AESGP Euro OTC News

Issue 324 | July – August 2020

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CROSS-SECTORIAL NEWS

COVID-19

PREPAREDNESS

Commission communication on Preparedness for future COVID-19 outbreaks

The European Commission released a guidance on short-term EU health preparedness for COVID-19 outbreaks.

This Communication aims at ensuring the EU's short-term health preparedness in case of further COVID-19 outbreaks in Europe. It draws particular attention to the need to reduce the burden of the 2020/2021 seasonal flu, so to mitigate the additional strain on health systems should this coincide with a further outbreak of COVID-19.

As such, the document highlights the need for a coordinated approach at EU level while emphasising at the same time the need for strong coordination and exchange of information in and between Member States and communities. It also presents some of the various initiatives conducted so far, namely (1) increasing test capacities, (2) improving surveillance and strengthening health system capacities, (3) measures to mitigate social and economic impacts that have been introduced.

The guidance emphasizes the need to enhance preparedness for further outbreaks of COVID-19 by:

1. Testing, contact tracing and public health surveillance
2. Medical countermeasures: smooth functioning of the single market and access to personal protective equipment, medicines and medical devices:

2.1. Establish overview on needs for medical supplies, national production capacities and stockpiles of essential equipment, map flexible production capacities/ conversion possibilities (Member States)

2.2 Support equitable access and deployment of needed medical countermeasures: - Ongoing contracts under joint procurements (PPE, ventilators, laboratory equipment, ICU medicines) (Member states) - New Joint Procurements (European Commission) - Emergency Commission procurements for Member States (ESI) - Strategic EU stockpiles (rescEU) and deployment plans covering the Union - Transport of medical supplies into the EU (ESI)

2.3 Member States to make full use of existing instruments such as the Joint Procurement Agreement to purchase and stockpile essential medical equipment, and ensure coordinated national stockpiling initiatives (Member States)

3. Healthcare surge capacity
4. Non-pharmaceutical countermeasures
5. Support to vulnerable groups
6. Reducing the burden of seasonal influenza:

Increase influenza vaccination coverage: anticipated start for vaccination campaigns and broadening of target groups (Member States) Member States should consider the anticipation of vaccination campaigns and broadening of target groups.

The document insists finally on the fact that every action must be underpinned by robust evidence and extensive public communication efforts. It also reminds of the major importance of individual behaviours and adherence to public health recommendations to prevent resurgence of cases.

MEDICAL DEVICES

Commission Q&A on conformity assessment procedures for protective equipment - Updated Version Published

The Commission published an updated version of the Q&A document on conformity assessment procedures for protective equipment.

The updated document can be obtained here.

Medicines

REGULATORY NEWS

CMDh highlights

The CMDh has published the report of the CMDh meeting held on 21-22 July 2020.

United Kingdom's withdrawal from the European Union

Following the ratification of the Withdrawal Agreement by the United Kingdom and the European Union in January 2020, the United Kingdom has formally left the European Union on 31 January 2020 and has become a third country to the EU. A transition period has started on 1 February 2020, which will end on 31 December 2020 as no extension of the transition period has been requested by the United Kingdom. During the transition period, EU pharmaceutical law as laid out in the 'Acquis Communautaire' will continue to be applicable to the UK, meaning that pharmaceutical companies can continue to carry out activities in the UK until the end of the year.

Marketing Authorisation Holders are reminded to make the necessary changes until 31 December 2020 to ensure that their authorised medicines comply with EU law and can remain on the EU market after the transition period.

Marketing Authorisation Holders are also reminded to familiarise themselves with the applicable rules in Northern Ireland after the end of the transition period as specified in the Protocol on Ireland/Northern Ireland and update their marketing authorisations as needed. More information on the IE/NI Protocol can be found in the "Notice to stakeholders - withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products".

