Cerevet

Product, Substance and Regulatory Bulletin

NOVEMBER 2014

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PRODUCTS: AVIAN

Nobilis IB Primo QX

EPAR published for new live vaccine against viral infectious bronchitis caused by strains of infectious bronchitis virus known as QX-like variants.

Product information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/002802/vet_med_000305.jsp&mid=WC0b01ac058008d7a8

More information: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/veterinary/002802/WC500176909.pdf

Release

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/DE_V_0125_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Tylogran

New product receiving positive opinion through the MRP / DCP procedure.

More information: http://mri.medagencies.org/veterinary/

Vetmulin

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0202_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

PRODUCTS: RUMINANTS

Ancesol

New product receiving positive opinion through the MRP / DCP procedure.

More information: http://mri.medagencies.org/veterinary/

Bilovet

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0404_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Bluevac BTV8

CVMP conducted the annual reassessments for Bluevac BTV8, and recommended continuation of the marketing authorisation under exceptional circumstances.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000156/vet_med_000237.jsp&mid=WC0b01ac058001fa1c

Cepralock

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0474_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Covexin 10

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0201_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Coxevac

CVMP Committee recommends converting the marketing authorisation from 'under exceptional circumstances' to a normal status (full) MA.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000155/vet_med_000219.jsp&mid=WC0b01ac058001fa1c

More information:

http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

Diclurazil

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0190_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Marbocoli

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/ES_V_0217_001_FinalPI.pdf

More information: http://mri.medagencies.org/veterinary/

Mastiseal

New product receiving positive opinion through the MRP / DCP procedure.

More information: http://mri.medagencies.org/veterinary/

More information: http://mri.medagencies.org/download/UK_V_0410_001_FinalSPC.pdf

Metacam

CVMP discussed an application for an extension to include a new strength for cattle and horses.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000033/vet_med_000142.jsp&mid=WC0b01ac058001fa1c&source=homeMedSearch

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

New Product

CVMP held an oral explanation on a new viral vaccine for sheep and cattle

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Release

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/DE_V_0125_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Sedaxylan

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/NL_V_0106_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

TAF spray

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0276_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Tylogran

New product receiving positive opinion through the MRP / DCP procedure.

More information: http://mri.medagencies.org/veterinary/

Vecoxan

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0113_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Zulvac 8 Bovis

The CVMP has discussed outstanding issues related to MA renewal.

Product information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000145/vet_med_000203.jsp&mid=WC0b01ac058001fa1c

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/09/WC500173147.pdf

Zulvac

ZULVAC 1 Bovis, ZULVAC 8 Bovis, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 8 Ovis and ZULVAC 1+8 Ovis: Quality changes mentioned in CVMP press release

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

Zulvac

Zulvac range: Quality changes mentioned in CVMP press release

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

PRODUCTS: SWINE

Bilovet

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0404_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Coglapix vakcina A.U.V.

CVMP has commenced a referral procedure due to concerns of a potential serious risk to animal health concerning efficacy for a vaccine against Actinobacillus pleuropneumoniae serotypes 1 and 2 authorised in Hungary, thought to be under MRP procedure.

Product information: https://www.nebih.gov.hu/szakteruletek/szakteruletek/allatgyogyaszati_igazgatosag/kozerdeku/torzskonyvezes/forgalmazhato/nemzeti

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/12/WC500179043.pdf

Marbocoli

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/ES_V_0217_001_FinalPI.pdf

More information: http://mri.medagencies.org/veterinary/

New Product

CVMP have heard an Oral Explanation for a new viral vaccine for pigs; exceptionally a second list of outstanding items was reported in CVMP October meeting minutes. The response to the questions was reviewed in the November meeting but no opinion was reported.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/10/WC500175041.pdf

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/11/WC500177167.pdf

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Nipoxyme

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/ES_V_0135_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Porcilis PCV M Hyo

Marketing Authorisation has been issued and Public Assessment report on the MA application has been published.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/003796/vet_med_000307.jsp&mid=WC0b01ac058008d7a8

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/veterinary/003796/WC500177274.pdf

More information: http://ec.europa.eu/health/documents/community-register/html/v175.htm#proc129827

Pracetam

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0181_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Release

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/DE_V_0125_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Suvaxyn PCV

Suvaxyn PCV: CVMP has reviewed post-authorisation measures.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000149/vet_med_000191.jsp&mid=WC0b01ac058001fa1c

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

TAF spray

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0276_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Tilmovet

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/BE_V_0017_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Tylogran

New product receiving positive opinion through the MRP / DCP procedure.

