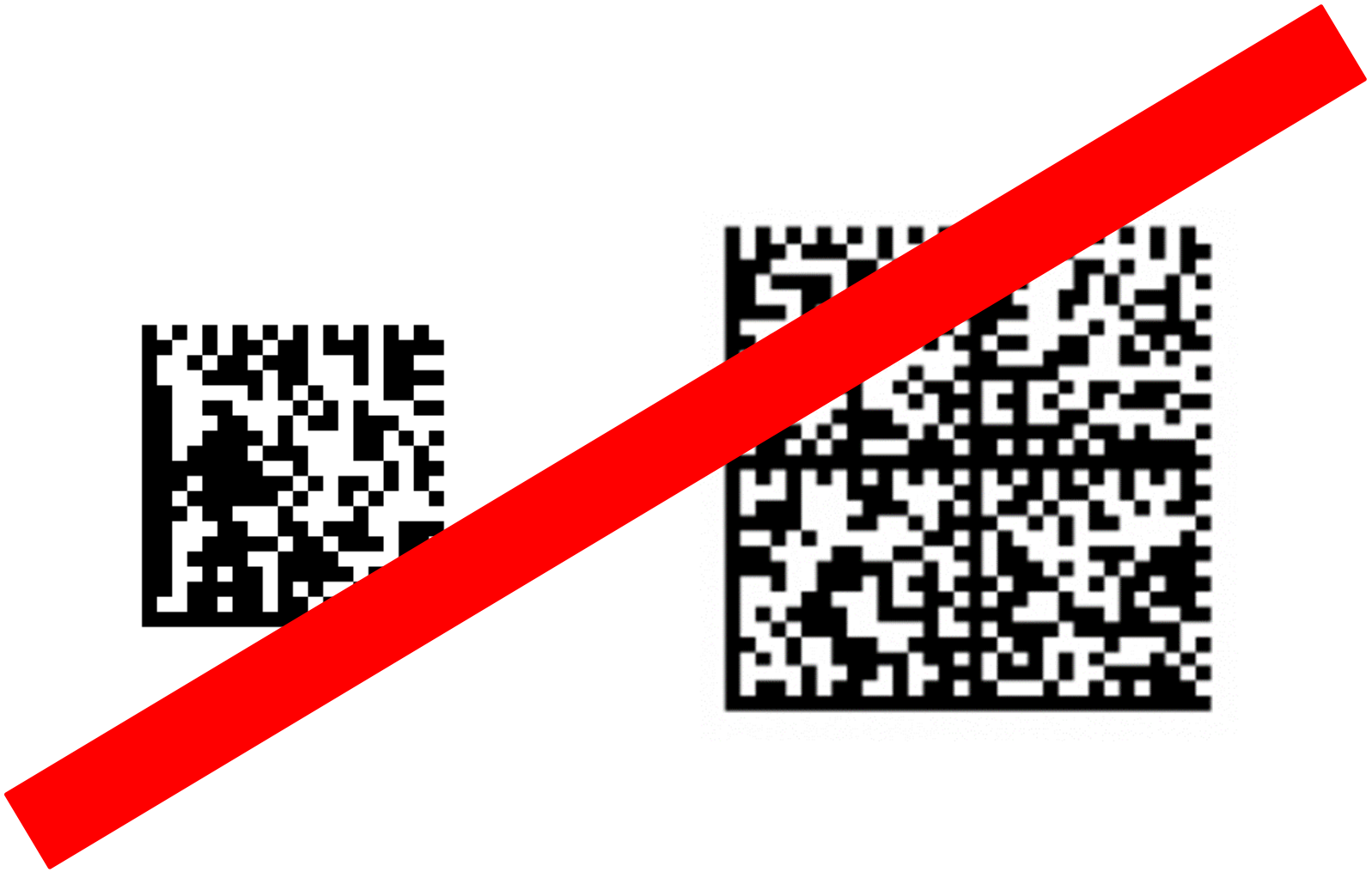
Statens legemiddelverk
Norwegian Medicines Agency

