French National Agency for Medicines and Health Products Safety (ANSM) :

Reinforcing the collaboration with healthcare professionals and patient associations

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Contents

1) Relations with healthcare professionals and patient associations in the ANSM organisation : Objectives, challenges, overview

2) Healthcare professionals : Collaboration and communication actions

3) Patients associations : Collaboration and communication actions

4) Perspectives
1) Relations with healthcare professionals and patient associations in the ANSM organisation : Objectives, challenges, overview

2) Healthcare professionals : Collaboration and communication actions

3) Patients associations : Collaboration and communication actions

4) Perspectives
Relations with healthcare professionals and patient associations in the ANSM organisation: Objectives and challenges

- **Informing patients and healthcare professionals: one of the ANSM’s main missions** (the 29 December 2011 Act Reinforcing the Safety of Medicines and Health Products)
  - Reinforcing the dialogue in a context of trust decline within the population
  - Maintaining transparency

- **Empowering them in the decision making process (members of Board of directors and commissions with vote)**

- **Integrating expertise all along the process leading to decision:**
  - Getting real life information about patient management
  - Framing collaboration:
    - Task forces that bring together healthcare professionals
    - Calls for projects (scientific research and patient associations)
    - Participation of associations of patients and users of the healthcare system in the Board of Directors and committees of the Agency, etc.
    - Conferences for information sharing
    - ...
Transparency of expertise, handling conflicts of interest

- Deontology department recently created
- Published on line:
  - Agendas and minutes of the meetings including minority opinions
  - Videos of commissions
  - Updated public declaration of interests published online
### ANSM governance and consultative authorities: representation of health professionals and health system consumer associations

<table>
<thead>
<tr>
<th>Board of Directors</th>
<th>2 (MD and PharmD Orders)</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific board</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>4 consultative commissions</td>
<td>The commission that performs the initial health product benefit/risk assessment</td>
<td>12</td>
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<tr>
<td></td>
<td>The commission that monitors the benefit/risk ratio of health products</td>
<td>12</td>
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<tr>
<td></td>
<td>The narcotics and psychotropics commission</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>The commission for the prevention of risks related to the use of categories of health products</td>
<td>14</td>
</tr>
</tbody>
</table>

+ Ad hoc auditions of HCP and associations
Formal expertise and exchanges with healthcare professionals and patient associations

<table>
<thead>
<tr>
<th>Committee</th>
<th>Professionals</th>
<th>Patient associations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical committee of pharmaco-vigilance risk assessment</td>
<td>Members</td>
<td>0</td>
</tr>
<tr>
<td>Technical committee of pharmaco-addiction assessment and information centers</td>
<td>Members</td>
<td>0</td>
</tr>
<tr>
<td>Technical committee of haemo-vigilance and biovigilance</td>
<td>Members</td>
<td>0</td>
</tr>
<tr>
<td>Technical committee of materio-vigilance and reacto-vigilance</td>
<td>Members</td>
<td>0</td>
</tr>
<tr>
<td>36 permanent working groups</td>
<td>Members + Ad hoc auditions</td>
<td>Ad hoc auditions</td>
</tr>
</tbody>
</table>
Punctual consultations and conventions

- Punctual auditions
  - Of national health care professional organisations (national societies, federations, colleges or individuals…)
  - Of patient associations
  - *Ad hoc* meetings with the involved ANSM directions
  - In commissions, Board of Directors…

- Financial support and conventions
  - Scientific researchers and patients associations: to receive subvention (laureates of call to projets)
  - Convention to settle a frame of continuous collaboration:
    - National Council of physicians’ Order
    - National Council of pharmacists’ Order
    - Some national societies (eg: French society of orthopedic surgery - SOFCOT)
Interface committees: Information sharing and transparent debate with the stakeholders

- Created in 2013

- 3 direct interfaces between the ANSM and the stakeholders:
  - interface committees with industries:
    - pharmaceutical industries
    - industries of medical devices and in vitro diagnosis
    - industries of cosmetics
  - Interface committee with healthcare professionnals
  - Interface committe with patients associations

