

**MNI activity report
October-December 2019**

17 December 2019

Topic	Objective	Update on recent developments and next steps
ENFit	<ul style="list-style-type: none"> Secure adoption of ISO/CEN 20695 standard 	<p>ISO/CEN 20695 standard voted</p> <ul style="list-style-type: none"> The ISO/CEN 20695 standard for the design and testing of enteral feeding systems was voted in October 2019. The standard provides for two orientations (female to male and male to female) which might increase risks of misconnections. The legal review of MNI intention to promote ENFit in female to male orientation did not identify any anti-trust concerns, to the extent (i) there is no obligation for MNI members to endorse only the female to male orientation, and (ii) suppliers who use a male to female orientation are not disadvantaged and (iii) no other anticompetitive actions are taken. MNI communication plans are on hold, until MNI Executive Committee decision on leadership for Communication plans (MNI or GEDSA). <p><u>Next steps:</u></p> <ul style="list-style-type: none"> MNI Executive Committee to confirm leadership of the ENFit campaign Standard due to be published in Q1 2020
ONCA	<ul style="list-style-type: none"> Promote screening and nutritional care strategies at the national level under the banner "Optimal 	<p>ONCA Conference Cambridge – 19-20 November</p> <p>Overall very successful conference. Main take away is the call for a Clinical Director for nutrition at NHS level, supported by former decision makers, BDA, BAPEN and BSNA. Another highlight is the unique opportunity for healthcare professionals, decision makers and patients from 18 different European countries to come together at one</p>

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	Nutritional Care for All” (ONCA)	<p>conference. BSNA will follow up with all stakeholders when the summary of the conference is finalised repeating once again the call for a Clinical Director message. All the presentations and press release can be found at: https://european-nutrition.org/homepage/events/conference2019/</p> <p>ENHA/ONCA leadership and future Frank de Man will step down at the end of 2020. Olle Ljungqvist will remain as co-chair until end 2021. MNI will need to reflect on ENHA/ONCA leadership and future in 2020.</p> <p><u>Next steps:</u></p> <ul style="list-style-type: none"> • Q2 2020: ENHA-EPF event in the European Parliament (date tbc) • 16-17 Nov 2020: ONCA conference in Copenhagen - Denmark
Cooperation with patient groups and other stakeholders	<ul style="list-style-type: none"> • Leverage patients voice on nutrition 	<p>Infographic on clinical nutrition guidelines The EPF presented at the ONCA Cambridge conference a new infographic on clinical nutrition guidelines and EPF recommendations to involve patients in clinical guidelines development. https://www.eu-patient.eu/globalassets/events/epf_clinical_nutrition_infographic.pdf</p> <p>Lay summary of ESPEN guidelines The project to develop lay versions of ESPEN guidelines is delayed, as the EPF awaits the availability of ESPEN ‘short guidelines’ to develop the ‘lay summaries’. The EPF plans to develop lay summaries of following guidelines: <i>CIF, Oncology, IBD, surgery, polymorbidity, hepatology, HEN</i> and of upcoming guidelines: <i>nephrology, hospital food, micronutrients, pulmonary diseases</i>.</p>
Regulatory affairs	<ul style="list-style-type: none"> • Ensure an appropriate Regulatory 	<p>EU</p> <ul style="list-style-type: none"> • EU delegated regulation on FSMPs: no relevant development to report.

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	<p>Environment for Enteral Medical Nutrition</p>	<ul style="list-style-type: none"> • EU organic project: next step is the identification of potential legislative options and related feasibility for organic claims for FSMPs <p>Global-Ex EU:</p> <ul style="list-style-type: none"> • Estrella Bengio was nominated to represent MNI in ISDI Board (pending validation by ISDI GA). • 2020 work plan - the RAWG will: <ul style="list-style-type: none"> ○ Monitor the regulatory landscape in China, Brazil, India, Indonesia, Turkey, Canada, South Africa, Colombia, Saudi, Taiwan, Mexico and Russia. ○ Identify horizontal topics of interest to support enteral medical nutrition e.g. stability, clinical studies, education, local malnutrition data ○ Map trade association in key countries in scope ○ Facilitate alignment on MNI and ISDI objectives <p><u>Next steps:</u></p> <ul style="list-style-type: none"> • Executive Committee to confirm budget for identification of legislative options and related feasibility of EU Organic project
Market Access	<ul style="list-style-type: none"> • Winning decision makers and HCPs awareness of nutritional therapies 	<p>Brazil</p> <ul style="list-style-type: none"> • Moreno Perugini met Brazilian GROW team on 25 September. • MAWG confirmed possibility to contract systematic literature review to collect evidence on cancer and malnutrition to support MNI cancer priority. <p><u>Next steps:</u></p> <ul style="list-style-type: none"> • Executive Committee to confirm budget for cancer/nutrition literature review
Communication	<ul style="list-style-type: none"> • Raise MNI profile 	MNI workshop on communication strategy and planning for 2020+

