

Call malta questionnaire medicines and supply

5.1.2e

Background:

- NL sees, like other European countries, a rise in shortages
- 2017 this sparked some controversy in Dutch parliament and strict measures were proposed to tackle shortages
- Researches were performed to look for options. In 2019 the Dutch MoH minister wanted two measures implemented to tackle shortages:
 - NL has a law that obliges wholesalers and MAH to have sufficient stocks. However, this is not quantified. Now we are in the process of implementing a defined stock obligation for 4 months at MAH level and 1 month by wholesaler.
 - This sparked the current discussion now held by MAH and wholesalers.
 - The Dutch minister of health wants a monitor system to keep track of this stock obligation. At the moment, the NL has 'Meldpunt' which is a monitoring system for expected shortages. MAH are obliged to report to the 'Meldpunt' when they are expecting a shortage within two months. We want to see if additional monitoring measures are effective.
- From industry voices were raised that 5 months for all medicines is out of line with what other member states re doing → therefore the questionnaire was sent out.

Maltese supply stocks

- Malta: indeed good not to wait for EC study is done, could take long time.
- 80% from Maltese medicines come from tenders
 - Industries can give quotes to the government, the best quote for the products wins the tender and is allowed on the Maltese market
 - In these tenders there are agreements on stocks for 3-6 months
 - For controlled medicines it is 9-12 months
 - Normally the stocks are 3 and 9 months, with covid and brexit 6 and 12 months
 - The 6 month will probably be lengthened even though it is a temporary solution
 - Controlled drugs are dangerous drugs such as fentanyl and morphine. These are guarded and to import these drugs, it can take some time
- 2013-2014 there was a study to manage shortages
 - If a medicine is registered they need to keep two months stocks
 - National Authority controls this
- Maltese perspective: good to have stock inside each country to tackle shortages
- Costs of wastage with stocks should be compared to the costs at the bedside of patients when shortages occur
- The stocks are delivered to the Maltese authority and they pay within 60 days. The responsibility is shared by the supplier and the government
- Space was an issue with building stocks
 - Huge amount needed to be stored
 - Companies involved and offered storage area for payment to the government
- Government also got complaints from the field when they held 6 months stocks, but the consumption went down. The field wanted to be compensated for this, but Malta did not agree with this but tried to find another solution. The actual number of consumption was looked up and tried to get this consumption higher
- The Maltese government meets with suppliers on regular basis, also with chamber of commerce and have meetings on how Brexit is affecting the Maltese market
- The private sector is a different case, they do not have stock piles.
- However, if the private sector has shortages, the government also supplies the private sector.
- Malta does not have an essential list, but does know seasonal demand ideas
- NL gets voices from the industry that it will become a less attractive market when obliging a buffer stock of a total of 5 months. Does Malta hear this as well?

- In Malta there is a tender process with competition, the best tender is allowed on the Maltese market. This tender is then for 2-3 years before a new tender is being made.
- If there are no tenders, Malta looks at the market and for example buys from England.
- There is a central procurement in Malta
- **OTC included?** Stocks are not obliged, but industry did hold paracetamol for example

Monitoring:

- Malta has a stock verification system that checks the stocks procured
- It started with an excel system
- Every week there is a division that reviews the stocks
- Low stocks are defined as 3-6 months for controlled medicines and 0-3 for the rest
 - Not all problems can be solved when reviewing and a shortage occurs
 - For example when it is an issue of registration
 - There is a platform where the Maltese government can put on emergency procurements, where the government will buy 2 months of stocks until everything goes back to normal
 - On the platform industry can see if they can deliver and whether their products are meeting the Maltese norms, if so they can give an offer
 - **This is an emergency route**
- The private sector is a challenge for the public authority
 - Private demand is not taken into the stocks
 - This could be hard for medicines with low volume; if a shortage in the private sector happens for a low volume product and the public authority has to help, it will have a fair share of its stocks to unforeseen demand
 - These products are on a positive lists