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Danish Health and Medicines Authority

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DANISH PHARMACOVIGILANCE UPDATE

Contents

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Short news

Mirabegron (Betmiga): New recommendations regarding the risk of increase in blood pressure

The DHMA has received reports of severe hypertension in patients treated with Betmiga (mirabegron). Mirabegron is now contraindicated in patients with severe uncontrolled hypertension. Blood pressure should be measured before starting treatment and monitored regularly during treatment, especially in patients with hypertension.

Advice for doctors:

- Patients with systolic blood pressure ≥180 mm Hg and/or diastolic blood pressure ≥ 110 mm Hg should not be treated with mirabegron.
- Mirabegron should be discontinued if the patient develops serious uncontrolled hypertension.
- Blood pressure should be measured before starting treatment and monitored regularly during treatment.

Indication for mirabegron
Mirabegron is indicated for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adults with overactive bladder (OAB) syndrome.

Please note that Mirabegron is subject to stricter monitoring, which means that doctors have to report any suspected adverse reactions to the DHMA.

A DHPC has been sent out to relevant doctors.

Childhood vaccinations and reported suspected adverse reactions in Q2 2015

Every three months, the reports of suspected adverse reactions to vaccines in the Danish childhood immunisation programme are reviewed and assessed by the DHMA and a vaccination panel composed of experts from relevant clinical specialties in Denmark.

Here are the results of the review for Q2 2015.

Since adverse reactions to the HPV vaccine have attracted attention over the last years, we present our review in two sections:

1. A review of the ADR reports related to vaccines in the childhood immunisation programme – excluding the HPV vaccine.

2. A review of the ADR reports related to the HPV vaccine.

The review covers primary vaccines in the childhood immunisation programme as well as booster vaccines (re-vaccination).

Reports of adverse reactions to vaccines in the childhood immunisation programme (excluding the HPV vaccine) Q2 of 2015

In the second quarter of 2015, the DHMA received a total of 78 ADR reports[1] about vaccines in the childhood immunisation programme (excluding the HPV vaccine). Seven were classified as serious[2].

Table 1a shows the number of ADR reports classified as serious and non-serious.

Vaccine	Serious	Non-serious	Total
Act-hib/pneumovax/prevenar 13	1	0	1
DT booster	1	3	4
DTaP-IPV Booster	0	4	4
DTaP-IPV /Act-Hib	0	28	28
DTaP-IPV/Act-Hib/Prevenar	0	1	1
DTaP-IPV/Act-Hib/Prevenar 13	2	17	19
DTaP-IPV /Act-Hib/Priorix	0	1	1

[1] All cases referred to in this article originate from the Danish Health and Medicines Authority's database of adverse drug reactions. The cases have been forwarded to all relevant pharmaceutical companies and to the EudraVigilance database. Therefore, the pharmaceutical companies are not to report these cases to the Danish Health and Medicines Authority.

[2] A report is serious when one or more of the adverse reactions are serious. A serious adverse reaction caused by a medicine for human use is a reaction that results in death, is life-threatening, requires hospitalisation or prolongation of hospitalisation, or which results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

Infanrix Hexa	0	3	3
Infanrix Hexa/Prevenar 13	0	2	2
MMR Vaxpro	1	8	9
Pneumovax	0	1	1
Prevenar 13	0	1	1
Priorix	2	1	3
Tetanus vaccine “SSI”	0	1	1
Total	**7**	**71**	**78**

Table 1a. ADR Reports by severity.

Review and assessment of the serious reports
When we assess the serious ADR reports, we investigate whether it is likely that there is a causal link to the vaccine.

The result of our causality assessment is based on four categories:

- Possible
- Less likely
- Insufficient documentation
- Unclassifiable

The categories were described in *Danish Pharmacovigilance Update, January 2015.*

Vaccine	ADR description	Assessment and causality
MMRVAXPRO	A 4-year-old boy vomited and had abdominal pain 11 days after vaccination.	Vomiting and abdominal pain are common in many virus infections, but the ADR report describes that the conditions occurred 11 days after vaccination. Causality is therefore considered **less likely**.
DT booster	A 65-year-old woman developed a rash and felt unwell the day after vaccination. She was admitted to hospital, but no symptom causes were found.	It is considered most likely that it was an allergic reaction. Causality is considered **possible**.
DTaP-IPV Act-Hib and Prevenar13	A 5-month-old child was admitted to hospital 5 days after vaccination. The child was dehydrated following prolonged diarrhoea, which started the day the child was vaccinated.	Tests for virus infections came out negative. There is a close temporal relationship between reactions and vaccination. In the summary of product characteristics, vomiting and diarrhoea are listed as common adverse reactions. Causality is therefore considered **possible**, although it cannot be ruled out that another viral infection was at play.