- 3 meetings/year; all agendas and minutes of the meetings online

- Work results presented each year to the Board of Directors
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3) Patients associations: Collaboration and communication actions

4) Perspectives
Healthcare professionals: Collaboration and communication actions

Interface committee with healthcare professionals

- Meetings allowing in depth explanations about the ANSM actions
- Experience sharing
- Transparency of debates

Topics in 2014:
- Shortage
- Health professionals reporting of side effects
- Medicine conditionning
- Early access to innovation
- Generics and biosimilars

http://ansm.sante.fr/L-ANSM2/Comites-d-interface/Comite-d-interface-avec-les-representants-des-professionnels-de-sante/Comite-d-interface-avec-les-representants-des-professionnels-de-sante2
Events with healthcare professionals in 2014

◆ Conferences and congresses

Booths:
- Congress of the GP teachers College (CNGE ; November 28)
- Young medical practionners conference ReAFJIR (September 19)
- 8th congress of general medicine in France (April 3-5)
- 15th national congress of general medicine residents (January 10-11)
+ presentations by ANSM in other congresses

◆ In-house ANSM symposia

- 7th innovation meeting (November 28)
- 1st Meeting Day with the ANSM (September 26)
- Facilitating access to medicines and therapeutical innovation (June 20)
- Micro-organism and toxines : Security good practice and biological safety (May 21)
Communication tools dedicated to healthcare professionnals

- **Publications**: Reports, synthesis

- **Warnings** *(message of sanitary security to be immediately taken into account)*

- **DHPC** *(ANSM or pharmaceutical companies)*
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4) Perspectives
Patients associations: Collaboration and communication actions

Interface committee with patient associations

- 7 members from associations and 7 ANSM representatives (+ surrogates)
- Topics:
  - Clinical trials and access to innovation
  - Reporting of side effects by patients
  - Re-assessment of benefit/risk ratio
  - Deontological aspects
  - Shortage...
- Meeting allowing in depth explanations about the ANSM actions
- Transparency of debates
- Diversity of associations (size, therapeutical fields), so different ways of expression and different raised issues
12 association representatives; 6 ANSM representatives

Advising on:
- Printed documents
- Internet website
- Specific topics:
  - Diffusion of ANSM information
  - Impact of communication
  - Adaptation to special needs (patients with mental diseases, disabled people...)
  - ...
Calls for patient associations’ projects

- Objectives:
  - to stimulate and support independent associations’ initiatives aiming at reducing the risks related to health products

- In 2012:
  - 39 projects received, 38 eligible
  - 9 selected
  - Total amount of grant: 260,000 euros

- In 2013:
  - 38 projects received, 36 eligible
  - 10 selected
  - Total amount of grant: 230,500 euros
2nd annual day of information and exchanges between the ANSM and patient associations

- January 22nd 2014
- About 100 participants
- Main topics:
  - First results of associations’ participation in the ANSM administrative council, commissions and interface committee
  - Innovation access
  - Associations representation at the PRAC of the EMA
  - Interface committee’s work plan for 2014
  - Results of previous call for projets
Communication tools : all publics

- **Website** (120 000 – 200 000 visitors per month)

- **Information release** (synthetic informations about current topic - 12,000 subscribed to daily information by email)

- **ANSM Info**

- **ANSM news** (monthly information synthesis)

- **Public data base on medicines** (since October 2013)

- **Twitter**
Communication tools: Patients and general public

- Leaflets patients
- Posters
- Website; reporting of side effects
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Perspectives

- Handling the flow of requests from both sides: Organising audiences in commissions and working groups’ meetings

- Relation with the EMA regarding patient association audition: information and input

- Internal charter of work with patient associations

- Defining a process and an information flow so as to favor the link between:
  - all the patient association representatives
  - all the instances
  - The patient associations represented in ANSM organisation and those who are not
Thank you
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