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	<ul style="list-style-type: none"> • Position malnutrition as a public health issue • Educate on the role of medical nutrition in disease management 	<p>MNI communication and public affairs experts attended the workshop on 21 November in Brussels and recommended to base MNI communication on two pillars:</p> <ul style="list-style-type: none"> • Pillar 1: Strengthen dissemination of MNI materials via digital media • Pillar 2: Launch a large-scale campaign addressing cancer patients and their carers, focusing on both digital media and traditional channels (in line with MNI public affairs strategy to focus on EU cancer plan). <p>Expected delivery for Q1 2020:</p> <ul style="list-style-type: none"> • Infographics (malnutrition & cancer) • Short movie with interviews of KOLs on HPN • Video animation explaining what HPN is (for HPN website)
<p>Relationship with ESPEN</p>	<ul style="list-style-type: none"> • Establish trust & ensure a good and sustainable relationship with ESPEN • Strengthen MNI's influence on ESPEN priority setting and activities 	<p>HPN guideline MNI was invited to review the final draft of the HPN guideline (in addition to the previous Delphi round). This is a deviation to the ESPEN guideline procedure. We understand it as a recognition of the value of MNI input in previous guidelines, and the result of our efforts to build a partnership with ESPEN over the years. The HPN guideline should be published by end of the year.</p> <p>ESPEN guideline app project After lengthy negotiations, MNI offered to support the user-test of the IBD app pilot. The user-test is funded by Nestlé and coordinated by Kala Kaspar. MNI committed to support the development of further apps for an amount of 40K€ if the user-test is positive, and if KPIs are met two months after the launch of the app. Results expected by end February. 40K€ budget to be reserved until then.</p> <p>ESPEN congress points attribution system</p>

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		Léa Coulet informed Rocco Barazzoni of MNI concerns in relation to the scheme by phone and contracted law firm Clifford Chance to ensure MNI acts within the remit of competition law.
PN	Raise awareness on benefits of parenteral nutrition in the ambulatory sector	<p>2020 plans: The HPN Task Force plans to step up efforts to raise awareness on the feasibility of HPN through 3 to 4 packages:</p> <ul style="list-style-type: none"> • Communication / Awareness & Education (improved website, SEO and dissemination) • Discharge protocol for HPN patients • HPN access mapping (legal basis, reimbursement, home care services, ...) • Review HPN prevalence and cost-effectiveness data (tbc) <p>Next steps in Q1:</p> <ul style="list-style-type: none"> • MNI Executive Committee to confirm budget • Short movie with interviews of KOLs on HPN • Video animation on HPN patient from hospital to home • HPN website updates planned, including search engine optimisation
National Industry groups / GROW project	Grow the medical nutrition market in Europe	<p>Poland</p> <ul style="list-style-type: none"> • The NIG was formally established as a legal entity in November 2019. • 4 companies involved: Baxter, Fresenius Kabi, Nutricia and Nestlé. • GROW submission to be confirmed. • <u>Next steps:</u> Inform stakeholders of the establishment of the industry association; agree on ways of working & funding; define a common agenda & work plan; develop a website. <p>Russia</p>