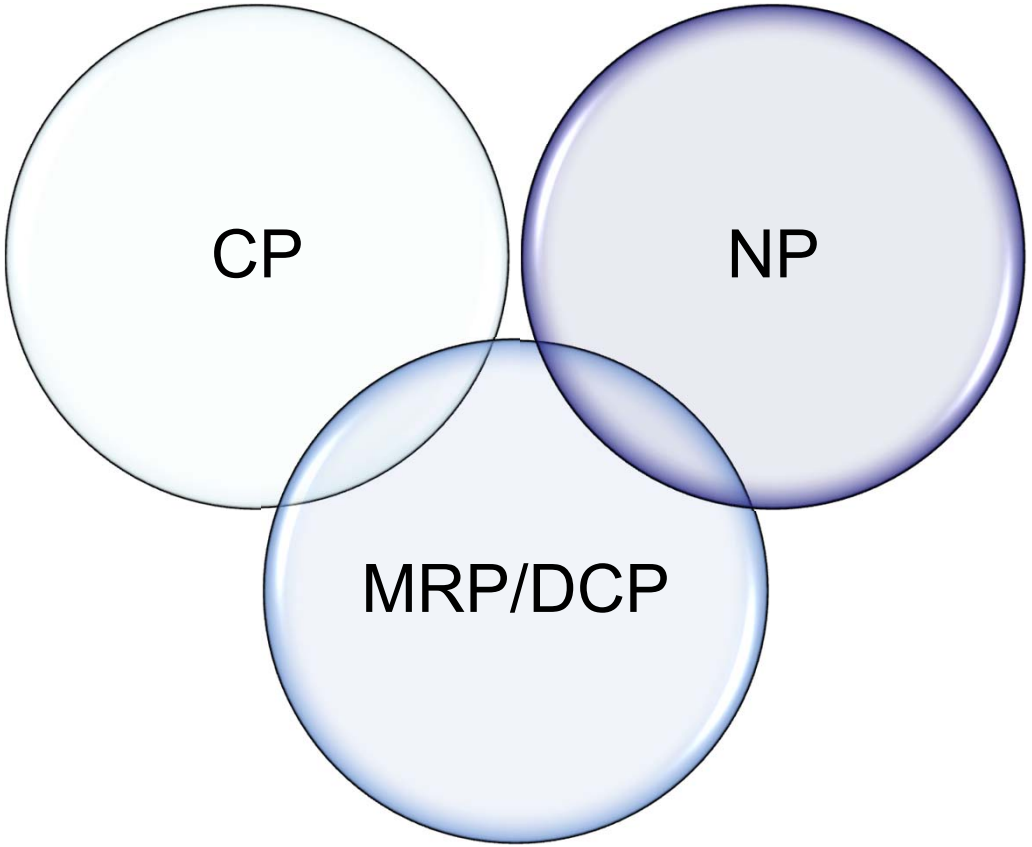
QR kode
- hva gjelder

Nina Malvik
Seksjon for produktinformasjon



Submission
Platform
Location
Information
Implementation

Submission



CP

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2015
EMA/493921/2015
Human Medicines Evaluation Division

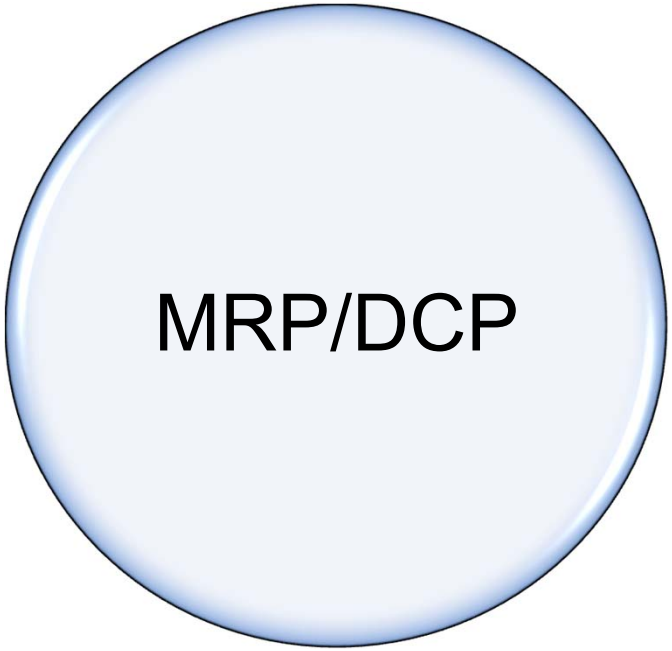
Request/declaration form for the provision of information via quick response (QR) codes in the centralised procedure.

