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Medicines

REGULATORY NEWS

CMDh highlights

CMDh minutes - June 2023

The **CMDh published the minutes of the CMDh meeting held on 20-21 June 2023**. The following may be noted:

USER TESTING OF THE PACKAGE LEAFLET

The EMA informed the CMDh about the outcome of the QRD discussions on the possibility of virtual/remote user testing of the package leaflet.

QRD agreed that in-person user testing remains the preferred option. However, also virtual/remote user testing can still be allowed. Due to the current legal framework, it was however stressed that a printed version of the package leaflet has to be used during the interview namely to address aspects as the design, layout, quality of paper etc.

PROPOSAL FOR INCLUSION OF INFORMATION ON DISPOSAL IN THE PI FOR TOPICAL MEDICINAL PRODUCTS CONTAINING DICLOFENAC

The CMDh was informed of the NcWP response to the CMDh question on the need to include information on the disposal in the PI for topical medicinal products containing diclofenac.

Following consultation with the SmPC advisory group, the NcWP provided a proposal for a wording to be included in the PI of concerned products.

Some concerns on the proposal were raised by some MSs. It was agreed that the CMDh concerns will be summarised for further discussion in July (Action: DE, DK, NO) and will then be sent back to NcWP for further consideration.

EMA ISG Meeting - Meeting 26 June 2023 – Presentations

EMA has published all **presentations** that were given at the **Industry Standing Group (ISG) meeting** that took place on **26 June.**

The presentations can be **accessed here**.

Nitrosamines – revised Q&A

EMA has published the revised EMA / CMDh's questions and answers document on nitrosamines in medicines. The revised document amends Q10 to include the Carcinogenic Potency Categorization Approach (CPCA) and the enhanced Ames test (EAT) for establishing Acceptable intakes (Ais) for N-nitrosamines. It also includes Appendix 1, listing the nitrosamines for which AI have been established by the Non-clinical Working Party (NcWP), including new AIs for Nnitrosamines determined using the CPCA.

TELEMATICS

2nd EMA Quarterly System Demo 2023 - Q&A

EMA has published on its website the Q&A document from the 2nd Quarterly System Demo 2023. This document contains a direct record of all questions asked through Slido.com during the System Demo and their written answers.

Questions not asked through Slido.com were not captured. Questions that did not receive written answers below were either responded to verbally or did not receive a response during the System Demo event.

eAF - Timeline delays in split CAPs and NAPs import

The latest **updates with respect to the timeline** of the **variations web-based electronic Application Form (eAF)** for Human medicinal products are now available.

EMA is continuing development work with the aim to incrementally build the new web-based eAF, leveraging Product Management Service (PMS) data. During recent testing, it became clear that the target date for the release of split CAPs and NAPs on the PLM Portal requires to be extended. This is due to the additional time needed to perform checks on data quality and the quality of the data transfer of NAPs data, investigate and address potential issues connected to product data transfer and (if needed) repeat the loading of the data.

Therefore, please be informed of the new target dates for the release of split Centrally Authorised Products (CAPs) and Nationally Authorised Products (NAPs) for use in web-based eAFs on the Product Lifecycle Management (PLM) Portal:

- **release of split CAPs**, making them available to use in the eAF, is now expected in **October 2023** instead of July-August 2023
- target date for the release of **NAPs** is now expected **between November 2023 and February 2024** instead of July-August 2023.

Consequently, the human variations web-based electronic Application Form (eAF) target timeline (last published in April 2023) has been reviewed. here is the **updated version**, which reflects the target dates for each milestone. Kindly note the eAF team expects to provide a further **update to confirm the timeline in September 2023**, based on latest testing outcomes.

Key milestones, following the split CAPs and NAPs release in web-based eAF on the PLM Portal, will be consequently rescheduled. In particular, the **external User Acceptance Testing** on the version of the web-based eAF intended to replace the PDF and trigger the transition will be rescheduled from November

2023 to a yet-to-be-defined date, which will be announced at least two months in advance, as per prior commitment. The **transition period** will also be announced in due time.