Updated CMDh documents

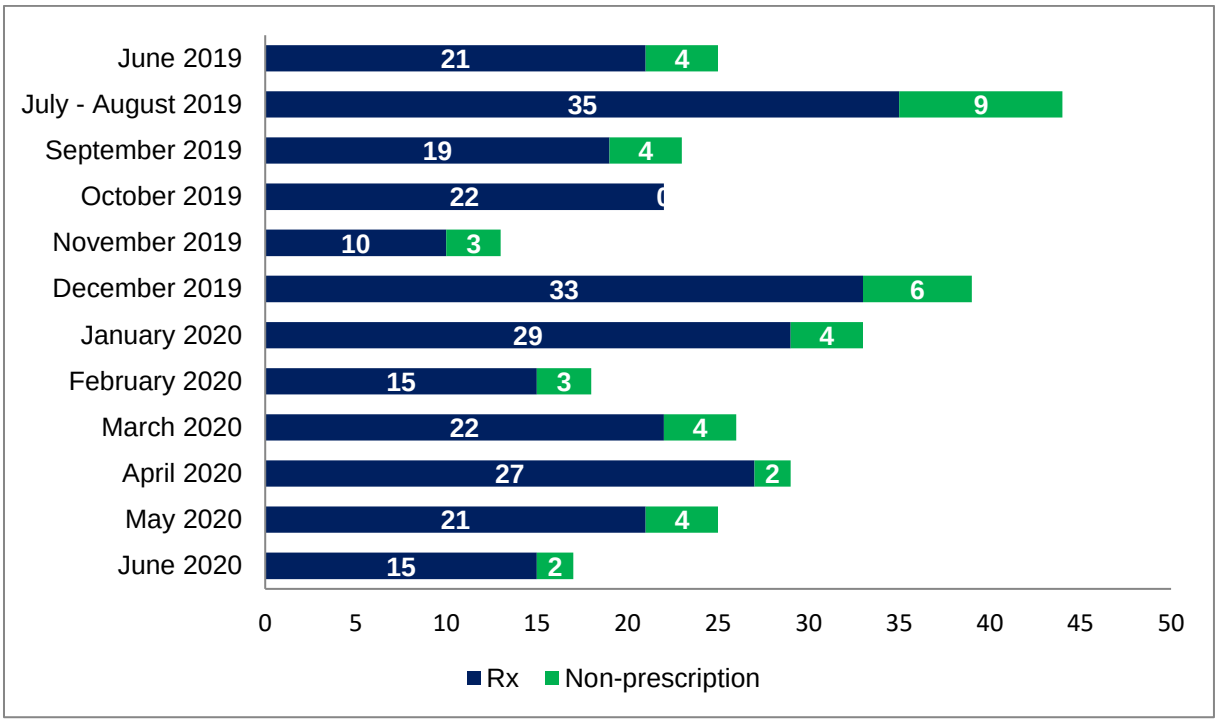
- RMS Day 70 Overview template
- RMS Day 120 Overview template
- Update of examples for acceptable and not acceptable groupings for MRP/DCP products*
- Questions and Answers on QP declaration