More information: http://mri.medagencies.org/veterinary/

Vetmulin

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0202_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

PRODUCTS: PETS

Acticam

CVMP reviewed a quality variation

Product information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000138/vet_med_000202.jsp&mid=WC0b01ac058001fa1c

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Alfaxan Solution

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0278_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Atopica

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0137_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

More information: http://mri.medagencies.org/download/FR_V_0137_002_FinalSPC.pdf

More information: http://mri.medagencies.org/download/FR_V_0137_004_FinalSPC_4of4.pdf

Enthryv

Enthryv is a transdermal solution containing thiamazole intended for treatment of hyperthyroidism and associated clinical signs in cats. Applicant Nexcyon Pharmaceuticals withdrew the application in June 2014 after CVMP considered the safety and efficacy data insufficient. The public assessment report has now been published.

More information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/002808/wapp/Initial_authorisation/vet_wapp_000019.jsp&mid=WC0b01ac058008d7ab

Loxicom

Loxicom: CVMP has reviewed post-authorisation measures.

Product information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000141/vet_med_000136.jsp&mid=WC0b01ac058001fa1c

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Marbotab

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0431_002_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Metacam

Metacam 1.5 mg/ml oral suspension will be subject to parallel distribution in Sweden, by Cross Pharma.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000033/vet_med_000142.jsp&mid=WC0b01ac058001fa1c&source=homeMedSearch

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/11/WC500177146.pdf

New Product

CVMP has received an oral explanation for a new haematological product for dogs.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

NexGard

CVMP reviewed a variation to change the SPC and the package leaflet due to new clinical data.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/002729/vet_med_000286.jsp&mid=WC0b01ac058001fa1c&source=homeMedSearch

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

NexGard Spectra

CVMP recommend a marketing authorisation be issued for a chewable tablets for dogs, intended for the treatment of flea, tick and gastrointestinal nematode infestations and the prevention of heartworm disease.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/003842/smops/Positive/vet_smop_000147.jsp&mid=WC0b01ac058008d7aa

Nobivac Bb

PET boxes to be introduced as outer packaging. Product literature has been updated.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000068/vet_med_000151.jsp&mid=WC0b01ac058001fa1c

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/veterinary/000068/WC500067345.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/veterinary/000068/WC500067346.pdf

Nobivac Ducat

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/DE_V_0207_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Oncept Melanoma

CVMP endorsement of withdrawal EPAR.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/11/WC500177167.pdf

Previcox

Previcox 227 mg Chewable tablet will be subject to parallel distribution in Sweden, by Cross Pharma.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000082/vet_med_000165.jsp&mid=WC0b01ac058001fa1c

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/11/WC500177146.pdf

Purevax

Quality changes mentioned in CVMP press release for Purevax RCPCh FeLV, FeLV and RCP FeLV

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

Release

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/DE_V_0125_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

TAF spray

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0276_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

PRODUCTS: HORSES

BioEquin FH

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/CZ_V_0127_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Butagran Equi

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/UK_V_0394_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Hippomectin

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/NL_V_0132_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Metacam

CVMP discussed an application for an extension to include a new strength for cattle and horses.

Product information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/medicines/000033/vet_med_000142.jsp&mid=WC0b01ac058001fa1c&source=homeMedSearch

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Release

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/DE_V_0125_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

Sedaxylan

SPC has been modified following MRP/DCP procedure.

Product information: http://mri.medagencies.org/download/NL_V_0106_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

TAF spray

New product receiving positive opinion through the MRP / DCP procedure.

Product information: http://mri.medagencies.org/download/FR_V_0276_001_FinalSPC.pdf

More information: http://mri.medagencies.org/veterinary/

SUBSTANCES: AQUATIC

Exiting Substance

CVMP discussed a report from a meeting held on 15 October 2014 between EMA/CVMP, ECHA and EFSA

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

New Substance

CVMP have reviewed (D120, list of questions) an MRL application (EMEA/V/MRL/004047/FULL/0001) for a new substance for goats, horses, fin fish & rabbits.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

SUBSTANCES: AVIAN

Colistin

Colistin: the referral (EMEA/V/A/106) on indications, prudent use warnings has been reviewed by CVMP (draft assessment report).