DTaP-IPV Act-Hib and Prevenar13	A 3-month-old child developed fever and seizures on the same day as the vaccine was given.	Febrile seizure is a known adverse reaction to the vaccine, and causality is therefore considered **possible**.
Prevenar13 and Pneumovax (MO-91)	A woman with hyposplenia developed invasive pneumococcal infection for the third time. She had previously had two invasive pneumococcal infections, was subsequently vaccinated, and antibody response was measurable*.	It is unusual for infection to develop when antibody response is observed, but vaccine failure is **possible**.
Priorix®	A child with vaccination granuloma suspected to be caused by the vaccine Priorix®. Suspicion of aluminium allergy.	Since Priorix® does not contain aluminium, it is considered **less likely** that the reaction is connected to the vaccine. Whether the granuloma was caused by another vaccine cannot be assessed.
Priorix®	Eight days after vaccination, a 5-year-old boy developed a fever, a rash and had difficulty walking with left-side weakness. The symptoms lasted for 3-4 months.	There are few details in the report, but it cannot be ruled out that the measles vaccine can give encephalitis-like symptoms. The vaccine's summary of product characteristics describes that the risk of encephalitis after vaccination is far below the risk of encephalitis caused by natural diseases. Based on the scarce information, a connection to the vaccine is considered **possible**.

Table 1b: Description of the suspected adverse reactions described in the serious ADR reports and subsequent causality assessment.

*Ballegaard VC et al: Recurrent severe invasive pneumococcal disease in an adult with previous unknown hyposplenia. BMC Infectious Disease 2015¸15:171:2-7.

Review of the non-serious ADR reports

Altogether 71 reports were classified as non-serious. The vast majority of them describe local reactions, especially granulomas, (45 of the ADR reports).

Most of the reports of granulomas were reported after vaccination with DTaP-IPV Act-Hib and Prevenar13. However, a few (3) were reported as suspected adverse reactions to Infanrix® Hexa.

Conclusion

In the second quarter of 2015, we received a total of 78 ADR reports that concerned vaccines in the childhood immunisation programme (excluding the HPV vaccine).

Seven were classified as serious. In five of these reports, a causal link to the vaccine was assessed as **possible**.

There are no new data shifting the benefit-risk balance, and therefore the DHMA assesses that the benefits of the vaccines still outweigh the possible risks.

ADR reports about the HPV vaccine received in Q2 2015

In the second quarter of 2015, the DHMA received a total of 308[3] reports of suspected adverse reactions to the HPV vaccine, of which 158 were classified as serious.

Table 2a shows the number of ADR reports related to the HPV vaccine classified as serious and non-serious.

Vaccine	Serious	Non-serious	Total
HPV vaccine	158	150	308

Table 2a. ADR reports by severity.

HPV vaccine	2009	2010	2011	2012	2013	2014	to 30 June 2015	Total
Number of reports	288	66	43	95	514	192	387	1586
– of which serious	25	7	9	18	186	96	202	543
Number of doses sold	347,690	151,476	163,374	349,730	488,224	114,467[4]	36,191	1,651,152

Table 2b: The total number of ADR reports related to the HPV vaccine received from 2009 to 30 June 2015 and the number of reports classified as serious. The number of HPV vaccine doses sold in Denmark is also shown. (Please be aware that when the DHMA receives additional information, this may imply changes. Consequently, there may be small variations between previously published cumulated figures and the above figures.)

The figures above show that we received many ADR reports within a relatively short period, and if we look at the number of doses sold in this quarter, the number of ADR reports is high. We have therefore looked closer into these ADR reports to find out when the reported symptoms began.

Reports received in the period 2009-2015 by adverse reaction onset

We have recorded the start date of suspected adverse reactions of the HPV vaccine for ADR reports received in the period 2009 to 30 June 2015. In case of no onset date (9.5%), the vaccine administration date is used instead. In case of no vaccine administration date (3%), the date when the ADR report was received is used instead, see table 2c.

A similar break-down on serious adverse reactions can be found in table 2d.