EMA is following the previously communicated **development steps for the products' release** on the PLM Portal:

1. Load product data into the test environment;
2. Test data quality and quality of the transfer;
3. Investigate issues, address them and repeat the first 2 steps;
4. Once ready, transfer product data into the production environment.

Reflection paper on the use of artificial intelligence in the lifecycle of medicines

EMA has published a draft reflection paper outlining the current thinking on the use of artificial intelligence (AI) to support the safe and effective development, regulation and use of human and veterinary medicines. This paper, which is now open for public consultation, reflects on principles relevant to the application of AI and machine learning (ML) at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting.

The reflection paper is part of the joint HMA-EMA Big Data Steering Group (BDSG) initiatives to develop the European Medicines Regulatory Network's capability in data-driven regulation. It has been developed in liaison between the BDSG, EMA's Committee for Medicinal Products for Human Use (CHMP) and its Committee for Veterinary Medicinal Products (CVMP).

In their press release EMA states the following:

"AI and ML tools have the potential to effectively support the acquisition, transformation, analysis, and interpretation of data across the medicinal product lifecycle. Their application can include, for example, AI/ML modelling approaches to replace, reduce, and refine the use of animal models during the preclinical development. In clinical trials, AI/ML systems may support the selection of patients based on certain disease characteristics or other clinical parameters; AI/ML tools can also support data recording and analyses which will in turn be submitted to regulators in marketing-authorisation procedures.

At the marketing-authorisation stage, AI applications include tools to draft, compile, translate, or review data to be included in the product information of a medicine. In the post-authorisation phase, such tools can effectively support, for example, pharmacovigilance activities including adverse event report management and signal detection.

This range of applications brings with it challenges such as the understanding of the algorithms, notably their design and possible biases, as well as the risks of technical failures and the wider impact these would have on AI uptake in medicine development and health.

The reflection paper highlights that a human-centric approach should guide all development and deployment of AI and ML. The use of AI in the medicinal product lifecycle should always occur in compliance with the existing legal requirements, consider ethics and ensure due respect of fundamental rights.

If an AI/ML system is used in the context of medicines' development, evaluation, or monitoring, and is expected to impact on the benefit-risk balance of a medicine, EMA advises developers to seek early regulatory support, e.g. through qualification of innovative development methods (for human medicines) or scientific advice."

All interested stakeholders are invited to comment on the draft reflection paper and to identify opportunities and risks of AI in the field of medicines. The public consultation is open until 31 December 2023 and the topic will be further discussed during a joint HMA/EMA workshop scheduled for 20-21 November 2023. The feedback from stakeholders will be analysed and considered for the finalisation of the reflection paper and future development of guidance as relevant.

EFSA

Call for data for the re-evaluation of gluconic acid (E 574) and related food additives (E 575-579)

EFSA has launched a call for data for the re-evaluation of gluconic acid (E 574) and related food additives (E 575-579).

The purpose of this call for data is to offer interested parties (e.g. food business operators, national food authorities, research institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the re-evaluation of the following food additives:

Name	E number	Synonyms/ Chemical name	EFSA-Q-Number
GLUCONIC ACID	E 574	D-gluconic acid; Dextronic acid / Gluconic acid	2011-00684
GLUCONO-DELTA-LACTONE	E 575	Gluconolactone; GDL; D-Gluconic acid delta-lactone; Delta-gluconolactone / D-Glucono-1,5-lactone;	2011-00685
SODIUM GLUCONATE	E 576	Sodium D-gluconate / Sodium salt of D-gluconic acid	2011-00686
POTASSIUM GLUCONATE	E 577	Potassium salt of D-gluconic acid / Potassium D-gluconate	2011-00687
CALCIUM GLUCONATE	E 578	Calcium salt of D-gluconic acid/ Calcium di-D-gluconate	2011-00688
FERROUS GLUCONATE	E 579	Ferrous di-D-gluconate dihydrate; Iron(II) di-gluconate dihydrate	2011-00689

These food additives were already included in a previous call for data published by EFSA in 2012.

