Regulatory Essentials – July 24, 2018

Health Updates

Feed back on Consultation on the Revised Fee Proposal for Drugs and Medical Devices

On July 23, Regulatory Management and Operations Directorate (RMOD) hosted a teleconference on the feedback received on the consultation on the Revised Fee Proposal for Drugs and Medical Devices. Ideas and inputs were sought around eight themes/topics which where:

- Fee Setting
- Annual Fee Adjustment
- Mitigation Measures
- Performance Standards
- Penalty Provision
- Timing of Payment
- Specific Fee Line Changes

The final Revised Fee Proposal for Drugs and Medical Devices will be posted to the Canada Gazette Part I in September or October and will be posted to Canada Gazette Part II in December. The Revised Proposal will come into force April 1, 2019. Please note that the generic email account for Cost Recover related inquiries has changed to hc.cro-brc.sc@canada.ca.

Nanotechnology in Cosmetics – Article by European Commission

The European Commission posted on their newsletter an article titled ‘ The Only Concern to Have About Sunscreen is… Did You Remember to put it on? This article focuses on the safety of nanotechnology in sunscreens. The article goes on to state that Scientific Committee on Consumer Safety (SCCS) published an Opinion stating that the use of nano-Titanium dioxide up to a concentration of 25% as UV filter in dermally applied sunscreen products was a safe to use on healthy, intact or sunburnt skin. The European Commission assures that nanomaterials in Cosmetics would already have gone thorough stringent safety assessment in the world. Therefore, consumer should not worry about using sunscreens but rather worry about not using them. The article can be found here.

National Pharmacare Consultation Online Questionnaire

Health Canada and the Public Health Agency of Canada’s Stakeholder Registry recently launched an online questionnaire to complement the current consultation on national pharmacare. Pharmacare is a system of health insurance that provides people with access to necessary prescription drugs. Its design can be determined by a number of factors, including which population groups are targeted, which types of drugs are covered, and how it is financed. The questionnaire can be found here.

Environmental Update

New Voluntary Public Engagement Initiative of the New Substance Program

Environment and Climate Change Canada (ECCC) recently released a transparency initiative of the New Substance (NS) Program. In an effort to engage Canadians in the risk assessment process of higher organisms regulated under the New Susbtances Notification Regulation (Organisms), ECCC and Health Canada are working with notifiers on a voluntary basis to facilitate greater public engagement. The NS Porgram will publish summaries of higher organism notifications. It will also provide an opportunity for the public to provide scientific information and test data that could be useful to inform the risk assessment process. The new initiative can be found here.

International Update

ICCR-12 – Successful Meeting in Tokyo, Japan

Cosmetics Alliance is pleased to provide the following summary of key developments and successful outcomes from the recent ICCR-12 Meetings in Tokyo, Japan from July 10 – 13, 2018. Attached is the official ICCR-12 Outcomes Report (press release) for your review.

This year saw participation from the 5 Full ICCR Members (Brazil, Canada, Europe, Japan and United States) along with 6 Observers (including 2 new observers: Israel and Thailand and returning observers: Columbia, South Africa, South Korea, and Taiwan). Interest in this important international dialogue forum is clearly growing!

This year's meeting saw the successful adoption and finalization of the following work products (confidential attached):

- "Integrated Strategies for Safety Assessments of Cosmetic Ingredients – Part II: Overview of Novel Assessment Methodologies (NAMs) that may be relevant to support Next Generation Risk Assessments (NGRAs) of Cosmetic Ingredients"

This is the follow-up report to the first phase of work undertaken by the Integrated Strategies for Safety Assessment Joint Working Group which outlined relevant principles for the use and consideration of NAMs to support NGRAs adopted at ICCR-11. This technical paper provides a brief overview of a selection of relevant NAMs that may be appropriate for cosmetic safety assessments. In addition, it outlines the strengths and limitations of these methods along with a brief analysis of how these tools may be applied from a cosmetic safety assessment perspective. As a joint regulator/industry work product, this report may prove to be an important resource when working with regulators in Canada and abroad when looking to leverage some of these new and emerging safety assessment tools, moving forward.