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		<ul style="list-style-type: none"> • Abbott, Fresenius Kabi, Nestlé and Nutricia confirmed interest for closer cooperation, within remit of competition law. Content of cooperation to be discussed during physical meeting. • <u>Next steps</u>: Meeting planned on 21 January to discuss common agenda and organisational issues <p>Italy:</p> <ul style="list-style-type: none"> • Launch of Manifesto for clinical nutrition in Italian Senate on 12 December 2019 (Manifesto and event programme attached) signed by Abbott, B.Braun, Fresenius Kabi, Nestlé and Nutricia. The Manifesto calls on Italian authorities to deliver appropriate treatment for malnourished patients. • Joint working group on ‘clinical nutrition’ with Assogenerici (pharma industry association) covering ONS, EN and PN did not materialise due to misalignment on compliance and governance issues with Assogenerici. Léa Coulet will offer support to lift stalemate. • <u>Next steps</u>: Inclusion of ONS for oncology in LEA (list of reimbursable products) expected in 2020. <p>France:</p> <ul style="list-style-type: none"> • Deep dive with French NIG (SFNS) confirmed in 28 February 2020. • No discussion took place between the three companies - at the time this report was sent- on a potential PN agenda in France.
Code of Conduct	<ul style="list-style-type: none"> • Develop a code of conduct to strengthen MNI reputation and credibility toward stakeholders 	<p>The WG delivered the final draft Code of Conduct, which was approved by the MNI Executive Committee on 29 November.</p> <p>The draft has been shared with MNI key stakeholders for their comments (EPF, ESPEN, ENHA).</p>

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		<p><u>Next steps:</u></p> <ul style="list-style-type: none"> • Q1: Review EPF, ENHA, ESPEN comments (if any) at WG level and finalise the code • CoC WG to be discontinued once the code is published.
Public Affairs		<p>MNI Public Affairs strategy: focus on cancer</p> <ul style="list-style-type: none"> • The kick off meeting took place on 15 November in Brussels. • WG members: Vicky Assardo (Abbott), Ioana Enache (Baxter & co-chair), Carsten Schmidt-Rimpler (FK), Ana Piekarcz (Nutricia & Chair). • In 2020, the WG will focus on one of the current European Commission priorities, 'Beating Cancer Plan'. The aim is to advocate the development of the following recommendations: <ul style="list-style-type: none"> ○ All cancer patients to be screened for malnutrition ○ Implement guidelines (e.g. ESPEN and ESMO guidelines) ○ Involve patients in their treatment ○ Establish multi-disciplinary teams in cancer wards, with dieticians/nutritionists <p>In addition, the WG will disseminate good practices and leverage ONCA campaign.</p> <ul style="list-style-type: none"> • In agreement with the MNI Executive Committee, all MNI working groups will support – where relevant- the new focus on cancer. <p><u>Next steps in Q1:</u></p> <ul style="list-style-type: none"> • Fine-tune the cancer strategy and articulate the objectives. • Publish infographic on cancer (based on data available in MNI Dossier) • Engage with EU decision makers to advocate and educate on the burden of disease-related malnutrition in cancer patients.

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News from the MNI secretariat		<p>MNI Q1 workshop The date of the workshop was initially set to 19 March. However a new date will need to be proposed at the request of a member company.</p> <p>MNI Intranet</p> <ul style="list-style-type: none"> • Following request from working groups, the secretariat will post minutes of all WG meetings and teleconferences on the Intranet. • The Intranet is now fully up-to-date with minutes since 1st October. <p>Bye Marie & welcome Paulina Marie Mahieux – MNI Association Manager- is moving on to another job. She is replaced by Paulina Santiago who will run the secretariat from now on. The Secretariat coordinates remain identical: secretariat@medicalnutritionindustry.com +32 2 320 25 42 We thank Marie for her great support and wish her good luck on her new assignment, and extend a warm welcome to Paulina will represent the MNI secretariat from now onwards.</p> <p>MNI secretariat end of year holidays The MNI team will be on holidays from 20 December 2019 to 3 January 2020. The MNI phonenumber will be operational except during 24 December – 2 January 2019.</p> <p>Important dates in 2020:</p> <ul style="list-style-type: none"> • 20 January: Executive Committee teleconference • 28 February: Executive Committee meeting – Paris • 28 April: GA and Executive Committee meeting – Maidenhead/UK • 3 July: Executive Committee meeting – venue tbc • 22 September: Executive Committee meeting – ESPEN – Lyon/France

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		<ul style="list-style-type: none"> • 16 or 17 November: ONCA conference (exact date tbc) • 27 November: Executive Committee teleconference – venue tbc