Data on uses and use levels in food were also already collected by EFSA by means of a “Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 5) published in 2016 and closed in 2017.

Interested parties that have already submitted information in response to the above calls do not need to reply again to the present call, unless they can contribute with additional information not previously provided to EFSA.

Call for data for the re-evaluation of food additives in gaseous form

EFSA has launched a call for data for the re-evaluation of food additives in gaseous form.

Interested parties and stakeholders should provide by **31/12/2023** the information described below, except for the information requested under point 3.a of this call for which specific timelines for submission will be communicated separately.

Within 4 weeks from the publication of this call, please communicate in writing by e-mail to: **RAL@efsa.europa.eu**, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons.

Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.

In accordance with Article 6(4) of the Regulation (EU) No 257/2010 the information not submitted within the final deadline will only exceptionally be considered and EFSA can finalise its opinions on the basis of the information already provided.

The purpose of this call for data is to offer interested parties (e.g. food business operators, national food authorities, research institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the re-evaluation of the following food additives:

Name	E number	Synonyms/ Chemical name	EFSA-Q-Number
Carbon dioxide	E 290	Carbonic acid gas; Dry ice (solid form); Carbonic anhydride	2011-00597
ARGON	E 938	Argon	2011-00712
HELIUM	E 939	Helium	2011-00713
NITROGEN	E 941	Nitrogen	2011-00714
NITROUS OXIDE	E 942	Nitrous oxide; dinitrogen oxide, dinitrogen monoxide	2011-00715
Butane	E 943a	n-Butane	2011-00716
Isobutane	E 943b	2-Methyl propane; 2-methylpropane	2011-00717
PROPANE	E 944	Propane	2011-00718
OXYGEN	E 948	Oxygen	2011-00719
HYDROGEN	E 949	Hydrogen	2011-00720

Call for data for the evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel (Foeniculum vulgare Mill. and Foeniculum piperitum (Ucria) C.Presl)

EFSA has launched a call for data for the evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel (Foeniculum vulgare Mill. and Foeniculum piperitum (Ucria) C.Presl).

Interested parties and stakeholders should provide by **04/10/2023** the information described below. Within 4 weeks from the publication of this call, please communicate in writing by e-mail to: nda_callfordata@efsa.europa.eu, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.

To facilitate the collaboration of all interested parties to provide the data needed, we are seeking your consent to disclose the name and address of your organisation/business to the other parties that has expressed an interest to provide the requested information. If you do not wish to make these contact details available, clearly indicate it in your first communication.

Specific objectives:

- **Specific Objective 1: occurrence data**

EFSA is looking for analytical data on the content of estragole, methyleugenol and safrole in foods (e.g. infusions, herbs, spices, compound foods) and food supplements.

- **Specific Objective 2: use levels for supplements**

EFSA is looking for use levels recommended by manufacturers for food supplements containing plant preparations that naturally contain estragole, methyleugenol and safrole.

- **Specific Objective 3: biological and toxicological data**

EFSA is looking for data on the absorption, digestion, absorption and metabolism (ADME) of estragole from fennel fruit preparations (i.e. when consumed in a food matrix) and whether ADME of estragole consumed in a food matrix is different to the ADME of estragole as pure substance.

EFSA is also looking for evidence for the extent to which the 1'-hydroxylation pathway is activated or sulphoconjugation of 1'-hydroxyestragole occurs at different levels of dietary exposure to estragole, as well as for the effect of the matrix (i.e. preparations from sweet and bitter fennel fruits) on the sulphoconjugation of 1'-hydroxyestragole, on DNA adduct formation and on the carcinogenicity of estragole.