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

New Substance

CVMP have reviewed (D120, list of questions) an MRL application (EMEA/V/MRL/004047/FULL/0001) for a new substance for goats, horses, fin fish & rabbits.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

tylvalosin

CVMP has adopted a revised positive opinion recommending the establishment of a maximum residue limit in chicken eggs with extrapolation to poultry eggs. The revision followed European Commission's request to review its previous opinion and retain some of the ADI for future use. CVMP reconfirmed its conclusions and clarifies its recommendation.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

virginiamycin

CVMP recommend the establishment of maximum residue limits for virginiamycin in chickens and to extrapolate these maximum residue limits to poultry.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Summary_of_opinion/2014/11/WC500177138.pdf

SUBSTANCES: RUMINANTS

Colistin

Colistin: the referral (EMEA/V/A/106) on indications, prudent use warnings has been reviewed by CVMP (draft assessment report).

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

diclofenac

Diclofenac referral on risk to vultures and other necrophagous birds: CVMP has reviewed the joint rapporteur's assessment report and presentations by stakeholders.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Exiting Substance

A modification for an MRL for an existing substance for bovines was discussed by CVMP but no Opinion was published.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

New Substance

CVMP have reviewed (D120, list of questions) an MRL application (EMEA/V/MRL/004047/FULL/0001) for a new substance for goats, horses, fin fish & rabbits.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Thiabendazole

Thiabendazole: EFSA have published a review of the pesticide risk assessment. Missing information and concerns were identified.

More information:
http://www.efsa.europa.eu/en/efsajournal/pub/3880.htm?utm_source=feed&utm_medium=rss&utm_campaign=ej

SUBSTANCES: SWINE

Colistin

Colistin: the referral (EMEA/V/A/106) on indications, prudent use warnings has been reviewed by CVMP (draft assessment report).

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

SUBSTANCES: HORSES

gentamicin

CVMP have concluded the referral procedure for all products containing gentamicin in solution for injection for horses, following concerns regarding the indications, dosing regimen and target animal safety. Harmonised indications and dosing regimen have been agreed, to be implemented through variation of the marketing authorisations of the concerned products. No further details are available.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

New Substance

CVMP have reviewed (D120, list of questions) an MRL application (EMEA/V/MRL/004047/FULL/0001) for a new substance for goats, horses, fin fish & rabbits.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

SUBSTANCES: ANTIMICROBIAL RESISTANCE

Colistin

Colistin: the referral (EMEA/V/A/106) on indications, prudent use warnings has been reviewed by CVMP (draft assessment report).

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

SUBSTANCES: SAFETY

chloramphenicol

CVMP have been updated on the draft EFSA CONTAM Opinion on Reference Points for Action for chloramphenicol. EFSA Panel on Contaminants in the Food Chain (CONTAM) has produced a Scientific Opinion on Chloramphenicol in food and feed, as the antimicrobial substance can be naturally produced by bacteria and enter the food chain.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

More information: http://www.efsa.europa.eu/en/efsajournal/pub/3907.htm

REGULATORY: AVIAN

Avian Flu

Avian Flu: EFSA is assessing the current situation on the H5N8 avian influenza A virus following an urgent request from the European Commission.

More information:
http://www.efsa.europa.eu/en/press/news/141126a.htm?utm_source=feed&utm_medium=rss&utm_campaign=prwns

REGULATORY: RUMINANTS

Oestrus Synchronisation

Oestrus synchronisation: CMDv are sending questions regarding the inclusion of oestrus synchronisation protocols on SPCs to CVMP for scientific advice.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/11/WC500177167.pdf

Sheep and goat pox

Sheep and Goat Pox: EFSA has published a report on sheep and goat pox.