**not yet published*

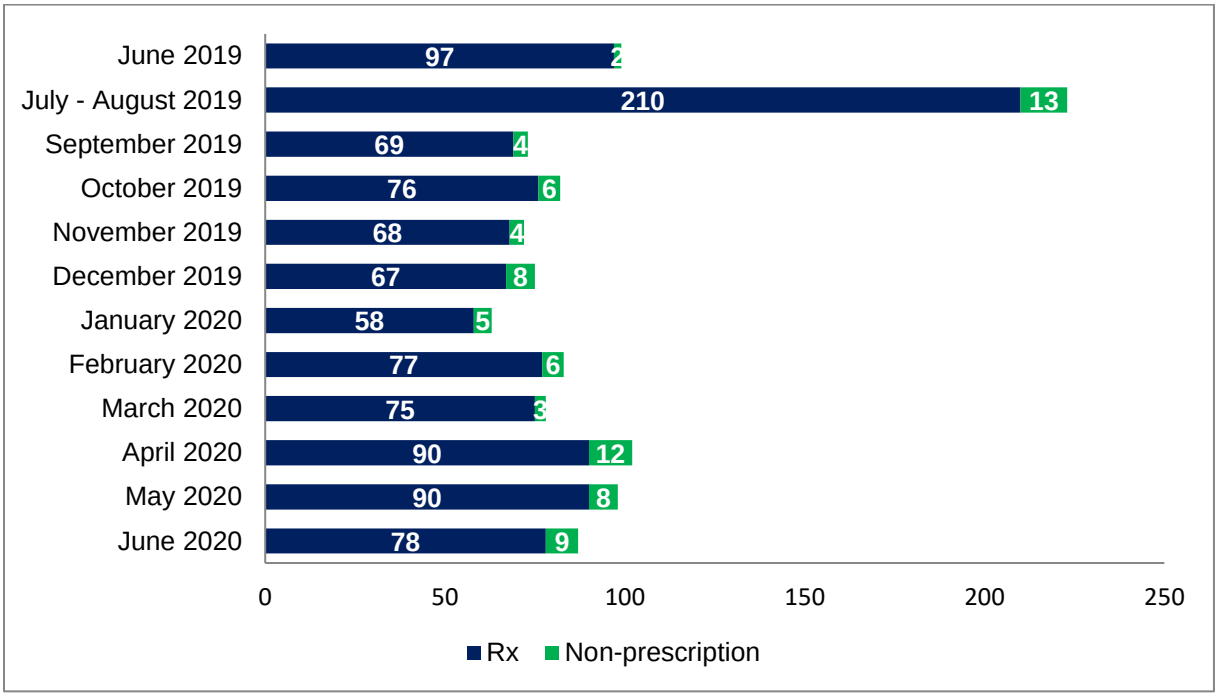
In addition, the CMDh published the minutes of the June CMDh meeting.

Statistics

Mutual Recognition Procedures (MRP)



Decentralised Procedures (DCP)



Update on Nitrosamines in medicines

Article 5(3) opinion published

The Article 5(3) opinion on presence of nitrosamines in medicines has been published. The CHMP opinion requires that companies take measures to limit the presence of nitrosamines in human medicines as far as possible and to ensure levels of these impurities do not exceed set limits.

Companies will be required to have appropriate control strategies to prevent or limit the presence of these impurities and, where necessary, improve their manufacturing processes. Companies will also have to evaluate the risk of nitrosamines being present in medicines and carry out appropriate tests if a risk is identified.

The full Article 5(3) assessment report is available here.

Detailed information for companies, including timelines, will soon be available in updated documents on EMA's nitrosamine impurities webpage. The EMA notes that, in the meantime, companies should continue to follow current instructions.

All medicines in scope

The EMA clarified that all medicines, including herbal medicinal products, were in scope of the Article 5(3) recommendation. Upon request from Industry, the EMA further clarified that herbal medicines were in scope of the article 5(3) recommendation but were NOT in scope of the systematic MAH review running until September 2022. This review is only for chemically synthesized medicines and now biologics (deadline for the latter is until 2023).

Following the same logic, we assume that homeopathic medicines are also in scope of the article 5(3) recommendation and also out of scope of the systematic review. It is currently unclear what being in scope of the article 5(3) entails in practice.

The EMA published the revised Questions and answers for marketing authorization holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products.

To allow marketing authorisation holders enough time to implement the Article 5(3) opinion, the European medicines regulatory network agreed new deadlines.

- Step 1:
  - For product containing chemically synthesised APIs, the step 1 risk evaluation should be concluded and reported at the latest by 31st March 2021.
  - For product containing biological APIs, step 1 risk evaluation should be concluded and reported at the latest by 01st July 2021.

- Step 2 should be started as soon as a risk is identified in API and/or FP and in accordance with product prioritisation.

- Step 3:
  - For product containing chemically synthesised APIs, confirmatory testing activities at Step 2 and submission of any changes required to Marketing Authorisations are expected to be finalized at the latest by 26th September 2022.
  - For product containing biological APIs, confirmatory testing activities at Step 2 and submission of any changes required to Marketing Authorisations (Step 3), are expected to be finalized at the latest by 1st July 2023.