[3] All cases referred to in this article originate from the Danish Health and Medicines Authority's database of adverse drug reactions. The cases have been forwarded to all relevant pharmaceutical companies and to the EudraVigilance database. Therefore, the pharmaceutical companies are not to report these cases to the Danish Health and Medicines Authority.

[4] A review of data from 2014 has implied a small change in the number of doses sold.

Age group	-2008	2009	2010	2011	2012	2013	2014	2015	
Over the age of 18	18	24	24	37	164	354	36	11	668
Under the age of 18	123	225	81	68	84	86	55	21	743
Unknown	33	24	3	4	35	58	12	6	175
Total	**174**	**273**	**108**	**109**	**283**	**498**	**103**	**38**	**1586**

Table 2c: ADR reports for the HPV vaccine received in the period 2009 to 30 June 2015 by ADR start date. If several adverse reactions with different start dates are described, the date of the first occurring adverse reaction is used.

	Year the adverse reaction started (serious adverse reactions)								Total
Age group	- 2008	2009	2010	2011	2012	2013	2014	2015	
Over the age of 18	6	6	10	14	68	127	9	5	245
Under the age of 18	27	70	32	35	42	32	21	5	264
Unknown	3	6	2	1	5	14	1	2	34
Total	**36**	**82**	**44**	**50**	**115**	**173**	**31**	**12**	**543**

Table 2d. Serious ADR reports for the HPV vaccine received in the period 2009 to 30 June 2015 by ADR start date. If several adverse reactions with different start dates are described, the date of the first occurring adverse reaction is used.

As shown in the above tables, we have received most ADR reports with adverse reaction onset in 2013, followed by 2012 and 2009. These are also the years when the most doses were sold. From August 2012 until end-2013, the HPV vaccine was offered free of charge to women from the 1985-1992 birth cohorts.

In the first half of 2015, we received many ADR reports (table 2b). Most of them describe adverse reactions starting before 2015 (table 2c and 2d). Several ADR reports received in the first half of 2015 concern adverse reactions that started earlier – in fact several of them involve adverse reactions that started years before, but until now were unreported. This can probably be ascribed to the recent period's awareness on adverse reactions; it is a well known mechanism to see rising numbers of ADR reports when there is much awareness on adverse reactions to a specific medicine. It happened in 2009 as well when the media focused heavily on atopic dermatitis as a suspected adverse reaction to the vaccine.

Age distribution

The HPV vaccine is the only vaccine in the Danish childhood immunisation programme that is also offered free of charge to women outside the childhood programme.

From August 2012 until end-2013, the HPV vaccine was, as mentioned, offered free of charge to women from the 1985-1992 birth cohorts. Since 1 January 2014, the HPV vaccine has been offered to women from the 1993-1997 birth cohorts. These birth cohorts have previously been offered the HPV vaccine. The offer is available until the end of 2015.

Table 2e shows the age distribution of the girls/women from the ADR reports we received in the second quarter of 2015.

Number of ADR reports about persons under 18	Number of ADR reports about persons aged 18 or over	Number of ADR reports, age unknown
178	125	5

Table 2d. Age of the girls/women from the ADR reports received.

Review and assessment of the serious ADR reports about the HPV vaccine
A total of 158 reports were classified as serious.

One of the women were vaccinated with Cervarix®; the others with Gardasil® or Silgard®.

In the serious ADR reports, an average of 17 suspected adverse reactions are described (spread 1-198). There are no serious adverse reactions involving boys/men in this quarter.

The classification of ADR reports after our causality assessment is as follows:

- Six of the ADR reports are classified as **possible**.

  Three patients developed Postural Orthostatic Tachycardia Syndrome (POTS). There is a close temporal relationship between symptom onset (verified by tilt table test) and vaccination.

  Two patients developed idiopathic thrombocytopenia shortly after vaccination. This is a known adverse reaction to the HPV vaccine.

  A patient developed demyelination of the spinal cord shortly after vaccination. This is a rare disorder, and in the given case, there is a close temporal relationship with no mention of other explanatory causes. Case reports describe this condition after vaccination.

- 72 ADR reports are classified as containing **insufficient documentation** to link it to the HPV vaccine.

  The temporal relationship is consistent, but the adverse reactions are not described in the literature. The vast majority of the reactions concern long-term symptoms with fatigue, headache, dizziness, complaints about pain from different organ systems with no cause being found.