More information:
http://www.efsa.europa.eu/en/efsajournal/pub/3885.htm?utm_source=feed&utm_medium=rss&utm_campaign=ej

REGULATORY: SWINE

Oestrus Synchronisation

Oestrus synchronisation: CMDv are sending questions regarding the inclusion of oestrus synchronisation protocols on SPCs to CVMP for scientific advice.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/11/WC500177167.pdf

REGULATORY: HORSES

Equine Influenza Strains

In line with OIE requirements, CVMP has adopted a guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines based on recommendations from the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition. Comments from the consultation are available.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177527.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Overview_of_comments/2014/11/WC500177526.pdf

REGULATORY: ANTIMICROBIAL RESISTANCE

CVMP Antimicrobial Working Party

Work plans for 2015 for the Antimicrobials CVMP Working Party have been approved and published.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2013/01/WC500137231.pdf

European Antibiotic Awareness Day 2014

European Antibiotic Awareness Day 2014: EMA, EFSA and European Commission supported the EAAD on 18 November.

More information: http://www.ecdc.europa.eu/en/eaad/Pages/Home.aspx

More information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002214.jsp&mid=WC0b01ac058004d5c1

HMA Meeting Rome, July 2014

HMA: The report of the HMA meeting in Rome in July 2014 has been published. The following items were discussed: Revision of veterinary medicines legislation, VICH and VICH Outreach Forum, Regulation (EC) 470/2009 on Maximum Residue Limits 5 years after implementation, Implementing and delegated acts on the MRL Regulation, Updating fee structure, draft Commission Guidance document on antimicrobial VMPs, PSUR Workshare and Key Aims of future Pharmacovigilance and withdrawal periods for VMPs used under the cascade.

More information: http://www.hma.eu/fileadmin/dateien/HMA_joint/03-Stakeholders_Info/2014_07_HMA_Rome_HJV_Press_Release.pdf

REGULATORY: GENERAL

Multinational Assessment Teams

CVMP have discussed implementation of multinational assessment teams and declarations of interest and expertise available in national competent authorities.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

Conflict of Interest

Conflicts of interest: EMA has revised its policy on handling declarations of interests for scientific experts and committee members, reflecting a more balanced approach. The aim is to maintain EMA's ability to access the best available expertise while restricting involvement of experts with possible conflicts of interest.

More information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002216.jsp&mid=WC0b01ac058004d5c1

CVMP Scientific Advice & Pharmacovigilance Working Parties

Work plans for 2015 for Scientific Advice and Pharmacovigilance CVMP Working Parties: have been approved and published.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014580.pdf

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014578.pdf

EMA Head of Administration

Personnel: EMA has appointed Luc Vanheel as new head of Administration.

More information: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002212.jsp&mid=WC0b01ac058004d5c1

EMA Executive Director: Appointment annulled

Executive Director Guido Rasi: Appointment annulled. European Union Civil Service Tribunal has on purely formal grounds, annulled the decision by the Management Board to select and appoint Guido Rasi as EMA Executive Director on 6 October 2011. This follows its upholding of a legal challenge concerning the Commission's decision adopting a

shortlist of potential candidates for the position of Executive Director. The European Commission and EMA are taking legal advice. Pending further decisions, Andreas Pott, the Deputy Executive Director, will take responsibility with immediate effect for the management and operations of the Agency.

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002213.jsp&mid=WC0b01ac058004d5c1

HMA Meeting Rome, July 2014

HMA: The report of the HMA meeting in Rome in July 2014 has been published. The following items were discussed: Revision of veterinary medicines legislation, VICH and VICH Outreach Forum, Regulation (EC) 470/2009 on Maximum Residue Limits 5 years after implementation, Implementing and delegated acts on the MRL Regulation, Updating fee structure, draft Commission Guidance document on antimicrobial VMPs, PSUR Workshare and Key Aims of future Pharmacovigilance and withdrawal periods for VMPs used under the cascade.

More information:
http://www.hma.eu/fileadmin/dateien/HMA_joint/03-Stakeholders_Info/2014_07_HMA_Rome_HJV_Press_Release.pdf

National requirements for samples

HMA: A revised table detailing the national requirements for submitting samples for visual and/or laboratory control has been published.