All MAHs should inform the concerned Competent Authorities of the outcome of their risk evaluation (step 1) irrespective if risk is found or not.

EMA Guideline on the quality of water for pharmaceutical use published

The EMA published the Guideline on the quality of water for pharmaceutical use.

This guideline replaces the Note for Guidance on quality of water for pharmaceutical use. The note for guidance has been updated to reflect the following changes in the European Pharmacopoeia:

- revised monograph for Water for Injections (0169) allowing the possibility to use methods other than distillation for producing water of injectable quality;
- new monograph for Water for preparation of extracts (2249);
- suppression of the monograph for Water, highly purified (1927).

The guideline has also been updated to reflect current expectations for the minimum acceptable quality of water used in the manufacture of active substances and medicinal products for human and veterinary use.

It is intended to provide guidance to the industry on the pharmaceutical use of different grades of water in the manufacture of active substances and medicinal products for human and veterinary use and should be considered for new marketing authorisation applications, as well as any relevant variation application to existing marketing authorisations.

The guideline comes into effect on 1 February 2021.

EMA CHMP recommends switch of Fortacin (lidocaine, prilocaine)

The EMA Committee for Medicinal Products for Human Use (CHMP) recommended a change in classification status from prescription to non-prescription for Fortacin (lidocaine / prilocaine), a medicine to treat men with primary (lifelong) premature ejaculation. For more information, please see the CHMP July meeting highlights or the dedicated EMA webpage.

> *The CHMP adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Fortacin.*
>
> *The variation concerns a change in the classification of Fortacin from "medicinal product subject to medical prescription" to "medicinal product not subject to medical prescription".*
>
> *This change is based on the fact that CHMP agreed that the criteria for classifying a medicine as subject to medical prescription as laid down in the European Commission Guideline do not apply to Fortacin. Therefore, the Committee recommended that the change in the supply classification is approvable.*
>
> *For information, the full indication for Fortacin is as follows:*
>
> *"Fortacin is indicated for the treatment of primary premature ejaculation in adult men."*
>
> *Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.*

ICH M7 on Genotoxic Impurities - Q&A document for public consultation

The EMA has released the Questions and answers (Q&A) on ICH guideline M7 on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk for public consultation.

This Q&A document is intended to provide additional clarification and to promote convergence and improve harmonization of the considerations for assessment and control of DNA reactive (mutagenic)

impurities and of the information that should be provided during drug development, marketing authorization applications and/or Master Files. The scope of the document follows that of ICH M7.

Comments on this document can be sent to AESGP using this template by **18 September 2020**.

PHARMACOVIGILANCE

PRAC highlights & other documents published

The EMA Pharmacovigilance Risk Assessment Committee (PRAC) has published:

- PRAC recommendations on signals adopted at the 8-11 June 2020 PRAC meeting
  - New product information wording
- List of signals discussed at the PRAC since September 2012 – updated
- List of European Union reference dates and frequency of submission of periodic safety update reports - updated

HERBAL NEWS

EMA HMPC highlights

The report from the 94th meeting of the EMA Committee on Herbal Medicinal Products (HMPC) held remotely on 6-8 July 2020 has been published.

New European Union herbal monographs

The HMPC adopted the final documents:

- EU herbal monograph on Herniariae herba (by majority)

Revised European Union herbal monographs

The HMPC adopted after systematic review and public consultation the following final revised documents:

- Revised EU herbal monograph on Tanaceti parthenii herba (by majority)
- Revised EU herbal monograph on Thymi aetheroleum (by consensus)

Public statement on the use of herbal medicinal products containing pyrrolizidine alkaloids (PAs)

HMPC adopted a draft revised Public statement for public consultation until 31 October 2020:

- Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including contamination with PAs (EMA/HMPC/893108/2011 Rev. 1)

The revision takes into account newly available data including those received upon the Call for data ending August 2019. Additionally, aspects on the contamination of Herbal MPs with PAs that are not intrinsically part of the active substance are now included. They were previously addressed in the Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016) regarding transitional safety and quality measures.