- "Review of International Standards on Analytical Methods Defined by ISO – Nitrosamine Standards and Validation Criteria for Analytical Results Using Chromatographic Techniques"

This report recommends the endorsement of the following 2 standards and established validation criteria by the ICCR Steering Committee:

o ISO 10130:2009 – Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC post-column photolysis and derivatization

o ISO 15819:2014 – Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS

o ISO 12787:2011 – Validation criteria for analytical results using chromatographic techniques

In addition to the final work products outlined above, the ICCR Steering Committee re-affirmed the need to continue with the following work products, with anticipation that Final Reports may be tabled in the next ICCR-13 cycle:

- Integrated Strategies for Safety Assessments of Cosmetic Ingredients – PART III (technical workshop and select case studies outlining applicability of NAMs in supporting modern cosmetic ingredient safety assessments)

- Allergens III – Integrated Approaches to Testing and Assessment (IATA) of Skin Sensitization Potential (3 OECD methods – TG 442C, D, E)

- Cosmetic Product Preservation – White paper identifying key elements that need to be considered when establishing and evaluating the relative efficacy of the cosmetic preservative palette

All three of these work products will represent important outcomes that could be integral in establishing common and consistent approaches to cosmetic ingredient safety assessments in the future.

The ICCR Steering Committee also agreed to initiate 2 new Joint Working Groups:

- Communications JWG to provide a forum to identify key topics for which joint communications may support broader regulatory convergence

- Microbiome JWG to address the emergence of cosmetic products claiming to influence skin microflora as potential cosmetic benefits

The continued importance and evolution of e-commerce as an emerging and rapidly developing distribution channel was confirmed as a key topic of industry concern. ICCR regulators agreed that this is an emerging issue for which a global regulatory dialogue might be beneficial. In this regard, the ICCR Steering Committee affirmed their interest

in the industry-lead project on this topic planned for finalization and presentation during the ICCR-13 cycle.

Finally, 2 animal testing interest groups registered for stakeholder presentations:

- Humane Society International (Japan Chapter)
- Cruelty Free Beauty

Both made representations before the ICCR Steering Committee on the topic of animal testing in support of Cosmetics. These presentations reflected similar points tabled at past ICCR meetings.

This year saw the introduction of an international symposium by the Japanese Joint Hosts (MHLW/PMDA and JCIA).

Before a packed auditorium of over 600 attendees, the ICCR regulators provided an overview of ICCR and highlighted the need for global cooperation and dialogue to seek efficiencies and understanding in regulatory approaches around the world. The symposium program featured:

- Overview of ICCR-12 outcomes (regulator and industry perspectives)
- Technical overview of two key projects (safety assessment and product preservation)
- A brief review of the current regulatory paradigms for cosmetics in each of the 5 ICCR jurisdictions (Brazil, Canada, EU, Japan, US)
- Panel discussion – Global Trends and Opportunities for International Collaboration (regulator panel – ANVISA, Health Canada, European Commission, MHLW, US FDA)

The highlight of the program was a Special Session – Recent Trends of the Cosmetics Industry presented by the Mr. Masahiko Uotani, President and CEO, Shiseido Col, Ltd., Vice-President, JCIA who outlined the importance of ICCR as ‘THE’ international forum for facilitating global dialogue on key opportunities for regulatory cooperation.

Copies of presentations from the symposium are available upon request.

With ICCR-12 drawing to a close, MHLW/PMDA and JCIA passed the torch to next year’s host – CANADA, where Health Canada along with Cosmetics Alliance Canada will have the opportunity to host for the third time this important international forum. We look forward to welcoming our ICCR Partners and Associates and ICCR observers to what is sure to be a jammed packed program, where we expect to discuss and adopt a number of key ICCR deliverables. ICCR-13 is shaping up to be what is likely to be one of the busiest ICCRs to date. Mark your calendars now!

Welcome ICCR-13 – JULY 9 – 12, 2019.

Any questions – please do not hesitate your CA Canada Regulatory Team!

The Canadian ICCR-12 (2018) Delegation

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