Monday, 7 June 2010 11:27 GMT Exporters claiming to be wholesalers in France affect national drugs supply - GIRP by Helen Collis

CANNES, June 7 (APM) - The head of Afssaps has warned that some French short-line wholesalers, claiming to be full-line wholesalers, are selling their products overseas, leaving medicine shortages despite their obligation to supply French people first.

Jean Marimbert, director general of Afssaps, France's healthcare products regulatory agency, said inspections over the last few years have revealed that despite laboratories and manufacturers continuing to supply the same levels of drugs, some areas have been experiencing shortages.

Speaking on Monday at the annual general meeting of the European wholesalers association, GIRP, in Cannes, Marimbert said further inspections revealed the shortages were due to some short-line wholesalers exporting their products.

Marimbert stressed that parallel trade was not illegal. However, he said in some cases, companies are registering themselves as full-line wholesalers to get guaranteed supplies from drug manufacturers and mostly sell on export markets and not the national market, for which the drugs were delivered.

As full-line wholesalers they would be obliged to comply with the public service requirement laws to fulfil first and foremost the medical needs of the people in France.

This problem "might disturb the national supply," Marimbert said.

## MONITORING SHORTAGES

Marimbert said to monitor these shortages, Afssaps relied on doctors, pharmacists and hospitals informing the agency of supply shortages.

"We must be careful and we must watch that there is no abuse of the full-line wholesaler status by people who use that status mostly for exporting drugs," he said.

Speaking to APM on the sidelines of the conference, Marimbert said once a wholesaler is suspected of abuse, inspections are carried out. He said they look to see if the company is registered as a (full-line) wholesaler or an exporter. If it is registered as a wholesaler, they check the accounts to see if the majority of sales are for export or the national market.

"In these cases we ask the operator to comply with the law. Should they not comply with the law, we are in a position to inflict penalties or withdraw authorisation," Marimbert said.

He said one case had gone to court recently, not only because of the problem of supply shortages and a drift from the public service requirements, but also due to lack of basic compliance with good distribution practices.

## **BATCH TRACEABILITY**

Marimbert also reminded the conference that from 2011, traceability by batch will be applied as part of the legal framework in France.

"This is something that we are preparing with the professionals and the stockholders of full-line wholesalers for many years and they will have to adapt quite a lot," he said.

Marimbert added that the agency is aware that the addition of batch traceability will not be the last stage of safeguarding and protecting the wholesale chain, which has seen numerous changes in recent years.

hlc/ra

Helen Collis
Reporter
APM Health Europe
www.apmhealtheurope.com