LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

DKMA Update is an electronic newsletter intended for anyone who work with medicines either clinically or in the pharmaceutical industry or the retail industry and people who would like to gain an insight into our work and get the most recent updates on medicines and medical devices. The newsletter contains information about current medicine issues, the most recent safety updates and reimbursements.

Issued by the
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DKMA Update

No. 1 • Volume 1 | September 2017

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Editorial: EMA, Brexit and new opportunities for the Danish Medicines Agency

By Thomas Senderovitz, Director General at the Danish Medicines Agency

The European Medicines Agency is to find a new home country, and at the Danish Medicines Agency, we are hoping that country will be Denmark. It will be good for both EMA and Copenhagen, and many are focusing their efforts to make it happen. But no matter which country succeeds in landing EMA, it is clear that Brexit by definition will have such a huge impact on European pharmaceutical collaboration. All drug regulatory authorities in Europe are getting ready for a new situation.

The pharmaceutical area has deep roots in the EU. Built up over many years, the EU collaboration is strong and trustful, and every EU country has clear advantages of drawing on the experts and data from other countries. Today, the vast majority of medicines containing new active substances are authorised throughout the EU at once in what is known as *the centralised procedure*. In this procedure, one EU country carries out the thorough scientific assessments on behalf of all the other countries in the EU. It saves crucial time for patients who are hoping for a breakthrough in the form of new medicines and for the authorities which can focus their efforts and become specialised thus reaching a strong critical mass.

From the perspective of the Danish Medicines Agency, the most far-reaching consequence of Brexit is that the British Medicines and Healthcare products Regulatory Agency, MHRA, will have to withdraw from the EU collaboration to a greater or lesser extent. It will probably have greater impact than the relocation of the European Medicines Agency itself.

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Editorial

If MHRA will be completely detached from the common European work, the European pharmaceutical collaboration would – at least in the short term – suffer in terms of capacity and expertise. The MHRA employs many highly qualified pharmaceutical experts, and they have always pulled more than their weight and handled many tasks related to the licensing of new medicines, pharmacovigilance, inspection tasks, etc. All EU countries will feel the impact when MHRA no longer contributes to the tasks in the same way as today. The tasks of MHRA will have to be distributed between other member states, which will obviously mean extra work for the countries signing up. But, it could also be an opening for countries like Denmark to play an even greater role in the new constellation. Denmark and many other countries want to leverage this opportunity and are therefore upgrading their drug regulatory authorities, and we are recruiting and training more employees. It is absolutely essential that the Danish Medicines Agency positions itself among Europe's best in class if we want to influence and set the future agenda. Brexit could very well be a welcome opportunity to rethink how the European pharmaceutical area is organised, and many new and interesting ideas are already in the pipeline, such as an even stronger common European collaboration, multinational *assessment teams* and better use of *big data* – work that we initiated and are spearheading as I am chairing the European Task Force on Big Data.

EMA's new location

Then there is the question of where the European Medicines Agency, EMA, will be headquartered after 1 April 2019. As is well known, EMA is a very attractive agency to host, and with good reason: It has 900 highly qualified employees who work every day at the agency and together with their families are expected to strengthen the *life science* environment in the country that will be its host. The agency will also increase the number

of meetings held in the host country. With some 40,000 delegates annually, there will be innumerable hotel stays and restaurant visits in EMA's home town.

A great many EMA activities take place in committees, networks, working parties and other groups with representatives from all EU countries. The Danish Medicines Agency participates in more than 50 scientific committees, working parties and other groups under EMA.

The central core of EMA is the Committee for Medicinal Products for Human Use, which recommends new medicines for authorisation to the European Commission. There is a corresponding committee for veterinary medicines. Then there is the European Pharmacovigilance Risk Assessment Committee, PRAC, which sounds the alarm if there are safety problems with specific medicines and has the possibility of initiating extraordinary safety reviews if a country raises doubt about a medicine. Add to this a number of other more specialised committees, working parties and other groups, such as the Paediatric Committee, the Committee on Herbal Medicinal Products, the Oncology Working Party, the Cardiovascular Working Party, and much more.