EU herbal monographs in preparation

New assessment – drafts

The HMPC continued its assessment of Saccharomyces cerevisiae and Vaccinii macrocarpi fructus and agreed on a draft monograph for Menyanthes trifoliata folium for possible release for public consultation at the HMPC September meeting.

Monograph reviews

The Committee discussed the availability of new data and the need to revise monographs for Agropyri repentis rhizoma, Carvi aetheroleum, Carvi fructus, Colae semen, Juniperi aetheroleum, Juniperi pseudo-fructus, Lavandulae aetheroleum and Lavandulae flos.

Monograph revisions – finalization

The HMPC endorsed the revised documents on Millefolii herba for peer review and possible final adoption at the HMPC September meeting.

In addition, the EMA published the minutes of the May HMPC meeting.

Food

FOOD SUPPLEMENT REGULATION

Norway notifies draft Regulation amending the Regulation on Food Supplements

Norway has notified the Draft Regulation amending the Regulation on Food Supplements to the European Commission through the TRIS procedure (*):

Brief Statement of Grounds

The aim of the Draft Regulation is to ensure that food supplements with vitamin E, vitamin B6, iron and zinc are safe. Norway implemented Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements in 2004. No common maximum amounts of vitamins and minerals per daily portion of consumption have been set in accordance with Article 5 of Directive 2002/46/EC.

The Ministry of Health and Care Services finds that, in the interests of protecting human health, there is a need for national regulation until common rules have been introduced in the EEA.

Main Content

National maximum limits for the amount of vitamin E, vitamin B6, iron and zinc in food supplements, cf. directive 2002/46/EC article 5. Separate maximum limits for young children from 1 and up to 3 years old, children from 3 and up to 11 years old, adolescents from 11 and up to 18 years old, and adults from 18 years old. Particular requirements for labelling of food supplements containing specific amounts of vitamin E, vitamin B6, iron and zinc per daily portion of consumption as recommended by the manufacturer.

National maximum limits are set to ensure that food supplements with these vitamins and minerals are safe. Separate maximum limits for various age groups (young children, children, adolescents, adults) make it possible to produce food supplements adapted to different consumer groups. Differentiating the maximum limits for separate age groups means that a food supplement for some age groups (usually adults) may contain amounts of vitamins/minerals that involve a health risk for younger age groups, since ULs for these age groups will be exceeded. We have therefore deemed it essential requiring additional mandatory food information legislation, in order to protect public health.

Particular requirements for labelling of food supplements containing specific and high amounts of vitamin E, vitamin B6, iron and zinc per daily portion, in one measured small unit quantity, shall ensure that the product reaches its right age group and that consumers are provided clear information that other age groups should not consume these food supplements.

This in accordance with article 39 and 45 in Regulation (EU) No 1169/2011 on the provision of food information to consumers.

The standstill period (**) will end on 7 October 2020. Further information on the status of this notification is available here.

Background on the 2015/1535 procedure (formerly known as 98/34 procedure)

(*) It allows the Commission and the Member States of the EU to examine the technical regulations Member States intend to introduce for products (industrial, agricultural and fishery) and for Information Society services before their adoption. The aim is to ensure that these texts are compatible with EU law and the Internal Market principles. It applies in a simplified manner to the European Free Trade Association (EFTA) Member States which are signatories to the Agreement on the European Economic Area (EEA) and to Switzerland and Turkey.

(**) Starting from the date of notification of the draft, a 3-month standstill period – during which the notifying Member State cannot adopt the technical regulation in question – enables the Commission and the other Member States to examine the notified text and to respond appropriately. More information on this procedure and what happen next can be found here.

EFSA PUBLIC CONSULTATIONS

EFSA Public consultation on the draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles

EFSA has launched a public consultation on the draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles.

