

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

## **Reinforcing the collaboration with healthcare professionals and patient associations**

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# 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
  - Maintining 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

		Professionals	Patient and consumer associations
Board of Directors		2 (MD and PharmD Orders)	2
Scientific board		12	0
4 consultative commissions	The commission that performs the initial health product benefit/risk assessment	12	2
	The commission that monitors the benefit/risk ratio of health products	12	2
	The narcotics and psychotropics commission	12	1
	The commission for the prevention of risks related to the use of categories of health products	14	2

+ Ad hoc audits of HCP and associations

# Formal expertise and exchanges with healthcare professionals and patient associations

	Professionals	Patient associations
Technical committee of pharmaco-vigilance risk assessment	Members	0
Technical committee of pharmaco-addiction assessment and information centers	Members	0
Technical committee of haemo-vigilance and biovigilance	Members	0
Technical committee of materio-vigilance and reacto-vigilance	Members	0
36 permanent working groups	Members + Ad hoc auditions	Ad hoc auditions

# 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 professionals
  - ❖ Interface committee 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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# 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 conditioning
  - Early access to innovation
  - Generics and biosimilars

# Events with healthcare professionals in 2014



## ◆ Conferences and congresses

Booths :

- Congress of the GP teachers College (CNGE ; November 28)
- Young medical practitioners 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 professionals



- Publications : Reports, synthesis
- Warnings (*message of sanitary security to be immediately taken into account*)
- DHPC (*ANSM or pharmaceutical companies*)





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# 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

# « Patient information » Working group, related to the interface committee



- ◆ 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 independant 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 projets received, 36 eligible
  - 10 selected
  - Total amount of grant : 230 500 euros

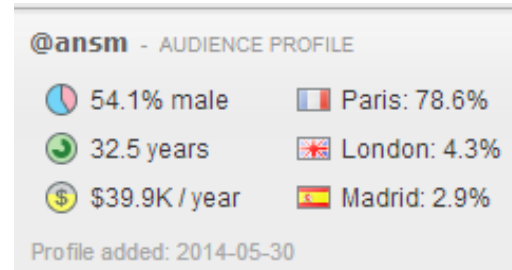
# 2<sup>nd</sup> annual day of information and exchanges between the ANSM and patient associations

- ◆ 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 projects



# 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

**an sm**  
Agence nationale de sécurité du médicament et des produits de santé

**VOUS et... vos médicaments dopaminergiques**  
(maladie de Parkinson, hypertonie, épilepsie, syndrome de l'armée russe, etc.)

**QU'EST CE QUE LA MALADIE DE PARKINSON ?**

La maladie de Parkinson est une maladie dégénérative du système nerveux central. Elle agit principalement sur les neurones producteurs de dopamine, substance naturelle intervenant dans le contrôle des mouvements mais aussi dans celui de la motivation, de l'humeur et des émotions. Cette maladie se traduit principalement par une rigidité, un tremblement au repos et une lenteur des mouvements.

**QUELS MÉDICAMENTS EXISTENT POUR LUTTER CONTRE LA MALADIE DE PARKINSON ?**

**an sm**

**VOUS et... Vos contraceptifs oestroprogestatifs**

Les contraceptifs oraux (pilules) ont, comme tous les médicaments, des effets secondaires. Une méthode pour les éviter est le suivi médical régulier.

**an sm**

**CE QU'IL FAUT SAVOIR AVANT DE COMMENCER UN TRAITEMENT PAR ISOTRÉTINOÏNE ORALE**

**Le risque de malformations graves du fœtus**

Une femme enceinte ou qui envisage d'être enceinte ne doit pas prendre d'isotrétinoïde oral. Ce médicament peut provoquer de graves malformations du fœtus.

**Le risque de dépression et autres troubles psychologiques**

Certaines personnes peuvent ressentir des effets secondaires psychologiques, tels que la dépression, l'anxiété ou d'autres troubles psychologiques.

**an sm**

**Ne vous mélangez pas les pipettes!**

Un dispositif d'administration n'est pas un médicament.

Les seringues orales, les pipettes, les cuillères-mesures et les compte-gouttes sont des dispositifs d'administration qui vous aident à prendre votre médicament. Ils ne sont pas des médicaments.

Un dispositif d'administration, s'il est mal utilisé, peut délivrer une dose trop importante ou insuffisante de médicament. Il peut aussi provoquer des dommages. Le dispositif d'administration est conçu pour vous aider à prendre votre médicament de manière sûre et précise.

Des règles simples vous permettront d'éviter les erreurs :

- Gardez toujours le dispositif d'administration dans sa boîte ou le médicament associé. Ne le mélangez pas avec un autre.
- En cas de perte ou d'absence d'un dispositif d'administration, consultez un professionnel de santé.
- Lisez toujours attentivement le notice ou le mode d'emploi. Ces documents contiennent des informations importantes pour l'utilisation des dispositifs d'administration.

**an sm**

**Attention danger!**

Attention danger pour les médicaments injectés au bras de l'épaule.

Ne pas injecter de médicaments dans le bras de l'épaule.

**Comment déclarer un effet indésirable**

- Déclarer un effet indésirable : mode d'emploi

**Déclarer un effet indésirable : mode d'emploi**

**Vous constatez un effet indésirable** que vous suspectez être lié :

- à la prise d'un médicament,
- à l'utilisation d'un dispositif médical (pansement, produit de comblement des rides, prothèse...)
- ou d'un autre produit de santé ou cosmétique.

Patients, associations de patients, contribuez à améliorer la sécurité des produits de santé que vous utilisez. Professionnels de santé, industriels, vous avez des obligations de déclaration.

**Vous déclarez**

- >> Médicament
- >> Dispositif médical
- >> Autres produits

L'ANSM, qui assure par différents moyens la surveillance des produits de santé, a mis en place des systèmes de recueil de signalements et d'alertes en provenance de patients, des associations de patients, des professionnels de santé et des industriels.



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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

### **Avertissement**

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