There can be no doubt that it will benefit Denmark if EMA relocates to Ørestad in Copenhagen, and we at the Danish Medicines Agency will be the first to give our new colleagues a very warm welcome if we succeed. We know that one of the essential criteria is for EMA to carry on business uninterrupted despite being relocated. Denmark has put in a very attractive bid that will make the transition as smooth as possible, but so have many other countries. A total of 19 countries have announced their candidacy – and the decision will inevitably be part of a wider political game. It will therefore be very exiting to follow the negotiations this autumn. The decision is expected to be made at the meeting of the heads of state or government this November.

But even if Copenhagen does not succeed in landing EMA, it is still essential that the Danish Medicines Agency takes the strongest position possible in the European collaboration and that we continue our efforts to become one of Europe's best in class! So positioned, Danish *life science* will benefit, clinical research in Denmark will get better conditions and Denmark will make its mark as a leading *life science* nation.

Tramadol subject to stricter reporting

There has been much debate recently about the degree to which tramadol is addictive. A number of pain management doctors have voiced their concern in the media because their experience shows that tramadol is far more additive than described in the product information. The Danish Medicines Agency (DKMA) has therefore decided to subject tramadol to stricter reporting from 11 September 2017 for a period of one year to get more knowledge about the extent of the problem based on specific information about dependence from doctors.

This summer's debate on tramadol has caused the DKMA to put tramadol on the list of medicines subject to stricter reporting requirements for a period of 12 months. The decision was made to collect more specific data on the concern about dependence that some pain management doctors have raised in the media. Presently, there is no data to support a suspicion about particular harmfulness or dependence-inducing effect of tramadol.

The change takes effect on 11 September 2017 when tramadol is included on the list of human medicines subject to stricter reporting requirements on the DKMA website.

That tramadol is subject to stricter reporting requirements means that doctors are required to report *all* adverse reactions of tramadol to the DKMA[1] – for as long as the stricter reporting requirement is in force. After that, doctors must report serious or suspected unexpected adverse reactions. A serious adverse reactions must be reported to the DKMA no later than 15 days after the doctor became aware of an occurrence.

From 1993, when tramadol was authorised, to 15 August 2017, the DKMA received a total of 49 ADR reports about tramadol dependence. It is a low number of reports compared to tramadol consumption, and we therefore encourage patients and relatives to also report adverse reactions of tramadol to us via the website www.meldenbivirkning.dk (report a side effect).

Monitoring is a shared responsibility

Like all other medicines, tramadol is monitored by both the authorities and the marketing authorisation holders. One way of monitoring tramadol is by the safety reports that the marketing authorisation holders submit every three years for assessment by the European Medicines Agency. In these reports, an overall assessment of the medicine’s benefit-risk balance is made based on studies and information derived from ordinary clinical use after marketing. In the case of tramadol, a medicine marketed for many years, the ADR reports and approaches made by doctors and other professionals are important. The latest tramadol report is from 2014, and the next report will be submitted in the autumn of 2017. Previous reports have shown that tramadol has a low dependence potential, and that

[1] Except for suspected adverse reactions resulting from medication errors.

dependence primarily occurs among people with previous abuse problems. The World Health Organization, WHO, reached the same conclusions in their report from 2014 (1).

The DKMA's literature review of tramadol and the risk of dependence
In the first half of 2017, the DKMA reviewed the scientific literature on tramadol and dependence. We conclude overall that there is very little evidence that tramadol has a dependence-inducing effect in patients. That said, it is clear that tramadol, especially in a number of Middle Eastern countries, is abused as a drug (2,3), and our review also shows that tramadol dependence occurs when used for prolonged periods of time and in patients with a history of drug abuse problems, or that it maintains already existing opioid dependence in patients (4,5). It is not possible to extrapolate these data to a wider patient group for several reasons: Firstly, the mentioned studies are often small with very few participants. Secondly, the trial subjects have usually been recruited from abuse clinics, and so do not represent the patient group that receives tramadol as part of ordinary pain treatment. Thirdly, the trial subjects often have a history of prolonged treatment, and in quite many cases already have a dependence to the drug at the beginning of the trial. Finally, a number of the recruited trial subjects use a far higher dose of tramadol than the recommended daily dose.

A few studies have been conducted with more representative cohorts. These studies use more or less precise methods to determine whether the patients have developed dependence. One study uses the tramadol users' pattern of redeeming prescriptions (6); two studies use questionnaires and telephone interviews (7,8); and a fourth study (9) looks at ”problematic use” three years after first-time use of tramadol. These studies estimate tramadol dependence to be less than 1%. The four studies describe prolonged use (6 months to 3 years), and an actual clinical evaluation is not used as a basis to determine if a patient is dependent on tramadol. It makes it difficult to interpret these data, and large well-controlled studies to clarify the topic are simply non-existent.