- 47 ADR reports are classified as being **less likely** to be linked to the HPV vaccine. They have received this classification because the reported adverse reactions are unknown and because there is no consistent temporal relationship (e.g. the symptoms existed before vaccination) or because of another present disease, which can more likely explain the symptoms (e.g. three women developed Epstein-Barr virus infection which is known to cause chronic fatigue), or there is lack of evidence in the literature to prove a link to the suspected adverse reactions.

- 33 ADR reports are **unclassifiable** because of very scarce information and/or there is no indicated time interval between vaccination and symptom onset.

ADR reports with specific diagnoses suspected as adverse reactions
In 25 of the ADR reports, specific diagnoses have been reported as suspected adverse reactions. In the following, we go through the causality of these reports.

Fibromyalgia

We received five ADR reports describing patients who developed fibromyalgia suspected to be an adverse reaction to the HPV vaccine. In four of these reports, **insufficient documentation** meant that a causal link could not be assessed. The last one was deemed **unclassifiable** due to inadequate information.

Rheumatoid arthritis

We received two ADR reports describing patients with rheumatoid arthritis suspected to be an adverse reaction to the HPV vaccine. One ADR report described that the patient developed rheumatoid arthritis about one year after vaccination. Causality to the vaccine is considered **less likely** as there is no temporal relationship between the symptoms and the vaccination, and because there is no description in the literature. The other woman experienced worsening of the disease after vaccination, which has not previously been described in the literature.

Systemic lupus erythematosus (SLE)

We received an ADR report about a patient with systemic lupus erythematosus (SLE) as a suspected adverse reaction. The SLE diagnosis was made six years after vaccination. Causality to the vaccine is considered **less likely** because of the long period between vaccination and diagnosis. Causality between SLE and the HPV vaccine is not described in the literature.

Benign intracranial hypertension

We received two ADR reports describing patients with the diagnosis of benign intracranial hypertension suspected to be an adverse reaction to the HPV vaccine. In the one case, it was considered **possible** that the diagnosis was related to the DT booster vaccine, which was given after Gardasil® and a short time before symptom onset. There are case reports describing the DT booster vaccine as causing benign intracranial hypertension.

There is no evidence in the literature to indicate causality between benign intracranial hypertension and the HPV vaccine.

Persistent fever of unknown origin

We received an ADR report about a patient who developed persistent fever of unknown origin. The patient had also been treated with MTX and Anakinra. No diagnosis is noted, but it is assumed that the patient had a rheumatic condition. There is **insufficient documentation** to link the condition to the HPV vaccine.

AV block

We received an ADR report about a patient who developed third degree AV block. The patient had had fever after vaccination. It is more likely that the condition was caused by an infection and not the vaccine. Causality is considered **less likely**.

POTS

Over the period, we received 13 ADR reports describing POTS as a suspected adverse reaction to the vaccine.

Three of these ADR reports have been classified as **possible** adverse reactions to the HPV vaccine. There is a consistent temporal relationship between the symptoms and the vaccination, and there is no mention of other diseases.

Six of the ADR reports are classified as containing **insufficient documentation**. In these ADR reports, no diagnostic tests were performed, or symptom onset was before the vaccination with subsequent worsening, or there are competing conditions (e.g. herpes meningitis and exercised induced dystonia).

Two ADR reports are classified as being **less likely** linked to the HPV vaccine because the temporal relationships are inconsistent.

Two ADR reports are **unclassifiable** due to lack of information.

Review of the non-serious ADR reports

The most commonly reported adverse reactions are fatigue, headache and dizziness. Syncope and joint pain are also described frequently.

Conclusion

We received a total of 308 ADR reports concerning the HPV vaccine in the second quarter of 2015. 158 of them were classified as serious.

Compared to previous periods, the number of ADR reports rose steeply in the second quarter of 2015. This could possibly be ascribed to the media's considerable awareness on and discussion of suspected adverse reactions to the HPV vaccine in the recent period. It is still only in a few ADR reports that the DHMA assesses causality to the vaccine to be possible.

We received a total of 25 ADR reports with specific diagnoses. 13 of them involved POTS as a suspected adverse reaction to the vaccine. Of these 13 ADR reports, only three described a consistent temporal relationship and did not mention other causes that could have triggered the condition.

There are still many ADR reports for which the literature provides insufficient documentation to indicate a possible causal link between the symptoms described and the vaccine. Like previous accounts, the vast majority of these adverse reactions concern long-term symptoms with fatigue, headache, dizziness and complaints about pain from different organ systems with no identified cause.

