

## Report from Norway for the EIPG General Assembly in Morocco 4 – 6th May 2018

### **Health policy:**

#### **Medicine Start – a new guidance service in the pharmacy**

The Pharmacy association (Apotekerforeningen) have been working with a new guidance service in the pharmacies called, “Medicine Start”. This service will guide patients to use their medicines more correctly and minimize and avoid wrong use of the medicines and dosages. The association finalized the structure of the guidance in 2017. The Ministry of Health and Care Services finally approved the guidance service, and it will be starting in the pharmacies on May 2, 2018. The Ministry essentially supports the Directorate's assessment and recommendations in its report of 27 February 2018. The Directorate of Health is assigned to follow up the implementation of the service.

#### **From the Norwegian Directorate of Health to Norwegian Medicine Agency (NOMA)**

From January 1, responsibility for managing the product regulations for medical devices is transferred from the Norwegian Directorate of Health is transferred to the Norwegian Medicines Agency. At the same time, the team is being transferred to medical equipment, ensuring continuity and competence.

#### **Nordic collaboration can provide faster access to medicines:**

Authorities in Norway, Sweden and Finland will collaborate on making joint health-economic assessments. The purpose is to provide faster access to medicines. The collaboration is called FINOSE. The collaboration involves conducting joint method assessments in cooperation with the Dental and Pharmaceuticals Agency (TLV) in Sweden and the Finnish pharmaceutical company FIMEA.

### **Drug shortages:**

Drug shortages in human and veterinary medicines is still an increasing problem in Norway. This is due, among other things, to material shortages, production failures, mismatches between supply and demand, and complicated sales structures in the global pharmaceutical market. In most cases, as a consequence of various production problems. Such conditions are beyond the control of Norwegian authorities measures.

The increase in the number of deficiencies is worrying. Norway is therefore actively involved in European cooperation to prevent and reduce the number of drug shortages in Europe. NOMA work with/on several preventive measures. Information's is published on their website [www.legemiddelverket.no](http://www.legemiddelverket.no). One of the initiatives for preventing shortages of medicines in Norway is that NOMA encourages companies to apply for new marketing authorization (MA) in order to prevent drug shortages of products which will be withdrawal/dismissal lack of marketing or vulnerable supply will create a shortage of circumstances. NOMA wishes to have more alternatives for medical products on the market in Norway. This applies mainly to medicines which are of immediate concern to public health. NOMA has currently no sanction possibilities, but the government is considering the introduction of a violation fee in case of non-notification. The government has also established a national site to monitor shortage in Norwegian hospitals (Nasjonalt senter for

legemiddelmangel og legemiddelberedskap i spesialisthelsetjenesten). This site is working in close collaboration with NOMA.

### **Adverse report**

The Norwegian Association of Pharmacists have received consultation paper from the Ministry of Health and Care Services. The consultation paper is a proposal for regulation of system for reporting of side effects of drugs.

### **Pharmaceutical Industry:**

Curida AS keeps growing and bought an Norwegian pharmaceutical manufacturer, and secures pharmaceutical production in Norway.

Vistin Pharma AS, manufacturer of the API metformin, has stated development of a new business area within energy trading.

### **Brexit**

There is a risk that Norway is becoming one of the countries most affected by Brexit, because Britain is so important for Norway and Norwegian trade. There are ongoing discussion and concerns in the industrial section. This topic still has many uncertainties, and creates speculations and discussions.

### **One of the world's most expensive drugs - Unethical high price**

Spinal muscle atrophy (SMA) is a very serious hereditary neurological disease. Children born with the most serious type of disease die early. The drug nusinersen (Spinraza) is the first drug that has shown effect on SMA.

With today's price, Spinraza is one of the world's most expensive drugs. Per patient, treatment costs NOK 7 million in the first year of treatment (seven syringes to NOK 1 million) and NOK 3 million in subsequent years (three syringes per year for the rest of the life). The first year is estimated to cost Norway NOK 200 million.

This is one of the most difficult case for the The National System for Managed Introduction of New Health Technologies within the Specialist Health Service must deal with.

This is one of the world's most expensive drugs. The price the pharmaceutical company requires is unethical. Before any decision is made, they will ask that the manufacturer significantly reduce the price.

### **Fish feed industries**

The amount of medicine fish feed production decreased in 2017, due to the use of non-medicated sealice treatment. The number of medicated feed treatment was decreased, but the rough treatment of the non-medicated treatment weakens the welfare of the fish. Non-medicated treatment has been disputed, and the medicine fish feed industries calls for alternative medicines which can be used to treat sealice with. This sector still requires more pharmacists with competence especially within GMP and production. The industries are working on two new drugs for medical treatments. One the company has applied for MA on their product.

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

There has been a lot of work and focus on the work of recruiting new members, and the association have now approx.3950 members. The goal is 4000 members in 2018.

In December 2016 NFF signed a main collective agreement with the Confederation of Norwegian Enterprise, NHO. Making collective agreements between NFF and most Norwegian drug companies possible.

On the 7<sup>th</sup> of June NFF and Norwegian Association of Pharmaceutical Manufacturers (LMI) are arranging The Manufacturing Day - where many Norwegian manufacturing companies are invited to present themselves. This annual event was arranged for the first time last year.

The association works continuously to highlights the need of pharmacists and increase the number of pharmacy students.

One important achievement is the “Medicine Start guidance service” in pharmacies and the possibility for the patients to order this service themselves. The service will highlight the role of pharmacist in general.

Florø, 25<sup>th</sup> April 2018

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