Forward-looking focus on opioid consumption
Many have brought opioid consumption into focus in the past years. In 2016, the Danish Health Authority issued a report in Danish about opioid consumption in Denmark *”Kortlægning af opioidforbruget i Danmark”*, and work is currently done to update the guideline on addictive medicine. The Institute for Rational Pharmacotherapy (IRF) has initiated work to update the National Recommendation List and has planned courses and articles in 2017 and 2018 on pain treatment. The DKMA has requested the Medicinal Products Committee to discuss the possibilities of changing the dispensing status of tramadol from A to A§4 (reportable medicines) at its next meeting in end-September.

Recommendations in the current product information of the pain-relieving medicine Nobligan containing tramadol:

- Tramadol should under no circumstances be administered for longer than absolutely necessary.
- If long-term pain treatment with tramadol is necessary in view of the nature and severity of the illness, then careful and regular monitoring should be carried out (if necessary with breaks in treatment) to establish whether and to what extent further treatment is necessary.
- Tramadol has a low dependence potential. On long-term use, tolerance, physical and psychic dependence may develop.
- In patients with a tendency to drug abuse or dependence. treatment should only be for short periods and under strict medical supervision.
- The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The lowest effective dose should generally be selected. A total daily dose of 400 mg should not be exceeded, unless there is a compelling clinical need.

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Strengthened recommendations to reduce risk of hyponatraemia in use of solutions for infusion

Strengthened recommendations are to improve the safety of treating hospitalised patients with solutions for infusion both with and without glucose. The strengthening comes after several patients were reported to have suffered hyponatraemia with serious symptoms.

The most important changes that will appear from the product information are:

- Attention in treatment with physiologically hypotonic fluids. Especially glucose-containing fluids metabolise rapidly, so glucose-containing fluids can become extremely physiologically hypotonic after infusion, which may cause hyponatraemia.
- Certain patients are at particular risk of hyponatraemia. This applies to patients with non-osmotic vasopressin release, e.g. in pain, stress, infections, burns or central nervous system diseases; patients with heart-, liver- and kidney diseases as well as patients treated concomitantly with vasopressin agonists.
- Hyponatraemia can lead to cerebral oedema, which may cause injury to the brain. Women in the fertile age, children and patients with reduced cerebral compliance (e.g. due to meningitis, intracranial bleeding, cerebral contusion) are at particular risk of cerebral oedema caused by hyponatraemia.

An anaesthesiologist alerted the DKMA about the problem

It was an anaesthesiologist who reported the problem to the DKMA in autumn 2015. The anaesthesiologist had seen several cases of hyponatraemia with severe cerebral symptoms after the use of hypotonic solutions for infusion and worried if the doctors paid adequate attention to the problem in the clinic.

The anaesthesiologist and the DKMA co-authored an article in the newsletter Danish Pharmacovigilance Update in March 2016 to make doctors aware of the problem. Because of the problem's nature, the DKMA also notified an ADR signal to the Pharmacovigilance Risk Assessment Committee, PRAC, and reviewed the literature and the reported suspected adverse reactions in the common European adverse reaction database.

The review brought evidence that hospitalised patients who routinely receive fluids for infusion, such as in planned minor surgery or common infectious diseases, may be at risk of developing significant hyponatraemia that may cause cerebral oedema and have very serious consequences.

Women in the fertile age and children are particularly at risk of developing severe consequences of hyponatraemia.

In many of the reported cases, the healthcare professionals did not at first suspect that low sodium levels were causing the patient's severe symptoms. Neither did they suspect that the symptoms were related to the fluid treatment, which in some cases meant that the proper treatment was initiated too late.

The decision to update the wording of the product information of fluids for infusion with and without glucose was made by the European Pharmacovigilance Risk Assessment Committee in July 2017. All the changes to the summaries of product characteristics can be found here: New product information wording – Extracts from PRAC recommendations on signals (see page 5).

New precautions for safe use of the antiepileptic Pro-Epanutin

Several medication errors involving the antiepileptic Pro-Epanutin have prompted a number of new safety precautions in the product information.