Data sought and data submission format

EFSA kindly invites interested parties to submit information as outlined below for each specific objective.
Specific objectives 1 and 2 (occurrence data and use levels for supplements)

To submit data in the context of specific Objectives 1 and 2, please fill in the Excel file downloadable on the EFSA webpage of this call. This Excel file contains a selection of different data fields to collect information considered as essential to assess the reliability of the data before being used for the exposure assessment. Dedicated data fields are also included for food supplements (dose forms, weight of the dose form, etc.) and tea/herbal infusions (e.g. preparation) to allow precise and accurate estimations of the dietary exposure.

Data providers are encouraged to provide the information on the use levels in the appropriate data field described in the above-mentioned Excel file. Should you require assistance when filling in the Excel file for analytical data/use levels or have specific questions on how to send the data, please contact nda_callfordata@efsa.europa.eu.

OTHER OPTION TO SUBMIT OCCURRENCE DATA

Please be informed that together with sending analytical data/use levels in the context of this call for data, it is also possible to submit analytical data as part of the 'EFSA Call for continuous collection of chemical contaminants occurrence data in food and feed'. These data must be submitted in electronic format (XML) to the EFSA Data Collection Framework (DCF) in SSD2 (Standard Sample Description version 2) format. You find all the details about this call here (deadline 31 August 2023).

Specific objective 3 (biological and toxicological data)

EFSA is seeking data for the evaluation of the following questions:

1. Is the ADME of estragole consmed in a fennel food matrix different from the ADME of estragole as pure substance ?
2. To which extent is the 1'-hydroxylation pathway activated and to which extent does sulphoconjugation of 1'-hydroxyestragole occur at different levels of dietary exposure to estragole?

What is the effect of the matrix (i.e. preparations from sweet and bitter fennel fruits) on the sulphoconjugation of 1'-hydroxyestragole, on DNA adduct formation and on the carcinogenicity of estragole?

FOOD ADDITIVES RE-EVALUATION

Call for technical data on the permitted food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

The **European Commission has published the enclosed Call for technical data on the permitted food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452).**

As this call concerns only technical data, the 2-step procedure used in previous calls for scientific and technical data is not followed. Therefore, **the deadline of this call is the final deadline for submission of the requested technical data**. The requested data need to be submitted by **5 March 2024**.

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of phosphates, information is sought on:

1. Safety evaluation strategy and corresponding testing strategy
2. Technical data for the revision of the specifications for phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)
3. Analytical method: the development of analytical methods for the determination of the different phosphate additives in the range of foods and beverages permitted to contain them.
4. Data on uses/use levels of the food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

Further details are available in the enclosed call for data and on the dedicated Commission website.

Business operators are requested to submit the above-indicated data by the agreed deadline using the online platform CIRCABC. The "Guidance for online data submission on Food Improvement Agents via CIRCABC Sante-Cad-In Group" provides practical information on how to use the CIRCABC platform for the online submissions.

Once the new data are received, they will be submitted to EFSA for evaluation and preparation of a scientific opinion, if appropriate.

TOLERABLE UPPER INTAKE LEVELS

EFSA 30th Working Group meeting on Upper Tolerable Levels minutes published

The minutes of the EFSA 30th Working Group meeting on Upper Tolerable Levels have been published.

ARTICLE 8

Plant preparations containing hydroxycitric acid

EFSA launched the Call for data for the Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid.

The purpose of this call for data is to offer interested parties (e.g. food business operators, national food authorities, research institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the re-evaluation of HCA from all sources in foods including preparations such as food supplements.

Deadline for registering interest: 07/08/2023
Deadline for submission of data: 05/10/2023

Members interested in submitting the requested information on plant preparations containing hydroxycitric acid are requested to **communicate directly their availability to EFSA by 7 August 2023** in accordance with the instructions detailed in the call for data.