Following a mandate from the European Commission, the European Food Safety Authority has developed a Guidance on Technical Requirements (Guidance on Particle-TR), setting out information requirements for applications in the regulated food and feed product areas, and establishing criteria for assessing the presence of a fraction of small particles. These requirements apply to particles requiring specific assessment at the nanoscale in conventional materials that do not meet the definition of engineered nanomaterial as set out in the Novel Food Regulation (EU) 2015/2283. The guidance document complements the EFSA Scientific Committee Guidance on Nanoscience and Nanotechnology.

The guidance provides mandatory information requirements for novel food applications submitted in accordance to Regulation (EU) 2015/2283, and for those regulated food products to which the engineered nanomaterial definition is also directly or indirectly applicable: food flavourings, food additives, feed additives, vitamins and minerals used in food in accordance with Regulation (EC) No 1925/2006 and/or in food supplements in accordance with Directive 2002/46/EC as well as vitamins, minerals or other substances used in food for specific groups in accordance with Regulation (EU) No 609/2013.

Written comments on the draft guidance may be submitted to EFSA via this link (to submit additional data or files to support your comments, there is an upload function available in the tool) by 9 September 2020.

Comments via AESGP should be sent to AESGP in line with the EFSA format (referring to the specific chapter/section and line number of the text) by **26 August 2020**.

EFSA aims to finalise the draft guidance by June 2021 and publish it by July 2021.

More information can be found here.

EFSA Public consultation on draft EFSA Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients

EFSA has launched a public consultation on draft EFSA Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients.

This Statement describes the specific considerations that should be followed for regulated products (particularly food additives and pesticides) that are also nutrients to ensure an integrated and harmonised approach for the hazard and risk characterisation, considering the intake from all relevant sources. The Acceptable Daily Intakes (ADIs) and the Upper Levels (ULs) represent the chronic oral exposure HBGVs for regulated products and for nutrients respectively. Some regulated products are also nutrients; this can lead to a complex situation in which two assessments, requiring the establishment of HBGVs for the same substance (i.e. a nutrient), are carried out under different regulatory frameworks, using similar but not identical scientific methodological approaches. This is a recurrent issue for food additives and pesticides, and may occasionally occur for other regulated products. This document compares the conceptual and methodological approaches used by EFSA and presents a proposal for harmonising the establishment of HBGVs for regulated products that are also nutrients.

Background: In November 2018, the FAF Panel consulted the Scientific Committee (SC) on the method to be used for setting HBGVs in the re-evaluation of phosphoric acid, phosphates and polyphosphates as food additives. There are similar issues with other additives that are also nutrients, such as chlorides, but also with other regulated products, such as copper used as active substance in plant protection products. The SC advised the FAF Panel to consider the total intake of phosphorus (including the intake from the diet) in the risk assessment. Having reviewed all the available scientific evidence from human and animal studies, the Panel identified a reference point for deriving an ADI from animal studies. In this specific case, however, with phosphorus being also a nutrient, the approach of the former Scientific Committee on Food (SCF) to derive a Tolerable Upper Intake Level (UL) could also be applied. The issue led to discussions within and between the Panels and units, and is just one of the several examples of similar situations still unresolved regarding the scientific methodology to be applied for additional exposure to nutrients through regulated products. It is important to consider also the implications regarding the advice to risk managers, for their decision making on each regulated use, as well as for enforcement. The FAF and NDA Panels supported by the respective units have suggested a clarification on the methodology to be used, and the approach for presenting the results in a way which is scientifically sound and fit for risk manager's needs through a Statement from the Scientific Committee.

Written comments on the draft statement may be submitted to EFSA via this link (to submit additional data or files to support your comments, there is an upload function available in the tool) by 15 September 2020.

Comments via AESGP should be sent to AESGP in line with the EFSA format (referring to the specific chapter/section and line number of the text) by **1 September 2020**.

It is expected that the Scientific Committee will finalise and formally adopt the Statement by the end of 2020.

More information can be found here.

Medical Devices

MDR/IVDR IMPLEMENTATION

15th Notified Body designated under MDR

France-based notified body `GMED` has been notified as the 15th Notified Body under the MDR (after BSI UK, TÜV SÜD, DEKRA, IMQ, TÜV Rheinland, DARE!! Services, BSI NL, DEKRA Certification B.V, Medcert, DNV GL Presafe AS, NSAI, CE Certiso Orvos, MDC MEDICAL DEVICE CERTIFICATION GMBH, Intertek Medical Notified Body AB).