[This request form accompanied by relevant information should be submitted to EMA in the context of an authorisation procedure within module 1.3.1 of the dossier.

All sections of the form should be completed. The applicant is required to confirm all the statements highlighted in bold within this form (declarations)] and sign at the end of the document. If not completed in full, the applicant may be requested to re-submit.

Name of the medicinal product / Procedure number	
Active substance	
Name and address of the applicant	
Authorised signatory	

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000254.jsp&mid=WC0b01ac058008c34c



Annex-2 Template for the Applicant declaration

APPLICATION FOR THE INCLUSION OF QR CODE IN MRP/DCP PROCEDURES

Procedure number (s)	
Name of the medicinal product in the RMS	
Name of the active substance	
Applicant	
Intended CMS in which the QR code will be included (s)	

I. Declaration of the QR content

The Applicant is requested to
1) Specify the information to be linked via QR Code and
2) Provide the URL linking such information (not needed when the information is provided via NCA website)

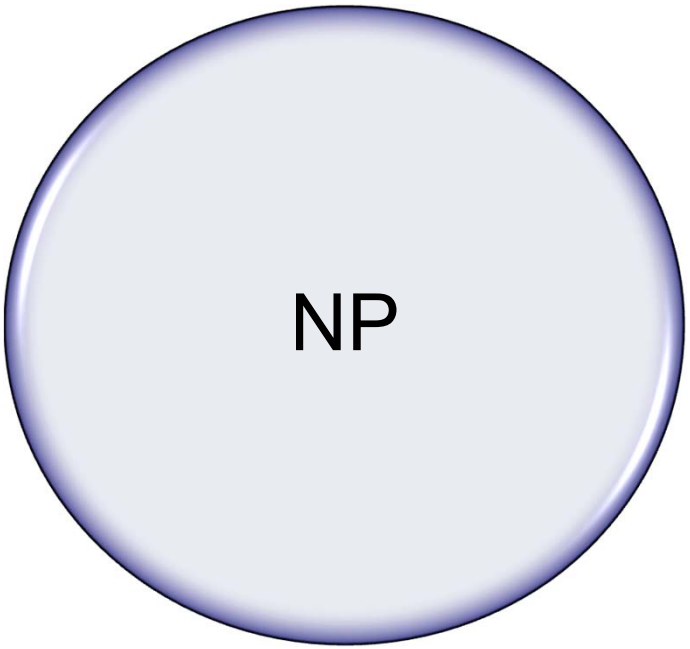
II. Intended location of the QR code in the product information

Applicant should declare the location of the QR code within the Product information (e.g. inner lid/inner flap of the carton, Package Leaflet, etc)

III. Location of the information to be provided via QR code (Links)

- NCA websites (MSs requiring link to their websites are detailed in Annex 1) ☐
- Website created by the MAH specifically for the QR code. ☐
- Standalone PDF document ☐

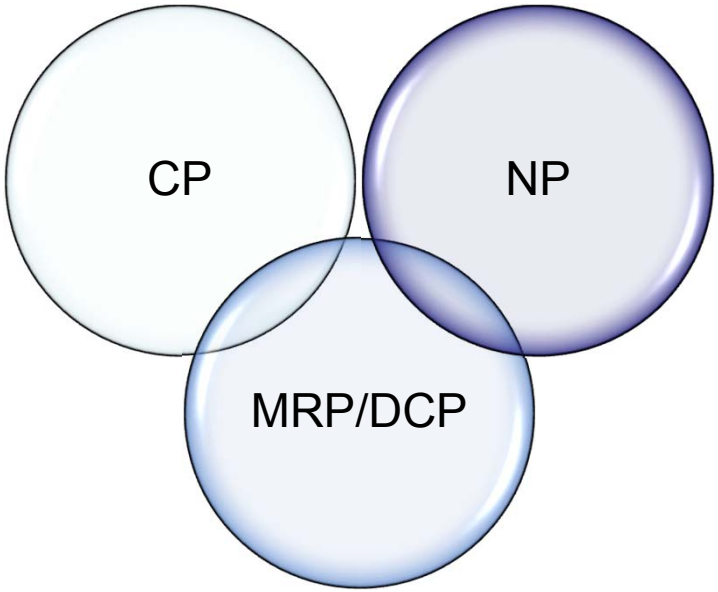
http://www.hma.eu/90.html



Recuest / declaration form
kommer januar 2016!