Within 4 weeks from the publication of this call, please communicate in writing by e-mail to: nda_callfordata@efsa.europa.eu, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.
To facilitate the collaboration of all interested parties to provide the data needed, EFSA is seeking your consent to disclose the name and address of your organisation/business to the other parties that has expressed an interest to provide the requested information. If you do not wish to make these contact details available, clearly indicate it in your first communication.

Specific objectives

Specific Objective 1: occurrence data

EFSA is looking for analytical data on the content of HCA in plant preparations and food, including food supplements.

Specific Objective 2: use levels for supplements

EFSA is looking for use levels recommended by manufacturers for food supplements containing HCA.

Specific Objective 3: biological and toxicological data

EFSA is looking for biological and toxicological data to support the assessment of a causal relationship between dietary exposure to HCA as single substance and/or in plant preparations and the a priori identified adverse effects, including data on absorption, digestion, absorption and metabolism for HCA and within the food matrix.

Plant preparations containing berberine

EFSA launched the Call for data for the Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine.

The purpose of this call for data is to offer interested parties (e.g. governments, food business operators, national food authorities, research institutions, academia) and/or other stakeholders the opportunity to submit documented information (published and/or unpublished) relevant to the safety evaluation of berberine in plant preparations used in food supplements.

In case a causal relationship will be identified between the dietary exposure to berberine and an adverse effect, EFSA will investigate whether protoberberine alkaloids which share the same molecular structure as berberine exert a similar effect through a similar mode of action. In such case, the combined exposure from berberine and the implicated protoberberine alkaloids will be assessed. Thus, EFSA is looking for data also on protoberberine alkaloids other than berberine, as listed in Table 1.

Deadline for registering interest: 07/08/2023
Deadline for submission of data: 05/10/2023

Members interested in submitting the requested information on berberine are requested to **communicate directly their availability to EFSA by 7 August 2023** in accordance with the instructions detailed in the call for data.

Within 4 weeks from the publication of this call, please communicate in writing by e-mail to: nda_callfordata@efsa.europa.eu, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.
To facilitate the collaboration of all interested parties to provide the data needed, EFSA is seeking your consent to disclose the name and address of your organisation/business to the other parties that has expressed an interest to provide the requested information. If you do not wish to make these contact details available, clearly indicate it in your first communication.

Specific objectives:

- **Specific Objective 1: occurrence data**

EFSA is looking for analytical data on the content of berberine and other protoberberine alkaloids listed in Table 1 n preparations of plants used in food supplements. The list of plants included in this assessment can be found in Appendix A.

- **Specific Objective 2: use levels for supplements**

EFSA is looking for use levels recommended by manufacturers for food supplements containing berberine and other protoberberine alkaloids listed in Table 1.

- **Specific Objective 3: biological and toxicological data**

EFSA is looking for biological and toxicological data to support the assessment of a causal relationship between dietary exposure to berberine as single substance and/or in plant preparations and the identified

potential adverse effects, including data on absorption, digestion, absorption and metabolism (ADME) for berberine and within the food matrix.
EFSA is interested in collecting data also on protoberberine alkaloids other than berberine, as listed in Table 1.

Data sought and data submission format
EFSA kindly invites interested parties to submit information as outlined below for each specific objective.

Specific objectives 1 and 2 (occurrence data and use levels for supplements)

To submit data in the context of specific Objectives 1 and 2, please fill in the Excel file downloadable on the EFSA webpage of this call. This Excel file contains a selection of different data fields to collect information considered as essential to assess the reliability of the data before being used for the exposure assessment. Dedicated data fields are also included for food supplements (dose forms, weight of the dose form, etc.) and tea/herbal infusions (e.g. preparation) to allow precise and accurate estimations of the dietary exposure.

Data providers are encouraged to provide the information on the use levels in the appropriate data field described in the above-mentioned Excel file. Should you require assistance when filling in the Excel file for analytical data/use levels or have specific questions on how to send the data, please contact nda_callfordata@efsa.europa.eu.

