

Summary call Estonia & Netherlands

Topic: Questionnaire Medicines supply stocks and monitoring

9th of February

Attendants:

- 5.1.2e – Adviser Department of Medicines
- 5.1.2e – Adviser European Union Affairs and International Co-operation
- 5.1.2e – Agency of Medicines
- 5.1.2e – Dutch Ministry of Health
- 5.1.2e – Dutch Ministry of Health

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.

Medicines' supply stock in Estonia:

- Familiar sounds in Estonia, many discussions as well. Not yet an obligation.
 - Rising shortages and media coverage lead to taking actions
- Estonia learned from the beginning of January last year, where they held round tables with stakeholders before COVID
 - This round table started with simple steps: sharing information, share earlier and share with doctors
- There were discussions in Estonia to have stronger stocking obligations. However Estonia could not lay these obligations on MAH, obligations for MAH needs to done on EU level
- The current wholesalers' obligation in Estonia is not enough. There are ongoing discussions with wholesalers to broaden the obligation
- Estonia has also discussed the topic of stronger monitoring stocks. The obligation during covid led to daily basis reporting. Since July it is now once a week only for covid wholesalers.
- MAH monitor for medicines without an alternative. If the stocks goes under the level of a one month supply, they monitor more closely, namely on a daily basis
- Estonia asks how the current Dutch obligation works with having sufficient stocks
 - NL: there is a legal obligation to hold sufficient amount of stock for MAH and wholesalers. However this is hard to control since sufficient amount is not quantified. Therefore in the Netherlands we are now quantifying this amount.
- In Estonia the agency of medicines notifies MAH when they see wholesalers have less than 1 month stocks.
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- This option was also discussed with MAH and they also said that the requirements of Estonia were too high and could possibly lead to more shortages.
- After these meetings Estonia lowered the stocks and discusses two months' supply for all prescribed medicines and a list of non-prescribed medicines.
- December 2020 in discussions with MAH and wholesalers they still said 2 months for all prescribed medicines is too high. Wholesalers said they already have 1 month' supply and pharmacies have around 1 month of supply as well. In principle, the two months' supply already lies in Estonia.
- Estonia has a lot of resistance in introducing an obligation for medicines' supply
- In Estonia it is easier to require the obligation of a medicines' stock at wholesaler level instead of the MAH. The stocks at the wholesalers are physically in Estonia, stocks of MAH are not. If the obligation lies at MAH level, the MAH could still sell it to Latvia and Lithuania, because they use the same package and MAH do not show the stocks to Estonia.
- MAH also said it would take 6 months before having the supply since production has to go up
- In April the minister of Social affairs spoke with 8 wholesalers and came to a good will agreement. The wholesalers said they would do their best to achieve a stock for 2 months for a an indicative list of 800 substances. The wholesalers showed the stocks was easy to achieve, however, in the summer the quantities went down to 1 month
- In NL we did not choose for a since we cannot foresee which medicines will have a shortage. Therefore we chose to increase all medicines stocks.
 - Field parties said this is not proportional
 - Now we are looking at the possibility to have a list.
 - Constructing a list is not easy task
 - Estonia used list how did you came up to this?
 - First considered all prescription medicines
 - Looked at WHO essential list
 - Medicines from quality / high prices
 - Antibiotics some, discussed with doctors associations
 - Exemption by expiry date
 - OTC also included: non-prescription medicines with systemic monoactive main substances such as ibuprofen
 - Also contraceptives should be two months
 - The list of 600 active substances with a discussed obligation of 4 months was made by the agency of medicines and looked at what substances were used most at home for chronic diseases
 - Also compared the list with Finland

Monitoring stock in Estonia:

- The agency of medicines in Estonia receives weekly and quarterly reports for more overview and statistics. The agency flags out medicines that are essential.
- The agency monitors mainly medicines without alternatives.
- Medicines with a low stock at wholesaler level are communicated to MAH and asks if they are aware of the situation and whether they expect to have a shortage.
- If the agency gets back from MAH they do not expect to have a shortage, the normal monitoring goes further.
- The MAH have the obligation to report as soon as possible when (they expect) a shortage will occur
- The reports are sent by excel. Lot of work done by hand. No other solution yet.
- Since July there is a legal obligation to provide data. Before July there was a quarterly requirement and now a weekly obligation for large wholesalers
- NL says field parties are resistant to share information on their stocks since it is sensitive information. How was this in Estonia?
 - Also resistance in Estonia, wholesalers were afraid the information got into the hand of other wholesalers and could calculate their stocks. But the information shared with the agency is not for others. The agency only uses this information to

communicate with MAH and if it does so, it doesn't say where the stocks lie. This is an important criteria for wholesalers.

Wrap up:

- Estonia says it would like to collaborate more on European level with stocks (and monitoring) since Estonia is a small market as well. At European level there would be a stronger voice.
- NL will share results of the questionnaire with an overview of other MS policies
- Estonia and NL are willing to keep in close contact to share further challenges and experience