I dag:
En beskrivelse skal vedlegges.

Platform



1. Platform hosting the information

- Type of platform that will host the information provided via QR code:

Website ☐ Webpage ☐ Smartphone app ☐ National Agency website ☐ other ☐

- State URL of the platform hosting the information.....

(Detailed description of the platform should be given also addressing the mechanisms to ensure that most patients can benefit from the information provided)

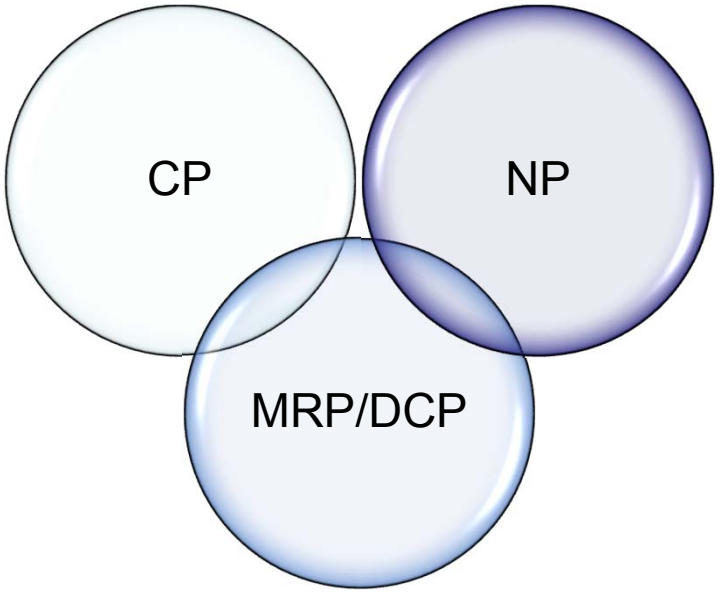
It is hereby declared that:

☐ **The final design of the platform has been provided**

☐ **The design of the platform allows easy access to the information in the EU official languages, as appropriate.**

☐ **The platform hosting the information is exempt of any promotional element (e.g. information relating to the marketing authorisation holder, links to corporate websites, etc.)**

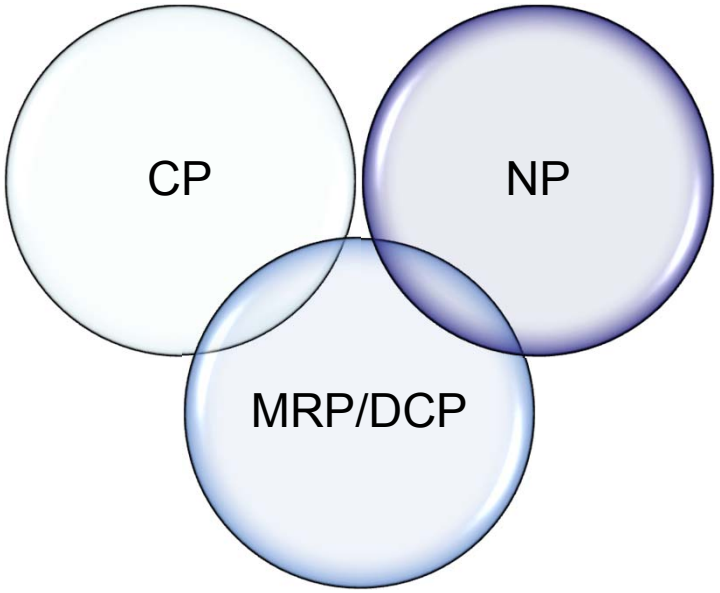
Location



- Pakningsvedlegget (nederst etter pkt. 6)
- På ytre emballasje

QR koden skal ikke være til hinder for «staturtory information» og plasseres slik at den ikke hindrer lesbarheten. Et egnet sted for koden kan være på innsiden av pakningen på en «flipp»