More details can be found on the link to the Commission database NANDO (New Approach Notified and Designated Organisations).

Designation of Expert Panels - Declaration of interest (DOI) form published

The Commission published a Declaration of interest (DOI) form (version July 2020) in relation to the setting up of the European Commission expert panels on medical devices and in vitro diagnostic medical devices.

Update on the state-of-play of joint assessments of Notified Bodies - July 2020

The Commission published an update on the state of play of joint assessment of Notified Bodies in the medical device sector (available here).

Per the first slide, it is indicated that 16 notified bodies are designated under the MDR while 15 official designations are published on NANDO. On this basis, it can be expected that the 16th notified body designated under the MDR will be published on the NANDO database soon.

This update is dated from 13 July 2020.

MDCG Guidance on the Application of transitional provisions concerning validity of MDD certificates - Revision published

The Commission has published a revised version of the MDCG Guidance on Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC.

The revised version takes into account the postponed date of application of the MDR.

Revision of MDCG Guidance documents following MDR postponement

The following MDCG Guidance documents have been revised by the Commission to reflect the postponed date of application of the MDR:

- MDCG 2020-2 rev1 - Class I transitional provisions under Article 120 (3 and 4) – (MDR)
- MDCG 2019-10 rev1 - Application of transitional provisions concerning validity of certificates issued in accordance to the directives

- MDCG 2019-15 rev1 - Guidance notes for manufacturers of class I medical devices
- MDCG 2019-16 rev1 - Guidance on cybersecurity for medical devices

MDCG Guidance on CEAR Template published

The Commission has published the final MDCG guidance document concerning the clinical evaluation assessment report template.

The document is available here.

EUDAMED

Actor Registration Demo published by Commission

The Commission has published a demo of the Eudamed Actor Registration module. The video is accessible on YouTube here.

Commission Factsheet on MDR requirements for transparency and public information published

The Commission has published a factsheet on MDR requirements for transparency and public information (available here).

The purpose of this factsheet is to list information which will be available to the public in accordance with transparency obligations in MDR considering that some requirements will be applicable only once the European database on medical devices (Eudamed) is fully functional.

In particular, the document lists the information which will be made available to the public respectively in Eudamed and outside Eudamed, respectively from the entry into application of the MDR (May 2021) and the release of Eudamed (planned for May 2022). It is further noted in the document that the listed information may be extended over time.

TECHNICAL COOPERATION PROGRAM BETWEEN EU AND TAIWAN (TCP III)

Team NB Position Paper

Team NB has published a position paper on the requirements for the EU MDR/IVDR Notified Body Partners under the Technical Cooperation Program on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports (TCP III).

Both the EU and Taiwan have aligned their medical device quality management system (QMS) regulatory requirements to ISO 13485. The TCP III program allows for the exchange of medical device QMS regulatory audit reports between EU notified bodies designated under MDR and/or IVDR, and the Taiwan Food and Drug Administration (TFDA) authorised medical device QMS auditing organisations. In order to get its report to be accepted by TFDA authorised auditing organisations, the notified body must become an EU Notified Body Partner under the Technical Cooperation Program TCP III established by TFDA.

Against this background, the position paper addresses how audit time reduction could be reconciled with the legal obligations for EU Notified Bodies as stipulated in the EU Medical Devices Regulations. In addition, it proposes how training requirements for EU Notified Body auditors qualified for auditing TCP III related aspects could be fulfilled and which input from TFDA would be required in order to implement these training requirements adequately.

Cross-Sectorial News

EUROPEAN MEDICINES AGENCIES NETWORK STRATEGY TO 2025

Launch of public consultation

The European Regulatory Medicines Network (ERMN) composed of EMA and HMA have launched a public consultation on the draft European medicines agencies network strategy to 2025: Protecting public health at a time of rapid change. The consultation takes the form of an online questionnaire which is accessible here and will remain open until 4 September 2020.

