Involvement of pharmacists in the monitoring of oral anticoagulant therapy: delivery of a notebook for the patient



Context and objectives

- → Around 600 000 patients are treated by vitamin K antagonists (AVK) in France
- Nearly 17 000 hospitalisations linked to iatrogenic events are caused by an haemorrhage with AVK (study implemented in 1998 by the French pharmacovigilance centres)
- → A lack of information of AVK treated patients was revealed by two surveys implemented in 2001 and 2003 by the French health products safety agency (AFSSAPS) :
 - 25% of patients didn't have regular laboratory controls of the anticoagulation intensity
 - More than 50% of patients didn't know the signs of an excessive anticoagulation
 - More than 50% of patients didn't know the drug interaction between AVK and non steroidal anti-inflammatory drugs (NSAIDs).

In this context, the AFSSAPS decided to launch a national awareness program for health professionals regarding the anticoagulant therapy monitoring. This program was designed to promote appropriate education and follow-up of patients in order to increase the safety and therapeutic outcomes of AVK therapy.

Realisations

Professional information on AVK treatment

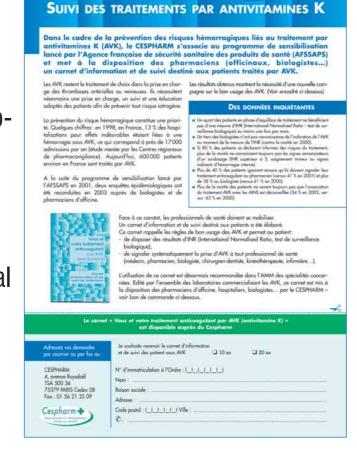
Information on AVK treatment was provided to all concerned health professionals through mail and internet by the AFSSAPS in 2001-2004. Pharmacists were specifically informed through the journal of the National Council of pharmacists in January 2004.

This information included:

- AVK indications
- proper use of AVK treatment
- drug and food interactions involving AVK
- importance of a regular coagulation monitoring by the International Normalised Ratio (INR) to ensure effective antithrombotic protection while minimizing the risk of bleed complications
- main therapeutic target area of INR.

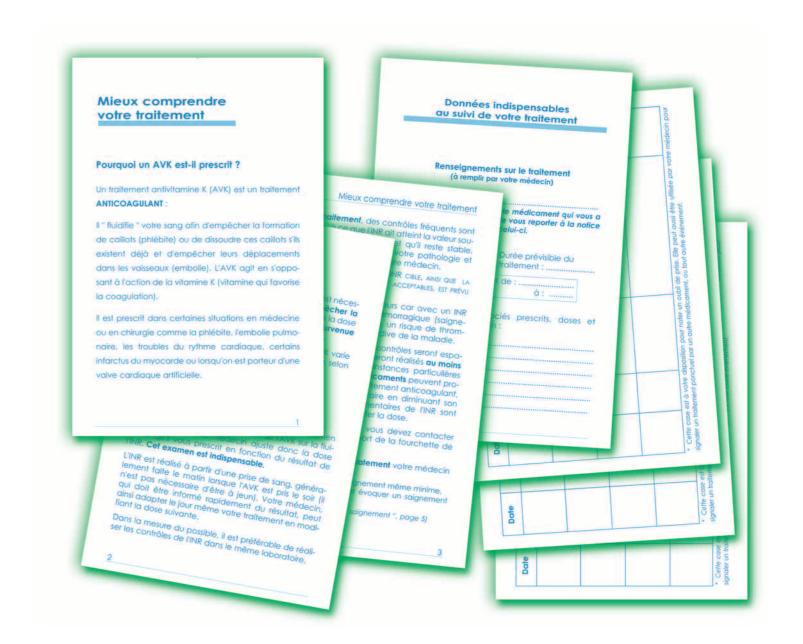
Conception of a notebook for patients

- A working group was created by the AFSSAPS in order to elaborate a notebook to be given to the patients treated by AVK. This working group gathered experts, members of the Health and social education committee for French pharmacy (Cespharm) and members of the French federation of cardiology (FFC).
- 4 pharmaceutical companies sponsored the notebooks' printing: Bristol-Myers-Squibb, Merck Lipha Santé, Novartis Pharma and Procter & Gamble Pharmaceutical France.



1 Health and social education committee for French pharmacy (CESPHARM) 2 French health products safety agency (AFSSAPS) 3 French federation of cardiology (FFC)

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The notebook includes:

- general information on AVK treatment for patients: proper use of AVK treatment, food and drug interactions, advice for day life, warning signs, importance of a laboratory monitoring...
- a table to collect laboratory data of INR, optimal target INR and particular advice of the physician.

Since January 2004, the use of the notebook has been recommended in the Summary of Product Characteristics (SPC) of concerned drugs.

Distribution of the notebooks

- → Since January 2004, the notebooks have been distributed free on request to health professionals:
 - to pharmacists and clinical biologists (specialists in laboratory medicine) by the CESPHARM,
 - to physicians and other health professionals by the FFC.
- → Between January 2004 and June 2005:
 - 12 500 pharmacists asked the CESPHARM for AVK notebooks. 55% of them were community pharmacists, 28% were clinical biologists and 7% were hospital pharmacists,
 - more than 200 000 notebooks were sent to these pharmacists.

The FFC received 17 500 requests from physicians (hospital and community cardiologists, general practitioners...), other health professionals and paramedics and sent nearly 390 000 notebooks.

Conclusion

These data illustrate the co-operation of different health professionals (pharmacists, physicians...), state institutions and professional organisations in the fight against drug iatrogeny, a major public health issue.

The strong mobilization of pharmacists in this health care program intended to limit adverse events linked to AVK treatment has to be underlined.

Such an initiative could be implemented to ensure the safety and therapeutic outcomes of other treatments with a narrow therapeutic range.



"You and your anticoagulant therapy by AVK" (vitamin K antagonists)

Information and treatment monitoring notebook