Pro-Epanutin contains fosphenytoin, which upon administration, is converted into the active substance phenytoin, but not in the ratio 1:1. One ml of Pro-Epanutin contains 75 mg of fosphenytoin sodium, which corresponds to 50 mg PE (phenytoin sodium equivalents) = 50 mg of phenytoin sodium.

Pro-Epanutin is used in acute situations such as in fever cramps in children or epileptic seizures. Pro-Epanutin is used very rarely, and some departments do not keep it in their standard range of products because it is not the first-line treatment for acute convulsions. Many staff members are therefore not familiar with the product, which increases the risk of dosing errors.

The problem with medication errors concerning Pro-Epanutin is not unique to Denmark, and has been reported in a number of other European countries.

The European Medicines Agency has decided to implement the following precautions:

- Pro-Epanutin is not indicated for use in children under 5 years of age and should not be administered to this patient group. International experience from spontaneous reports indicates that while medication errors leading to fatal overdoses have occurred in all age groups, a disproportionate percentage of fatal overdose cases have been reported when Pro-Epanutin is used off-label in patients under the age of 5.
- Medication errors have been reported for Pro-Epanutin: Pro-Epanutin has been given at doses which were too high, infusion rates which were too fast, maintenance dose was given too soon. There have been cases of medication errors associated with cardiac arrest and/or death.
- It is essential that Pro-Epanutin is administered at the correct dose, at correct rate of infusion (for IV infusions), and that the maintenance dose is not administered prior to the time interval described in the summary of product characteristics.
- Pro-Epanutin should always be prescribed and dispensed in phenytoin sodium equivalents (PE).
- The risk of cardiovascular toxicity increases if Pro-Epanutin is administered at infusion rates that are too fast. In emergency treatment of status epilepticus, the infusion rate of a bolus injection must not exceed 150 mg PE/minute in adults. In children (5 years of age and older), Pro-Epanutin should be administered intravenously at a rate no greater than 3 mg PE/kg/minute or 150 mg PE/minute, whichever is slower.
- When Pro-Epanutin is ordered, stored and entered in IT systems, prescriptions and automated dispensing cabinet databases, the total drug content (500 mg PE/10 ml) in mg per ml should be displayed to ensure that the total drug content can be clearly identified.

Along with the new precautions added to the product information of Pro-Epanutin, letters have been sent out to relevant doctors with information about the changes. A dosing aid for treatment of patients with status epilepticus is also available. It can be found together with the letter on the DKMA website and will be enclosed with the product packages from 2018.

Letter to doctors and dosing aid can be found in Danish here: Fosphenytoin sodium. Pro-Epanutin® 75 mg/ml (50 mg/ml phenytoin sodium equivalents (PE), concentrate for solution for injection: Medication errors and off-label use in children under 5 years.

The DKMA and the Danish Patient Safety Authority also reported a number of adverse events in 2014 involving dosing errors with Pro-Epanutin:

Confusion about the dosing of Pro-Epanutin (fosphenytoin) (in Danish only)

Focus on correct dose of Pro-Epanutin

Safety information about Klexane, low-molecular weight heparin, sent out to doctors

Following an update of the summary of product characteristics (SmPC) for enoxaparin, letters have been sent out to relevant doctors and healthcare professionals. The update was made in response to substantial differences between the recommendations of the individual EU countries with regard to the expression of strength of enoxaparin, the authorised dose regimen in deep vein thrombosis/pulmonary embolism and in severe kidney impairment. It was therefore decided to implement one harmonised SmPC in the EU applicable to all enoxaparin-containing products.

The most important changes are:

- The active substance enoxaparin, previously indicted in mg, will now be expressed in international units (IU), anti-Xa-activity and in milligram (mg). One mg enoxaparin sodium corresponds to 100 IE anti-Xa-activity.
- The dose has been clarified in the treatment of deep vein thrombosis and pulmonary embolism.
- It is not advised to use enoxaparin sodium in patients with end-stage kidney disease (creatinine clearance <15 ml/min) except in prophylaxis of thrombosis in dialysis patients.
- Contraindications were harmonised to reflect the following:
  - History with immune-mediated heparin-induced thrombocytopenia (HIT) within the past 100 days or the presence of circulating antibodies.
  - Active clinically significant bleeding and conditions with a high risk of haemorrhage, including recent brain haemorrhage, gastrointestinal ulcer, malignant neoplasm at high risk of bleeding, recent brain, spinal or ophthalmic surgery, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities.
  - Spinal or epidural anaesthesia or loco-regional anaesthesia when enoxaparin sodium is used for treatment in the previous 24 hours .