OTHER OPTION TO SUBMIT OCCURRENCE DATA

Please be informed that together with sending analytical data/use levels in the context of this call for data, it is also possible to submit analytical data as part of the 'EFSA Call for continuous collection of chemical contaminants occurrence data in food and feed'. These data must be submitted in electronic format (XML) to the EFSA Data Collection Framework (DCF) in SSD2 (Standard Sample Description version 2) format. You find all the details about this call here (deadline 31 August 2023).

Medical Devices

MDR IMPLEMENTATION

MDCG Position Paper on the Application of Art. 97 MDR - Addendum Published

The Commission has published on its website an **addendum to the MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate.**

The document is **accessible here**.

Pursuant to the addendum and in light of Regulation 2023/607, the MDCG considers that the application of Article 97 MDR in accordance with MDCG 2022-18 to situations where a MDD/AIMDD certificate has expired prior to the issuance of a MDR certificate has achieved its objective and is not relevant any more. It further states that the MDCG recommends that national CAs limit the application of Article 97 MDR as set out in MDCG 2022-18 to very exceptional situations, e.g. where the national competent authority (CA) has received information justifying the application of Article 97 MDR prior to 20 March 2023.

At the same time, it is clarified that where, after 20 March 2023, a competent authority has required or requires a manufacturer, in accordance with Article 97 MDR, to carry out the applicable conformity assessment procedure, the condition set out in Article 120(2), second subparagraph, point (b), of the MDR is not met. Therefore, the expired certificate will not be considered valid and the extended transitional period set out in Article 120(3a) MDR does not apply.

39th NB Designated under MDR

The **Cyprus based notified body 'G.F.I. Health Technology Certification Ltd` has been notified as the 39th* 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, GMED, DQS Medizinprodukte GmbH, 3EC International a.s., UDEM Adriatic, SGS FIMKO OY, ISTITUTO SUPERIORE DI SANITA, Eurofins Expert Services Oy, KIWA CERMET ITALIA S.P.A, Eurofins Product Testing Italy S.r.l., TUV Rheinland Italia SRL, CERTIQUALITY S.r.l., SGS Belgium NV', TÜV NORD CERT GmbH, ITALCERT SRL, SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY – SIQ, TUV NORD Polska Sp. z o.o, Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH, CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS, BUREAU VERITAS ITALIA S.P.A, POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A, ENTE CERTIFICAZIONE MACCHINE SRL; INSTITUT PRO TESTOVÁNI A CERTIFIKACI, ICIM S.P.A.; SLG PRÜF UND ZERTIFIZIERUNGS GMBH, SZUTEST Konformitätsbewertungsstelle GmbH).

The **link to the Commission database NANDO** (New Approach Notified and Designated Organisations) for more details.

Adjustment of designations in the NANDO database: Please note that the designated UK notified body "BSI UK" under the MDR and IVDR, as well as under the current medical device directives, has been removed from the NANDO database given the fact that the EU/UK Brexit withdrawal agreement period came to an end.

52nd CAMD Meeting Statement

In the context of the Swedish Presidency of the Council of the European Council, the **European Competent Authorities for Medical Devices (CAMD) met for its 52nd meeting** on the 1st – 2nd June 2023 and resulted in the **CAMD statement that can be accessed here**.

Some of the major topics discussed at the CAMD plenary meeting:

- How the CAMD network best support and deliver on the implementation and practical application of the MDR and IVDR, e.g., to increase safety of patients and medical devices available in Europe and improving harmonisation, consistency, and predictability in its application.
- The MDR/IVDR provide for a broad set of requirements on medical technologies accessing the EU internal market. In addition, the sector is impacted by reform of other legislations such as the pharmaceutical legislation and horizontal legislations such as EHDS, AI and HTA. The interplay between horizontal and sectoral legislation and its impact on economic operators and competent authorities was raised with the view of ensuring a common understanding and awareness of practical implications.
- In light of the new regulatory framework for medical devices and in vitro diagnostics, the CAMD governance was discussed to further strengthen its operation in coordination, communication and cooperation within the European regulatory system.