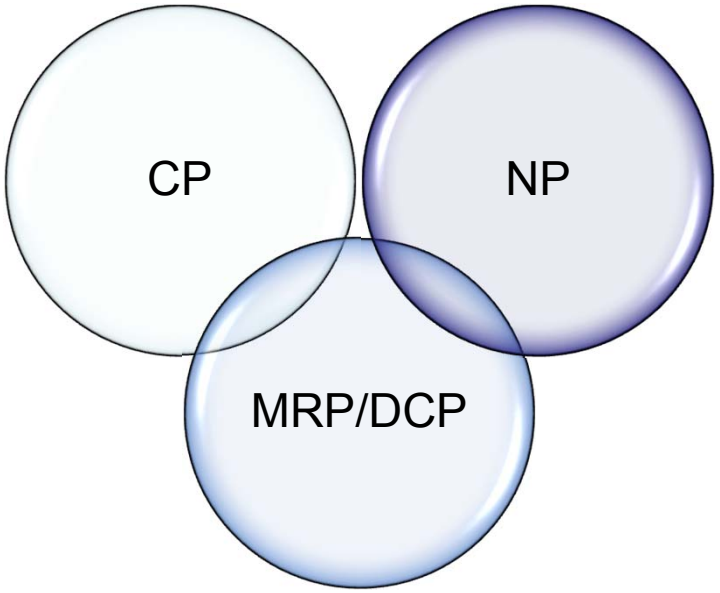
Information



Statutory information

Additional information

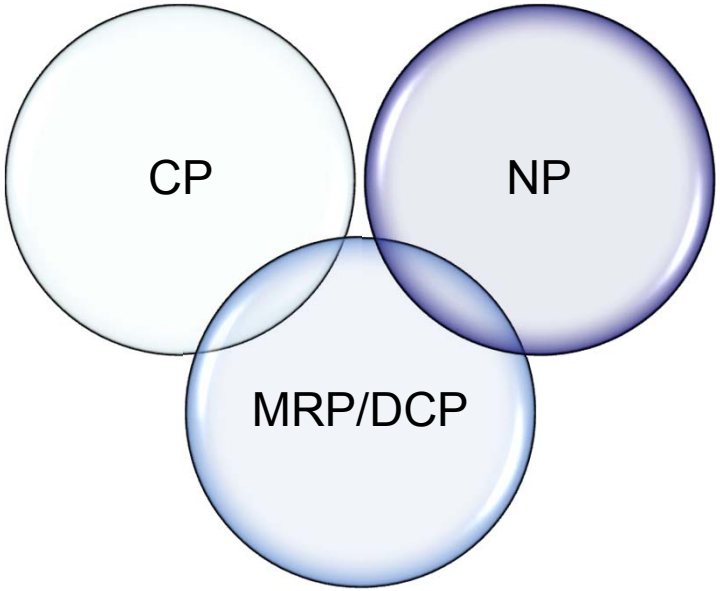
Information



Statutory information:

- Produktinformasjon (deler eller i sin helhet)
- RMP materiell

Information

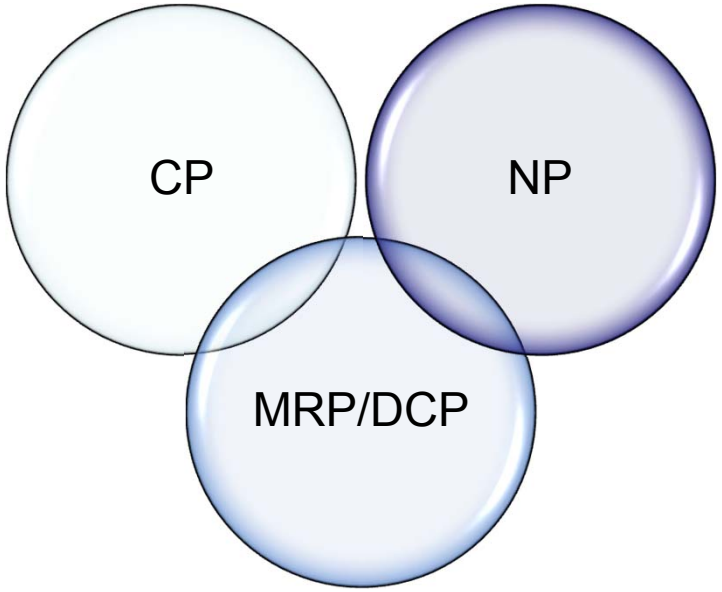


Additional information:

- Vurderes fra sak til sak
- Må godkjennes
- Må være i tråd med Art. 62 2001/83/EC
  - Ikke reklamepreget, Basert på produktinformasjonen
- CAP likt for alle land/ NAP ulikt innhold i QR koden mulig.