The DHMA has reviewed the ADR reports closer to check when the reported symptoms started, concluding that the majority of reports received describe adverse reaction onset in 2009 as well as 2012-2013 when sales of HPV vaccine doses were highest. Most of the ADR reports received in the first half of 2015 describe adverse reactions starting before 2015.

Additional review of the safety profile of HPV vaccines
The European Medicines Agency's Pharmacovigilance Risk Assessment Committee, PRAC, will be making an additional review of the HPV vaccines and their risk profile in response to a request by the DHMA. The review is to supplement the documentation that is already available for the vaccines. In its review, the European Medicines Agency, EMA, will investigate the available data, focusing on POTS and CRPS (Complex Regional Pain Syndrome), a chronic pain condition affecting the limbs.

DHMA's review of all serious ADR reports
The DHMA has completed its re-examination of the ADR reports of suspected adverse reactions to the HPV vaccine classified as serious. We have investigated if it is possible to identify new unifying features in the ADR reports through an examination with focus on reported symptoms rather than diagnoses. The WHO's collaborating centre, Uppsala Monitoring Centre, has contributed to the project with expert knowledge and searches in their database of adverse reactions reported globally for the HPV vaccine. The results are gathered in a report, collecting experience from Japan and recent, published scientific articles. In early September, the report was forwarded to the European Medicines Agency's Pharmacovigilance Risk Assessment Committee, PRAC, to be included in its current review of the safety of the HPV vaccine.

The report highlights the necessity for initiating a review of the reported symptoms, including a combination of symptoms, instead of focusing solely on separate assessments of each of the individual diagnoses. Any causality between the reported adverse reactions and HPV vaccination cannot be determined by means of the reported data on suspected adverse reactions to the HPV vaccines. The DHMA recommends in the report to consider possible further studies to confirm or disprove possible causality as part of the European reviews of HPV vaccine safety.

Read the report here: *Report from the Danish Health and Medicines Authority for consideration by EMA and rapporteurs in relation to the assessment of the safety profile of HPV vaccines*

Based on the overall review of data, the DHMA assesses that the benefits of the vaccines still outweigh the possible risks.

Maintained focus on the safety of HPV vaccines
The DHMA will keep following the scientific development, including experience from other countries. We contribute actively to the EMA review, and our focus will remain aimed at monitoring and providing information about adverse reactions.

We incessantly recommend doctors and patients to continue reporting suspected adverse reactions to the HPV vaccine for inclusion in the important assessment of the safety profile of HPV vaccines. Adverse reactions can be reported electronically at *www.meldenbivirkning.dk* (report a side effect).

Regional examination centres
Since the summer of 2015, practitioners and hospital departments have been able to refer vaccinees to a specialist department in their region of residence. The doctors take responsibility for examination and possible treatment of girls who present with diffuse symptoms that could be caused by adverse reactions to the HPV vaccine. The departments are responsible for coordinating care pathways and drawing on relevant medical expertise as needed.

Use of prescription-only cough suppressants for treatment of patients with asthma or COPD

The DHMA was contacted by a pharmacy where prescription-only cough suppressants were often redeemed together with prescription-only asthma medicine. Possibly, the cough suppressants were intended as replacement for adequate, preventive treatment of asthma.

Cough suppressants for asthma and COPD patients

In asthma patients, cough is often a symptom of absence of or inadequate asthma management and indicates initiation or optimisation of treatment. Cough suppressants are not recommended in asthma patients.

In chronic obstructive pulmonary disease (COPD), cough ensures open airways, and cough suppressants are not recommended in COPD.

The DHMA has therefore investigated to what extent asthma and COPD patients also use prescription-only cough suppressants.

Analysis

In collaboration with Data Delivery and Medicinal Products Statistics at Statens Serum Institut, National Institute for Health Data and Disease Control (SSI), we have investigated the extent to which cough suppressants are prescribed to asthma or COPD patients.

Our analysis is based on a data extract of the period 1 January 2014 to 31 December 2014. The number of patients with asthma and COPD was found based on the revised RUKS[5] algorithms, and data was extracted on 13 March 2015.

The medicines included in the analysis are codeine (ATC code R05DA04), dextromethorphan (R05DA09) and the combination product Pectyl® (Camphor, Liquorice extract, Opium) (R05FA02).