The DHPCs are available at the DKMA website – most of them in Danish only: Direct Healthcare Professional Communication (DHPC) sent to healthcare professionals.

Updated and expanded list of biological medicines and biosimilars with special registration requirement

The DKMA has updated and expanded the list of selected biological medicinal products for which doctors must, if possible, provide the name and batch number of the medicine when reporting suspected adverse reactions to the DKMA.

The previous criteria for including biological medicines on the list was that it had to be a new biological medicine or a biological medicine with both a reference medicinal product and a biosimilar version. Both the reference medicinal product and the biosimilar version were included on the list. Excluded were biological medicinal products authorised exclusively for the treatment of cancer as well as vaccines where there were no marketed biosimilar versions.

Expanded focus
From August 2017, the list was expanded to include also cancer medicine, whereas vaccines are still excluded.

The DKMA will continue to assess if medicines should remain on the list. After a prolonged period with no signals and/or only very few incoming ADR reports compared to a certain consumption level, we will remove medicines from the list – but not until after two years after marketing.

On the updated list you will therefore find new biological medicines – including cancer medicines – while other biological medicines will have been removed. A total of 29 medicines appear on the current list of selected biological medicinal products.

EU's list of recommendations on safety signals

As part of routine surveillance of medicines in the EU, the Pharmacovigilance Risk Assessment Committee (PRAC) assesses signals of possible adverse reactions every month to determine whether further measures are needed to improve medicines safety.

The list of signals leading the PRAC to recommend further measures is published on the website of the European Medicines Agency, EMA, every month.

The most important safety signals discussed on the PRAC meetings from 6 to 9 June and 3 to 6 July 2017 concern the following products:

- **Gabapentin** – respiratory depression without concomitant opioid use

- **Amoxicillin; amoxicillin, clavulanic acid** – drug reaction with eosinophilia and systemic symptoms (DRESS)
- **Ciprofloxacin; meropenem** – incompatibility leading to possible precipitation when co-administered intravenously
- **Darbepoetin alfa; epoetin alfa; epoetin beta; epoetin theta; epoetin zeta; methoxy polyethylene glycol-epoetin beta** – severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)
- **Fulvestrant** – anaphylactic reaction
- **Intravenous (IV) fluids containing electrolytes and/or carbohydrates** – hyponatraemia
- **Prednisolone; prednisone** – induced scleroderma renal crisis

See EU's list of recommendations on safety signals: PRAC recommendations on signals as well as the Danish translations of the product information from June 2017 and Danish translations of the product information from July 2017

Safety signal

An ADR signal is a new observation that raises suspicion of a potential association between a medicine and an adverse reaction or a new aspect of a known adverse reaction, e.g. that the adverse reaction is more common than described previously.

ADR signals can come from a multitude of sources, including ADR reports, clinical studies or scientific literature.

The DKMA uses Danish ADR reports to detect possible new ADR signals. Signals about new possible adverse reactions are forwarded in the EU system to the European Pharmacovigilance Risk Assessment Committee (PRAC). The PRAC assesses if there is sufficient documentation to establish causality and, for example, if changes to the medicine's product information are warranted.

Most recent Direct Healthcare Professional Communications (DHPCs)

Below is a list of the most recent DHPCs that have been sent out to relevant doctors and healthcare professionals with safety information and updated recommendations about medicines:

- **Bendamustine:** Increased mortality observed in recent clinical studies of bendamustine. Sent out May 2017.
- **Uptravi (selexipag):** Concomitant use of strong inhibitors of CYP2C8 (e.g. gemfibrozil) is now contraindicated. Sent out 14 June 2017.