Eks.: instruksjonsvideoer, lenke til felleskatalogen (NAP)

Implementation

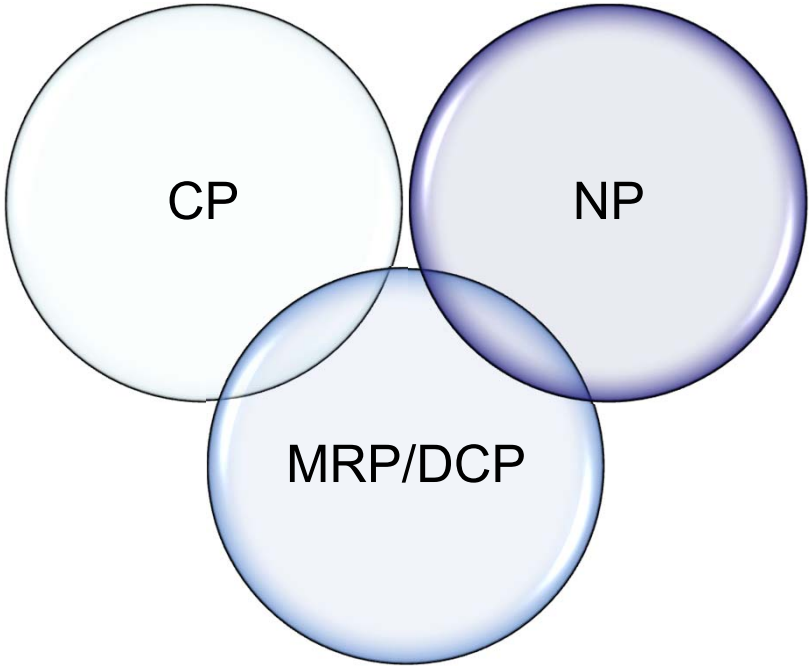


Statutory information:

- Fortløpende ved godkjenning av oppdatert materiell.

Additional information:

- Endring må søkes og godkjenning må avventes før dette kan oppdateres.



- Submission
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2015
EMA/493897/2015
Human Medicines Evaluation Division

Quick Response (QR) codes in the labelling and package leaflet of centrally authorised[1] medicinal products

General principles of acceptability and rules of procedure

1. Introduction

With the availability of new communication technologies it has become apparent that patients/users of medicinal products may benefit from information provided through electronic formats. In this context, there has been an increased demand by applicants to the centralised procedure to include QR codes in the labelling and/or package leaflet (PL) of medicinal products as an additional way of providing information to patients and health care professionals.

According to article 62 of Directive 2001/83/EC, "*the outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of any element of a promotional nature.*" This provision allows the inclusion of QR codes for the purpose of providing information.

Applicants to the centralised procedure should inform EMA of their intention to use QR codes in the labelling and/or package leaflet of centrally authorised medicinal products. The inclusion of QR codes should be applied for in the context of an evaluation procedure, as appropriate.