More information: http://www.hma.eu/uploads/media/281114_CMDv_GUI-30_Specimens___samples.pdf

MUMS

CVMP has issued a concept paper for consultation proposing revision of the CVMP guidelines on data requirements for veterinary medicinal products for minor use minor species (MUMS). The paper concerns revisiting current MUMS guidelines in light of experience gained and the latest revised policy, to bring guidance into line with current knowledge and best practice.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500177461&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

veterinary nanomedicines

CVMP have noted the Australian Pesticides and Veterinary Medicines Authority (APVMA) draft report on regulatory considerations for nanopesticides and veterinary nanomedicines.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/11/WC500176885.pdf

More information:
http://apvma.gov.au/sites/default/files/docs/report-draft-regulatory-considerations-nanopesticides-veterinary-nanomedicines.pdf

Novel methodologies for drug development

Novel methodologies for drug development: EMA has launched a new, voluntary, scientific pathway to obtain a qualification opinion or advice on innovative methods or drug development tools from CHMP. The qualification process involves an ongoing interaction between the CHMP and the applicant as scientific knowledge and the intended use of a new method may change in line with the generation of additional data. The CHMP evaluation is open to public consultation to ensure that CHMP shares information and is open to enlarged scientific scrutiny and discussion.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004201.pdf

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/12/news_detail_002236.jsp&mid=WC0b01ac058004d5c1

Translations

Translations: EMA has updated the list of contact points for translations review.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004437.pdf

Transparency: Access to EMA documents

Transparency: EMA has published a practical guide on access-to-documents requests. The guide is intended to aid public access to any unpublished document held by EMA.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC500177739.pdf

Transparency: redactions

Transparency: The European Ombudsman has posed questions to EMA concerning their redactions from documents requested by an individual. EMA has noted the request and is formulating a response.

More information: http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/58319/html.bookmark

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002210.jsp&mid=WC0b01ac058004d5c1

REGULATORY: QUALITY

Equine Influenza Strains

In line with OIE requirements, CVMP has adopted a guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines based on recommendations from the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition. Comments from the consultation are available.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177527.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Overview_of_comments/2014/11/WC500177526.pdf

Excipient: propyl 4-hydroxybenzoate

CVMP have adopted a positive opinion recommending the establishment of maximum residue limits for propyl 4-hydroxybenzoate and its sodium salt in all food producing species. Previously these were considered as for food additives with a valid E-number in table 1 of the annex to Regulation (EU) No 37/2010 with a 'No MRL required' classification. However since the suspension of the E-numbers E214-E219 ('parabens') by EFSA, these substances are no longer covered by the entry for food additives.

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002205.jsp&mid=WC0b01ac058004d5c1

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Summary_of_opinion/2014/11/WC500177137.pdf

GMP: FDA & EMA Cooperation

GMP – FDA and EMA cooperation: United States Food and Drug Administration (FDA) met with a cross-agency team from EMA, the European Commission and GMP experts from EU Member States in order to make progress on mutual reliance between the FDA and EU on GMP inspections. This is the first face-to-face meeting of both complete teams on this topic.

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2014/11/event_detail_001071.jsp&mi

d=WC0b01ac058004d5c3

Ph.Eur. supplement 8.5

The contents of the next supplement 8.5 (1st July 2015) have been published. New texts include Permethrin (25:75) (1762) and Triclabendazole for veterinary use (2609). Revised/corrected texts include Selamectin for veterinary use (2268) and Lufenuron (anhydrous) for veterinary use (2177).

More information:
http://www.edqm.eu/en/Contents-of-Supplement-85-Discover-now-the-list-of-new-and-revised-texts-that-will-be-implemented-on-1st-July-2015-1586.html?mbID=253

REGULATORY: SAFETY

CVMP Safety & Environmental Working Parties

Work plans for 2015 for Safety and Environmental Risk Assessment CVMP Working Parties have been approved and published.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014581.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014575.pdf

Excipient: propyl 4-hydroxybenzoate

CVMP have adopted a positive opinion recommending the establishment of maximum residue limits for propyl 4-hydroxybenzoate and its sodium salt in all food producing species. Previously these were considered as for food additives with a valid E-number in table 1 of the annex to Regulation (EU) No 37/2010 with a 'No MRL required' classification. However since the suspension of the E-numbers E214-E219 ('parabens') by EFSA, these substances are no longer covered by the entry for food additives.