Regulation 2023/607 - Third Country Factsheet - Final Version Published

The **Commission has published the final version of the *factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices*** on its website.

The document can be **accessed here**

Regulation 2023/607 - Updated Q&A on Practical Implementation - Final Version Published

The **Commission has published the final version of the updated Q&A on the practical implementation of the extension of the MDR transitional period** on its website.

The document can be **accessed here**.

Study On Governance & Innovation - First Stakeholder Consultation Workshop

Regarding the **First Stakeholder Consultation Workshop** within the ongoing **"Study on Regulatory Governance and Innovation in the field of Medical Devices"**, the **date has been moved to Thursday 21 September 2023**, due to organisational issues and to allow a wider participation of the different interested parties.

The link to participate, in person or by remote, has been updated with the new date and deadlines for registration: **https://ec.europa.eu/eusurvey/runner/MDRworkshopregistration**. **In case you have already registered, it is necessary to re-register for 21 September.**

Commission Implementing Decision (EU) 2023/1410 and Commission Implementing Decision (EU) 2023/1411 published in the OJEU

The Commission Implementing Decision (EU) 2023/1410 of 4 July 2023 amending Implementing Decision (EU) 2021/1182 as regards harmonized standards for sterilization of health care products and biological evaluation of medical devices has been published in the OJEU.

This Decision has entered into force and can be accessed here.

In addition, please be informed that the Commission Implementing Decision (EU) 2023/1411 of 4 July 2023 amending Implementing Decision (EU) 2021/1195 as regards a harmonized standard for sterilization of health care products has been published in the OJEU.

This Decision has entered into force and can be accessed here.

Planned Meetings of Medical Device Coordination Group (MDCG) and Subgroups in 2023 - Update (July 2023)

The Commission has updated the planned meeting dates of the MDCG and subgroups for 2023.

The updated document is available here.

Cross-Sectorial News

ASPARTAME (E 951)

IARC / JECFA evaluations published

The summary of findings of the evaluation of aspartame at the International Agency for Research on Cancer (IARC) Monographs Programme's 134th Meeting, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 96th meeting has been released today. The joint press release published by IARC and JECFA is available here.

C***iting "limited evidence" for carcinogenicity in humans:***

- ***IARC classified aspartame as possibly carcinogenic to humans (IARC Group 2B) and***
- ***JECFA reaffirmed the acceptable daily intake of 40 mg/kg body weight.***

The published information essentially indicates that:

- *The two bodies conducted independent but complementary reviews to assess the potential carcinogenic hazard and other health risks associated with aspartame consumption. This was the first time that IARC has evaluated aspartame and the third time for JECFA.*

- *After reviewing the available scientific literature,* ***both evaluations noted limitations in the available evidence for cancer (and other health effects).***

- ***IARC classified aspartame as possibly carcinogenic to humans (Group 2B) on the basis of limited evidence for cancer in humans*** *(specifically, for hepatocellular carcinoma, which is a type of liver cancer). There was also limited evidence for cancer in experimental animals and limited evidence related to the possible mechanisms for causing cancer.*

- ***JECFA concluded that the data evaluated indicated no sufficient reason to change the previously established acceptable daily intake (ADI) of 0–40 mg/kg body weight for aspartame. The committee therefore reaffirmed that it is safe for a person to consume within this limit per day. For example, with a can of diet soft drink containing 200 or 300 mg of aspartame, an adult weighing 70kg would need to consume more than 9–14 cans per day to exceed the acceptable daily intake, assuming no other intake from other food sources.***

Importantly, we recall that the two bodies carried out a different assessments of aspartame:
- IARC assessed the potential carcinogenic hazard
- JECFA assessment the health risks associated with aspartame consumption.

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