- **INOmax (nitrogen oxide) cylinders:** Risk that the delivery of gas will stop in the month of expiry when used with INOmax DSIR system. Sent out 23 June 2017.
- **Cinryze (C1-inhibitor (human)):** Information to healthcare professionals regarding expected supply shortage of: Cinryze, 500 units containing powder and solvent for intravenous injection. Sent out 27 June 2017.
- **Pro-Epanutin (fosphenytoin sodium):** Fosphenytoin sodium, Pro-Epanutin 75 mg/ml (50 mg/ml phenytoin sodium equivalents (PE), concentrate for solution for infusion/injection): Medication errors and off-label use in children under 5 years. Sent out 29 June 2017.
- **DepoCyte (cytarabine):** Follow-up letters to healthcare professionals about supply difficulties in the EU. Sent out July 2017.
- **Klexane (enoxaparin)**: Update of the expression of strength, dose regimen in deep vein thrombosis/pulmonary embolism and use in patients with severe kidney impairment. Sent out 4 July 2017.
- **Ibrutinib (Imbruvica):** Risk of hepatitis B virus reactivation. Hepatitis B virus status to be established before initiating treatment with Imbruvica. Sent out 17 July 2017.
- **Flolan (epoprostenol):** Two different sterile solvents for Flolan will be temporarily available, each with different instructions for reconstitution, storage and administration of Flolan solution. Sent out August 2017.
- **Trisenox (arsenic trioxide):** Supply shortage of Trisenox (arsenic trioxide, 1 mg/ml concentrate for solution for infusion): Alternative treatment to be considered for patients newly diagnosed with low or intermediate risk acute promyelocytic leukaemia (APL). Sent out 1 August 2017.
- **Medicines containing methylprednisolone and lactose:** New contraindication for medicines containing methylprednisolone and lactose for treatment of allergic reactions in patients allergic to proteins in cow milk. Sent out 30 August 2017.

The DHPCs are available at the DKMA website – most of them in Danish only: Direct Healthcare Professional Communication (DHPC) sent to healthcare professionals.

Problems with accessing collected data in connection with the control of clinical trials

To be able to ensure the quality of data and the safety of trial subjects in clinical trials, the DKMA and the pharmaceutical company or the investigator sponsoring the clinical trial must have direct access to the medical records of trial subjects according to the Danish Committee Act and the Danish Medicines Act. With the implementation of the electronic medical records in hospitals, the DKMA has nonetheless experienced increasing problems with gaining lawful access to the hospital medical records of trial subjects when monitoring clinical trials in hospitals.

There have been other hurdles for our inspectors in the form of non-responsiveness or extremely late responses to announced inspections, lack of time/unwillingness to accept inspections and/or submit documents prior to inspections.

In early 2017, the Danish Ministry of Health approached the regions to remind them of their obligation to ensure access to the collected data – including health data about trial subjects – for the Danish Medicines Agency, the pharmaceutical companies sponsoring the trials as well as the investigators.

The DKMA has now followed up on the Ministry's approach to the regions, requesting the hospital management to solve the problems of access to medical records and acceptance of inspections.

New and improved version of the SmPC website produktresume.dk

Healthcare professionals can now enjoy easier access to the current recommendations for medicines authorised in Denmark. The Danish SmPC website produktresume.dk has been relaunched with new search functions and a more user-friendly design.

The redesigned produktresume.dk can now display results by publication dates in week intervals, and the SmPC updates now appear in a diagram.

The website is in Danish and help to use the new search functions is provided under ”Hjælp til søgning” at produktresume.dk.

The SmPCs of centrally authorised medicines are available on the website of the European Medicines Agency: www.ema.europa.eu.

Short news

Follow the Danish Medicines Agency on social media

In recognition of modern media flows and the public's increasing use of social media, the Danish Medicines Agency has started using social media for our communication. We are active today on Facebook, LinkedIn, YouTube, Snapchat, and on Twitter we now have a Danish and an English profile. We use the different channels to support factual information intended for the public about current pharmaceutical topics, and we aim to use a tone and voice on level with our users and to be present where the patients and healthcare professionals are.

The topics we most often cover are about medicines, medical devices, our work processes, job openings, good research and the European and international collaboration, etc. Especially Facebook turned out to be effective for the withdrawal cases we reported this year. Here it soon became clear that users were quick to share information with relevant patient groups and promptly forwarded information to specific patients in response to something we posted on Facebook. We also use Facebook to engage in active dialogue with citizens on complicated matters, such as the HPV vaccine and medical cannabis. Most recently we posted information about the flea and tick product Bravecto that many people were concerned about, and the topic was discussed and shared frequently in various dog communities on Facebook.

Follow the Danish Medicines Agency on social media