The data basis for asthma and COPD patients having redeemed at least two prescriptions for cough suppressants is based on the sale of medicines from Danish pharmacies in 2014 (Register of Medicinal Product Statistics). For dextromethorphan and the combination product Pectyl®, all redeemed prescriptions are included since these two medicines are

[5] Register of selected chronic diseases (Danish name: **R**egisteret over **U**dvalgte **K**roniske **S**ygdomme)

used for cough only. Codeine, on the other hand, has several indications, and only those prescriptions prescribed for cough are therefore included.

Age group (year)	Proportion of asthma patients having redeemed at least two prescriptions for cough suppressants (%)	Proportion of COPD patients having redeemed at least two prescriptions for cough suppressants (%)
5-9	< 0.1	-
10-19	< 0.1	-
20-39	0.3	0.7
40-64	1	1.6
65 +	1.75	1.8

Table 1. Proportion of asthma and COPD patients by age group having redeemed at least two prescriptions for cough suppressants during 2014 (source: Register of Medicinal Product Statistics, Statens Serum Institut, National Institute for Health Data and Disease Control, SSI)

Conclusion

The number of asthma and COPD patients having redeemed at least two prescriptions for cough suppressants in 2014 is very small, less than 2% for all age groups. There is therefore nothing to suggest that mistreatment or overtreatment with cough suppressants occurs in asthma and COPD patients.

New action plan on biological medicines, biosimilars and vaccines for 2015-2016

The DHMA and the Danish Ministry of Health have jointly prepared an action plan for better monitoring of biological medicines, biosimilars and vaccines.

Above all, the focus areas of the action plan are intended to ensure targeted and product-specific monitoring and ultimately a secure and safe treatment of patients.

An area under development

Biological medicines, biosimilars and vaccines are areas under development. New biological medicines are continually being developed with new or improved treatment possibilities, specifically within the areas of cancer, diabetes and rheumatic conditions as well as within growth hormone treatment. It is also expected that more biosimilars will be developed as patents for biological medicines expire in the coming years. Moreover, it is expected that new vaccines will be developed to prevent various types of cancer and other conditions.

Action plan with four focus areas:

1. Activities to encourage monitoring at product level.
2. Information campaign to promote understanding among health professionals on product-specific monitoring and the safety of citizens in using biological and biosmilar medicines as well as vaccines.
3. Digital solutions at hospitals and in medical practices to make ADR reporting easier for health professionals.
4. Focus by the Danish Health and Medicines Authority on monitoring the safe use of these medicines.

The action plan will be implemented jointly by the DHMA and a working group with representatives from the Danish Medical Association, Danish Association of the Pharmaceutical Industry, Danish Generic Medicines Industry Association, Danish Association of Parallel Importers of Medicine and Danish Regions.

The action plan will be evaluated in April 2016 and at end-2016.

Read the action plan here (in Danish only: *New action plan on biological medicines, biosimilars and vaccines in 2015-2016*.

Most recent Direct Healthcare Professional Communications (DHPCs)

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

- **Zofran (ondansetron):** New updated information concerning dose of ondansetron for iv treatment of chemotherapy- and radiation-induced nausea and vomiting.
- **Betmiga (mirabegron):** New contraindication for patients with serious uncontrolled hypertension following reports of cases of serious hypertension. In addition, new recommendations concerning monitoring of blood pressure before and during treatment.

The DHPCs are available in Danish at the DHMA website: *Direct Healthcare Professional Communication (DHPC) sent to healthcare professionals*

New European report on medicine users and ADR reports

Health Action International (HAI), a non-governmental European organisation, has published a new report that describes and analyses the ADR reporting systems used by medicine users in seven EU Member States, including Denmark. Read the report here: *HAI paper on Direct Patient Reporting in the EU.*

Help make medicine safer – the DHMA's campaign targeting general practitioners and medical students

The DHMA has just launched a new campaign intended to raise awareness among general practitioners on adverse drug reactions. The aim is to make doctors aware that the reporting of adverse reactions to the DHMA makes a difference – and that the doctors help make medicine safer through ADR reporting.

The campaign is also intended to make medical students pay more attention to the rules and the importance of reporting adverse reactions.

The campaign is launched in response to declining ADR reporting rates among general practitioners.

Follow this link to read more about the campaign at the DHMA website (in Danish only).
Help make medicine safer – report adverse reactions.

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