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/07/WC500190405.pdf

MRP/DCP

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

CMDh POSITION PAPER ON THE USE OF QR CODES TO PROVIDE INFORMATION ABOUT THE MEDICINAL PRODUCT

Doc. Ref.: CMDh/313/2014, Rev.3
November 2015

PROBLEM STATEMENT

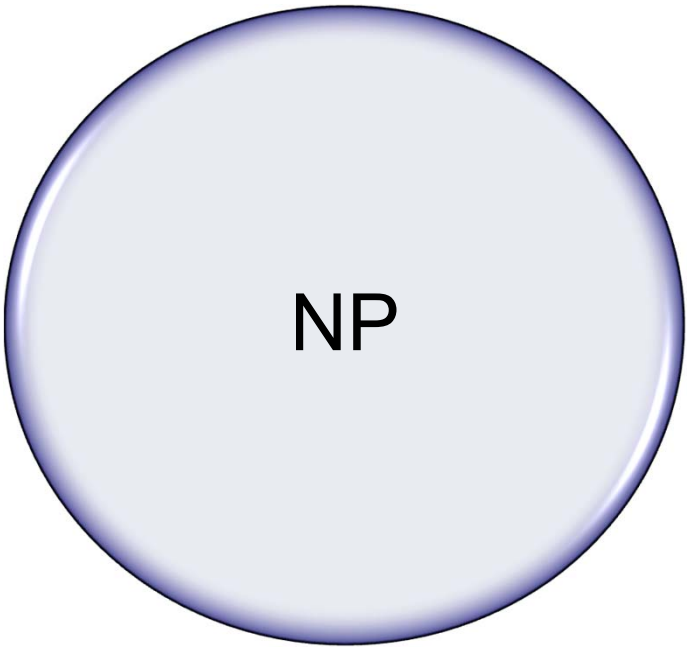
The QR code (abbreviated from Quick Response Code) is a two-dimensional bar code that is used to provide easy access by patients and/or Health Care Professionals to information through a smartphone.

The possibility of using these codes as a way for providing information, in a broad sense, on medicinal products is currently being considered not only by the Pharmaceutical Companies but also the National Competent Authorities (NCAs).

QR codes and 2D barcodes in medicines' packaging have been proposed (1) to access web pages (either maintained by the industry or by NCAs) with information about the medicine, (2) to provide batch number and expiration date to visually handicapped, (3) for manufacturing processing and stock control or (4) as the safety features included in the falsified medicines legislation.

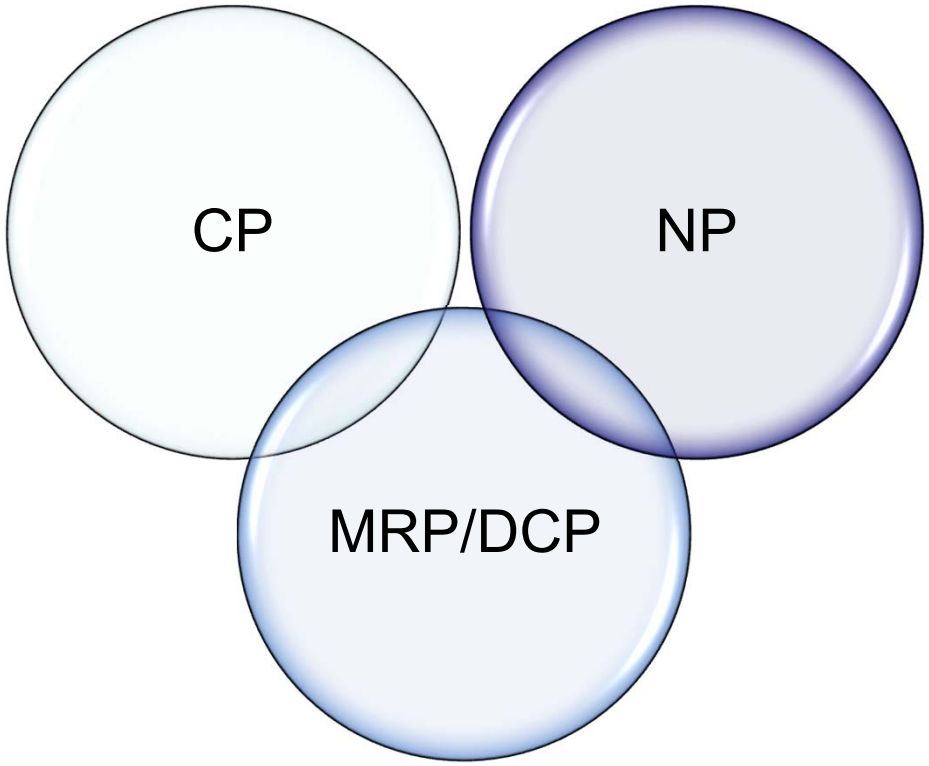
This paper only addresses the use of QR codes to access web pages with information about the medicinal products. Therefore, 2D barcodes that are solely used for internal manufacturing processing stock control or anti-counterfeit measures and does not contain information o the medicinal product, are considered out of the scope of this paper.