The draft strategy builds on the previous one issued in 2015 and established for the first time by the ERMN; its 4 pillars were (1) supporting development and availability of medicines for human health, (2) increasing availability of veterinary medicines, (3) optimizing the operation of the network itself and (4) continue to develop resources sharing and regulatory convergence at global level.

The high-level goals proposed for the next 5 years are consistent and build upon those of the previous strategy. The draft details how the European medicines agencies' network can continue to enable the supply of safe and effective medicines that meet patients' needs in the face of challenges posed by ever-accelerating developments in science, medicine, digital technologies, globalisation as well as emerging health threats, such as the COVID-19 pandemic.

The key themes are aligned with those covered by the Commission roadmap for a new Pharmaceutical Strategy. It is noted that the strategy will remain a living document and its implementation will be monitored and reviewed, with its goals and objectives adjusted if necessary.

The strategy outlines six strategic focus areas. Among others, the following strategic goals can be highlighted:

1. **Availability and accessibility of medicines**
    - Strengthen the availability of medicines to protect the health of European citizens, via identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including by the stakeholders and increased transparency are the essential steps towards this goal

2. **Data analytics, digital tools and digital transformation**
    - Enable access to and analysis of routine healthcare data and promote standardisation of targeted data
    - Promote dynamic regulation and policy learning within the current regulatory framework

3. **Innovation**
    - Enhance collaboration with medical device experts, notified bodies and academic groups

4. **Antimicrobial resistance and other emerging health threats**

5. **Supply chain challenges**
    - Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs)
    - Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries

6. **Sustainability of the Network and operational excellence**

The document addresses each of these strategic goals in detail as well as the main challenges in attaining them. It also highlights the initiatives that are already ongoing in the respective areas.

Next steps: The strategy will be considered for adoption by the HMA and EMA Management Board towards the end of 2020. The publication of the final strategy is foreseen for November 2020.

MICROPLASTICS

ECHA restriction proposal - Public Consultation on SEAC draft opinion

The SEAC draft opinion on the proposal to restrict the use of microplastics that are intentionally added to products on the EU/EEA market has been published. With its publication, it is subject to a public consultation for 60 days that runs until 1 September 2020.

The final opinion of RAC on the proposal to restrict the use of microplastics that are intentionally added to products on the EU/EEA market has been published as well.

The draft SEAC opinion and final RAC opinion are available on the ECHA website.

Based on a preliminary review of the draft SEAC opinion, the following is to be noted:

- **Food is excluded from the scope of the ban relating to the use of microplastics.**

  Substances or mixtures containing food additives as defined in EU Regulation (EC) No.1333/2008 are excluded from the scope of the ban relating to the use of microplastics. As there could be some releases of microplastics under reasonably foreseeable conditions of use, the importers or downstream users placing products on the market containing food additives and benefiting from this derogation shall be required to report the quantities used and released to the market to ECHA, so the legislator can decide on any further EU action if needed. In addition, products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment.

- For **medicinal products**, no key change has been identified. As from the beginning, medicinal products are excluded from the scope of the ban relating to the use of microplastics. As there could be some releases of microplastics under reasonably foreseeable conditions of use, the importers or downstream users placing medicinal products on the market and benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. In addition, medicinal products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).

- **Medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745** are subject to the ban relating to the use of microplastics with a transition period of 6 years. Therefore, explicit reference is made to substance-based medical devices while they are understood as being similar to cosmetics per the information provided in the draft opinion. The draft opinion also points out that more specific information on the substitution process in substance-based medical devices would be needed to substantiate that six-year transitional period is appropriate. In fact, as part of the public

consultation, specific questions are posed about the impacts of the proposed ban for substance-based medical devices, as well as of the six-year transitional period. It is further asked whether there are significant differences (function of microplastics, level of performance required for the product, etc.) between such substance-based medical devices and cosmetic products, and whether a different transitional period would be justified, with supporting evidence.