent, by the R&D Committee, to a project funded in the 2005 program (to consult the final ranking report). For all other topics (topics 2 and 3 in area 1; all topics in areas 2 and 4) a letter of intent was considered required to a specific project, taking into account that funding did not exceed 500,000 Euro and that the willingness to contribute was communicated before the assessment of the letter of intent. Letters of intent were submitted by 30 September 2006, and the final assessment had to be completed by 30 November 2006.\n
In order to use available resources on important though neglected areas of interest, EMBERS OF THE 2006 CALL FOR PROPOSALS was taken into account: (From high tech to high touch) the evaluation procedure mirrors the accredited standards established by the EMEA. The evaluation of the study protocols entailed the organisation of independent study sessions, involving more than 20 experts (half from Italian institutions and half from abroad). In order to guarantee independence in the evaluation procedure, in the first step, sessions were organised of experts invited to sit on their own initiative and members of the R&D Committee (as observers) were considered to be in a conflict of interest. In the second step, independent study sessions, involving more than 20 experts (half from Italian institutions and half from abroad) were held in Rome, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.

Letters of intent were not accepted if the content was considered duplicated, by the R&D Committee. The following topics were considered for the 2006 program: (in order of the interest given by the final ranking report)\nA. Lack of commercial interest for the objectives of the study, due to the limited availability of the drug in the NHS;\nB. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nC. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nD. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nE. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nF. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nG. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nH. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nI. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nJ. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nK. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nL. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nM. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nN. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nO. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nP. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nQ. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nR. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nS. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nT. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nU. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nV. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nW. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nX. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.\nY. Relevance of the expected results for the clinical practice, if the results could not be considered in more than three letters of intent submitted for the research area.\nZ. Potential impact on the regulatory activity of AIFA, with specific attention to guide the decision about drug reimbursement and introduction of similar drugs within the NHS.
When submitting a letter of intent to the 2006 AIFA program on independent research on drugs, the following information was taken into account:

Each proponent might present, as principal investigator, only one letter of intent.

Principal investigators of projects funded in the 2005 program could not apply (as principal investigators) for the 2006 call for proposals.

Letters of intent were not accepted if the content was considered equivalent, by the R&D Committee, to a project funded in the 2005 program (to consult the titles: www.agenziafarmaco.it).

Clinical units where patients were planned to be enrolled could not be involved in more than 3 letters of intent pertaining to the research areas 2 and 3.

If a multinational study was proposed, it should have been considered that the funding from AIFA was limited to the Italian portion.

This call focused on clinical research and consequently letters of intent focusing on the drugs mechanism of action were not accepted.

Phase I and phase II clinical studies were not considered acceptable, with the exception of adequately motivated studies concerning orphan drugs designated by the EMEA.

AIFA funded projects in area 1 up to a maximum of 300,000 Euro for each proposal (the cost of therapies was funded separately).

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GENERAL RULES FOR THE 2006 CALL FOR PROPOSALS

The evaluation procedure mirrors the accredited standards of internationally recognised scientific institutions. The assessment of projects is based on the following criteria:

- Relevance of the expected results for the clinical practice within the NHS;
- Scientific validity, in order to select projects with the highest scientific merit;
- Potential impact on the regulatory activity of AIFA, with specific attention to guide the direction of drug reimbursement and restrictions of use within the NHS;
- Lack of commercial interest for the objectives of the study, in order to use available resources in important though neglected areas of interest.

A two step review process has been implemented. In the first step, researchers are required to submit a letter of intent which is assessed by the R&D Committee. Investigators admitted to the second phase of the evaluation procedure are required to present a full study protocol.

The evaluation of the study protocols involved the organization of independent study sessions, including more than 20 experts from Italian institutions and half from abroad. In order to guarantee independence in the evaluation procedure, no R&D Committee members were included in the study sessions.

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Two written comments were obtained for each study protocol before the study session meeting. Each protocol was also thoroughly reviewed in a plenary discussion, and a final score, representing the average of each expert’s vote, was achieved.

Study protocols were ranked on the basis of the final score and, starting with the highest score, the available funds (35 million Euro in 2005 and 31 in 2006) were distributed accordingly.

When submitting a letter of intent to the 2006 AIFA program on independent research on drugs, the following information was taken into account:

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