More information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002205.jsp&mid=WC0b01ac058004d5c1

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Summary_of_opinion/2014/11/WC500177137.pdf

Groundwater & VMPs

CVMP have agreed that the Environmental Risk Assessment Working Party and the Safety Working Party (vet) should work on a guideline on the assessment of the toxicological risk of veterinary pharmaceuticals in groundwater.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/11/WC500177167.pdf

HMA Meeting Rome, July 2014

HMA: The report of the HMA meeting in Rome in July 2014 has been published. The following items were discussed: Revision of veterinary medicines legislation, VICH and VICH Outreach Forum, Regulation (EC) 470/2009 on Maximum Residue Limits 5 years after implementation, Implementing and delegated acts on the MRL Regulation, Updating fee structure, draft Commission Guidance document on antimicrobial VMPs, PSUR Workshare and Key Aims of future Pharmacovigilance and withdrawal periods for VMPs used under the cascade.

More information:
http://www.hma.eu/fileadmin/dateien/HMA_joint/03-Stakeholders_Info/2014_07_HMA_Rome_HJV_Press_Release.pdf

VICH Genotoxicity & Residues

CVMP have adopted VICH GL23 on genotoxicity testing. The objective of this guideline is to ensure international

harmonization of genotoxicity testing in establishing the safety of veterinary drug residues in human foods

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177529.pdf

REGULATORY: EFFICACY

CVMP Efficacy & Immunologicals Working Parties

Work plans for 2015 for Efficacy and Immunologicals CVMP Working Parties have been approved and published.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014576.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014577.pdf

Equine Influenza Strains

In line with OIE requirements, CVMP has adopted a guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines based on recommendations from the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition. Comments from the consultation are available.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177527.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Overview_of_comments/2014/11/WC500177526.pdf

vector-borne diseases concept paper

CVMP has issued for consultation a concept paper (EMA/CVMP/EWP/309734/2014) recommending a new guideline on data requirements for the prevention of transmission of canine and feline vector-borne diseases, intended to give guidance on study design to demonstrate prevention of transmission of vector-borne diseases.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500177462&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

REGULATORY: IMMUNOLOGICALS NEW TECHNOLOGIES

CVMP Efficacy & Immunologicals Working Parties

Work plans for 2015 for Efficacy and Immunologicals CVMP Working Parties have been approved and published.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:

http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014576.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014577.pdf

EMA/HMA workshop

CVMP have nominated A. Holm (as CVMP representative) and E. Werner (as IWP representative) as members of the scientific steering group to the joint EMA/HMA workshop on the requirements for the authorisation of vaccines in the EU. The workshop is planned to take place in March 2015.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/11/WC500177167.pdf

Equine Influenza Strains

In line with OIE requirements, CVMP has adopted a guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines based on recommendations from the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition. Comments from the consultation are available.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177527.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Overview_of_comments/2014/11/WC500177526.pdf

Equine Influenza Strains

CVMP discussed the guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines, but did not adopt the guideline as expected at the September meeting.

More information: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/09/WC500173147.pdf

REGULATORY: PHARMACOVIGILANCE

CVMP Scientific Advice & Pharmacovigilance Working Parties

Work plans for 2015 for Scientific Advice and Pharmacovigilance CVMP Working Parties: have been approved and published.

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177135.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014580.pdf

More information:
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/11/WC500014578.pdf

Harmonised Birth Dates

Harmonised EU Birth dates: HMA has issued the revised list of harmonised product birth dates, data lock points and reference member states.

More information: http://www.hma.eu/442.html#c4870

HMA Meeting Rome, July 2014

HMA: The report of the HMA meeting in Rome in July 2014 has been published. The following items were discussed: Revision of veterinary medicines legislation, VICH and VICH Outreach Forum, Regulation (EC) 470/2009 on Maximum Residue Limits 5 years after implementation, Implementing and delegated acts on the MRL Regulation, Updating fee structure, draft Commission Guidance document on antimicrobial VMPs, PSUR Workshare and Key Aims of future Pharmacovigilance and withdrawal periods for VMPs used under the cascade.

More information:

http://www.hma.eu/fileadmin/dateien/HMA_joint/03-Stakeholders_Info/2014_07_HMA_Rome_HJV_Press_Release.pdf