Report from Norway for the EIPG General Assembly in Budapest 24 – 26th May 2019

EIK, new IT-solutions for the pharmacy industry

The Pharmacy industry have for many years a common IT-system, PharmaPro. The work on a new IT-solutions/system, called EIK, are now under progress.
EIK, the new industry system will include three functional areas that exist in today's pharmacy system:
Recipe management, refund and reporting.
In addition, new functions will be developed: information and advice, pharmaceutical services and journaling.
It has also been developed and implemented functionality that enables pharmacies to comply with the falsification directive.
It's planned that EIK will be deployment in pharmacies from January 2021.

Drug shortages:

In 2018, 684 cases of drug deficiency were reported in Norway. This was a sharp increase from 2017 when 358 cases were reported. There has been a strong increase in shortcomings in the past ten years.
The increase in drug deficiencies is due, among other things, to raw material shortages, production failures, miscalculation of the relationship between supply and demand, and structural changes in the global pharmaceutical market. In most cases, deficiency is due to various production problems.
The Norwegian Medicines Agency (NOMA) collaborates with the Norwegian Center for Medicinal Lack and Pharmaceutical Preparedness in the specialist health service (Mangelsenteret), the pharmaceutical wholesalers, the pharmaceutical producers and the pharmacies to solve the problems. In most cases, the patients receive satisfactory treatment, but the increase in the number of deficiencies is worrying. Norway participates actively in European cooperation to prevent and reduce drug shortages in Europe.
The Directorate of Health are working on a report on preparedness for drug shortages. The report is expected to be finalized within summer 2019.

Nordic collaboration, FINOSE, faster access to medicines:

FINOSE is an HTA collaboration network between Fimea (Finland), NoMA (Norway) and TLV (Sweden). In practice, the co-operation means that the three agencies will write joint assessment reports for pharmaceutical products that contain both relative clinical and health economic assessments.
For example, pharmaceutical companies who have a new, but not yet authorized, medicinal product may contact any of the three agencies to discuss about the possibility for conducting a joint FINOSE assessment for the medicinal product in a certain indication. If a company chooses to participate FINOSE, it should send a submission file or equivalent health economic documentation to all three agencies. The company shall also sign the waiver of confidentiality to make it possible for the three agencies to share information between agencies. After the joint assessment, national decisions or recommendations will be made in each country, following national rules and regulations.

FMD, 9th February 2019:

Norway has been working to keep the deadlines, European Counterfeit Directive (FMD) (2011/62 / EU) in force. However much remains to be done. The Norwegian Medicines Verification Company (NOMVEC) is now leading this process further, under close observation from both the Ministry of Health and Care Services and the NOMA.
NOMA monitors developments both through the EU Commission's expert group and as an observer in the NoMVO board. They also participate in working groups with the industry to create routines for the treatment of nonconformity situations. Proactive routines, what to do when potential counterfeits are a reality.

Pharmaceutical Industry:

AbbVie undertook a downsizing av conversion, and cuts 25 positions in Norway. This was sad and surprising news for those who were affected.

Sanivo Pharma (raw material manufacture and supplier) decided to wind up its operations in Norway. This will affect the pharmacy industry in Norway. Curida AS and hospital pharmacy in Oslo, Ullevål, decided to become manufacturer for these products, and secures pharmaceutical production in Norway.

The pharmaceutical wholesaler NMD (Norwegian Medical Depot) had problems with its multi-dose suppliers. This causes serious problems for the patients. Several measures have been taken to address the problem.

Brexit

If the UK goes out of the EU without a hard Brexit, it could lead to temporary cessation and delays in the flow of goods with the UK, which may affect drug and medical supplies.

The authorities and the pharmaceutical companies cooperate well to ensure that Norwegian patients continue to receive the medicines they need in the event of a hard Brexit, and several measures have been taken to prevent the lack of medicines in Norway, including through adjustments in the regulations for distribution and sales in the EU/EEA area.

The Directorate of Health follows closely the situation in the UK and has close dialogue with the NOMA and the Norwegian Institute of Public Health.
This topic still has many uncertainties and creates speculations and discussions.

Fish feed industries

The amount of medicine fish feed production decreased in 2018, due to the use of non-medicated sealice treatment. This sector is working with alternatives to breed salmon/fish, land based, to avoid sealice problems. One of the technologies which are increasing is Recycling Aquaculture Systems – RAS. There are still many uncertainties, and the system is not well tested yet, and there are discussions about different diseases that might occur, which require medical treatment. The industries are working with different drugs for medical

treatments. This sector still requires more pharmacists with competence especially within GMP and production.

Activites carried out by The Norwegian Association of Pharmacists (NFF):

The association are still recruiting new members.
In October NFF arranged one event with the subject “QP- liability and insurance” and another event with the subject “Fish health”, with medicated fishfeed, vaccines, pharmaceutics competencies, manufacturing veterinary products as topics.

In November NFF arranged an event with the subject “Nothing is as expensive as a bad reputation – how can we learn from other unpopular Industries”.

In November the Annual meeting decided to start a reorganization of NFF. During January and February 18 Membership meetings were held all over the country and reorganization was one of the main topics at these meetings. How the organization will change will be decided at the Annual meeting in November-19.

In March-19 NFF arranged for members to visit Pharmaq facility in Kløfta (Norway). Pharmaq develop and manufacture fish vaccines.

On the 5th of June NFF and Norwegian Association of Pharmaceutical Manufacturers (LMI) are arranging The Manufacturing Day - where many Norwegian manufacturing companies are invited to give a speech about their companies and activities. This annual event was arranged for the first-time in 2017.

Florø, 8th May 2019

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