HARMONISED TRACEABILITY OF GADOLINIUM-CONTAINING CONTRAST AGENTS; UPDATE OF PRODUCT INFORMATION (PI) WORDING WITH REGARDS ELECTRONIC PATIENT RECORDS

CMDh/310/2014, Rev 0
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Background

In July 2010, the EC issued a decision following the CHMP positive opinion on the review under article 31 referral of the risk of nephrogenic systemic fibrosis (NSF) in patients receiving gadolinium-containing contrast agents (GdCAs) – *gadoversetamide, gadodiamide, gadopentetic acid, gadobenic acid, gadofosveset, gadoxetic acid, gadoteridol, gadobutrol and gadoteric acid.*

The grounds for the CHMP positive opinion included several conditions to the marketing authorisations of GdCAs to minimise the risk of NSF associated with their use. One of the conditions was "***The need to have a harmonised traceability method across Europe for effective monitoring of the use of GdCAs was agreed. The use of "sticky labels" detachable from the vials and syringes are considered an appropriate method to be implemented for all GdCAs.***"

The changes introduced at that time made clear reference to this condition as follows:

SmPC wording:

6.6 Special precautions for disposal and other handling

[*Use currently approved text for information on disposal*]

The peel-off tracking label on the {vials/syringes/bottles} should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded.

PL wording

Section: The following information is intended for medical or healthcare professionals only:

The peel-off tracking label on the {vials/syringes/bottles} should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded.

Labelling

Outer labelling:

The peel-off tracking label on the {vials/syringes/bottles} should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded.

Inner labelling for vials/syringes/bottles:

Peel-off tracking label detailing name of the product, batch number and dose presentation.

The traceability method and respective wording in the product information are therefore in place since 2010 as a risk minimisation measure.

Reason for the requested update of the product information

In many EU Member States, the patient records have transferred from a paper system to an electronic system. The current text in section 6.6 with transfer of the "sticky label" into the patient record is not fully suitable in countries where electronic patient records are also in use.

At is meeting in February 2014, the PRAC discussed a proposal for an adaptation of the product information to make it better suited for electronic patient record systems, hence ensuring that the traceability is adhered to by the HCP in case only electronic patient records are available. The PRAC stressed the importance of the traceability method to be in place whenever a gadolinium contrast agent is used, allowing the individual tracking of the contrast agent used, dose and batch via patient's records regardless if this is kept electronically or in paper. The proposed new wording is for the same information contained in the detachable label (product name, dose and batch) to be recorded in the electronic patient record.

PRAC recommended the following update of the Product Information (PI) wording with regards electronic patient records (new text in ***bold and underlined***):

SmPC wording:

6.6 Special precautions for disposal and other handling

[*Use currently approved text for information on disposal*]

The peel-off tracking label on the {vials/syringes/bottles} should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded. ***If electronic patient records are used, the name of the product, the batch number and the dose should be entered into the patient record.***

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Inner labelling for vials/syringes/bottles:

Peel-off tracking label detailing name of the product, batch number and dose presentation.

The name of the product, batch number and dose used should be recorded in the patient record.

MAHs are requested to discuss the recommended core wording, particularly the proposed wording to the inner label considering the pharmaceutical form (vial /syringe/ bottle), and update their SmPC, PL and labelling through submission of a type IB variation application, category C.I.z.