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_313_2014_Rev3_2015_11_clean.pdf

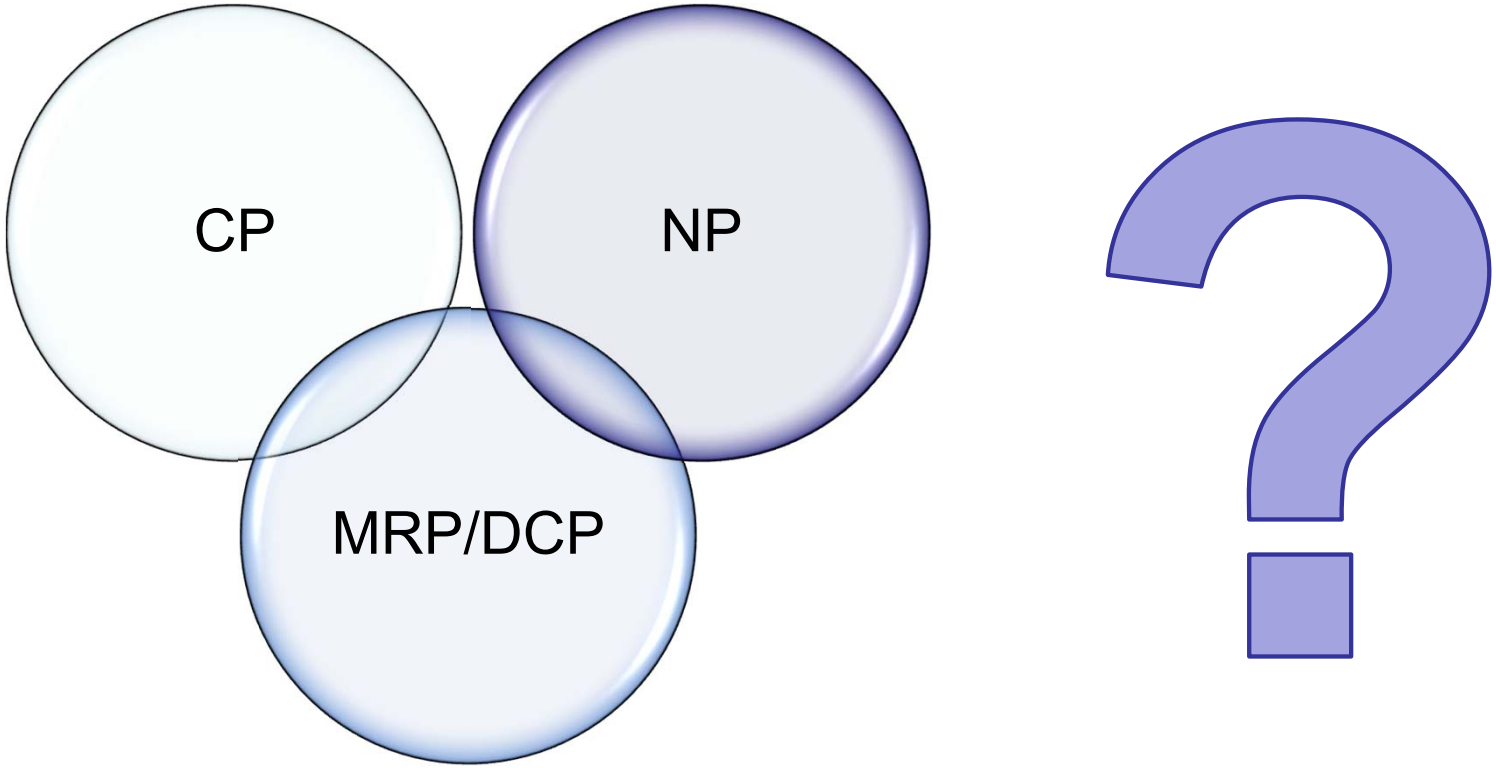


- Ingen egen guideline, CMDh position paper for MRP/DCP gjelder.
- www.legemiddelverket.no
  (kommer januar 2016!)

Henvendelser vedrørende QR koder



pi@legemiddelverket.no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