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Report by the Expert Panel on Caffeinated Energy Drinks

An Expert Panel on Caffeinated Energy Drinks (the Panel) was convened by Health Canada and met on October 26, 2010 in Ottawa. The Panel was representative of diverse backgrounds and areas of expertise, including: pediatrics, cardiology, pharmacovigilance, food science, epidemiology, drug safety, etc.

Further information regarding the Panel, including the Terms of Reference, Panel Member List, and Meeting Agenda are available in Appendices A-C. The Panel received extensive background information for review prior to the October 26, 2010 meeting, which is available in Appendix D.

Methodology:

On October 26, 2010, the Canadian members of the Panel met face-to-face and the Panel members from Europe joined by teleconference. Opening remarks were made by Nancy Richards, A/Director General, Natural Health Products Directorate, Health Canada and Noni MacDonald, Chair, Expert Panel on Caffeinated Energy Drinks. Two formal Health Canada presentations on caffeinated energy drinks followed. The first presentation was made by Alison Ingham of the Natural Health Products Directorate and the second presentation was made by David Cunningham of the Marketed Health Products Directorate. Each presentation was followed by a question period for clarification of information presented and to discuss points of interest and concern. Following the formal presentations and question periods, due to time constraints, the European members of the Panel left the call.

The Canadian Panel members undertook formal review of the four questions raised by Health Canada and drafted this report. The report begins with the Panel’s overall response and recommendations to Health Canada based on the information reviewed, presentations, and the four questions posed by Health Canada. The report then provides the four questions posed by Health Canada, the Panel response to these questions with rationales, and the recommendations proposed by the Panel. The conclusion of the report is the five (5) priority recommendations presented to Health Canada.

Overall Response by the Panel to Questions Raised By Health Canada:

There is significant confusion regarding the term “energy” drinks and these caffeine stimulant “energy” drinks. Historically, the former drinks are mandated as foods and consist of carbohydrate-electrolyte replacement beverages (e.g., Gatorade™, Powerade™). These drinks are safe and recommended for all ages including children. The Panel noted that the latter group of drinks, those containing significant levels of caffeine, makes the term “energy” drinks very confusing for the public. The term “energy” drinks is a marketing term and should not be used. Its usage adds to the public perception that these latter drinks are foods, not drugs, being delivered in a liquid format.
Furthermore, the addition in some of these caffeine products of electrolytes, similar to those found in electrolyte replacement specific beverages (e.g. Gatorade\textsuperscript{TM}, Powerade\textsuperscript{TM}), adds to this confusion. Many of these newer “energy” drink products are, in reality, oral delivery systems for stimulant drugs such as caffeine. These stimulant drugs are not being given for a disease indication but are being ingested in large numbers by members of the public who are predominantly in good health (i.e., not for a medically indicated condition). With respect to usage, according to numbers presented by Health Canada for a recent 30-month period, approximately 7 million units of caffeine-stimulant (“energy”) beverages were sold each month.

**Overall Panel Recommendations:**

1. Health Canada desists from using the term “energy drinks”. A more accurate designation to consider might be “stimulant drug containing drinks”. This term should be clearly indicated on the front panel of the product.

2. Health Canada must act to mitigate the growing confusion for the general public between electrolyte replacement beverages and these stimulant drug containing drinks as more of these stimulant drug containing drinks now contain electrolytes and are marketed as sports drinks.

3. Health Canada recognizes that, given the large number of these products sold on a monthly basis, there is evidently a large number of Canadians “exposed” to the drug. Even if the risk (probability of occurrence) of serious adverse events is expected to be very low, cases of serious adverse events have occurred. Therefore, due to the high volume of use, the risk of adverse events is considered to be a public health issue as these stimulant drug containing drinks are not being medically prescribed for a health indication. In the absence of real therapeutic and medically indicated benefits, the Panel considers that the risks associated with the use of these drugs outweigh the benefits. Public health at the federal/provincial/territorial levels need to be apprised of the risks and efforts made to co-ordinate steps to mitigate risk.

4. Health Canada, at a minimum, maintains stimulant drug containing drinks in the category of natural health product (NHP) and NOT move them to foods due to the significant drug effects of the caffeine added to these products. This is recommended regardless of how other countries have chosen to deal with these products.

   N.B.: Some members of the Panel noted that these products should be formally handled as drugs (i.e., even more stringent than under NHP).

5. Concern was expressed at the number of stimulant drug containing products on the Canadian market that do not have an NHP licence nor an exemption number. Some of these products do not meet NHP labeling guidelines. Many
contain high levels of caffeine and could pose a hazard to consumers. Strategies need to be implemented to rapidly deal with these products as soon as possible (i.e., meet NHP requirements or be removed from the market).

At present, there are 9 product licences, representing 18 products, containing caffeine.

The current labeling for market-authorized caffeinated energy drinks includes the statements:

- Recommended dose: (adults),
- Drink X ml, 1 (to 2) times a day, as needed,
- Not recommended for children, pregnant or breastfeeding women, caffeine-sensitive persons or to be mixed with alcohol,
- Developed for periods of increased mental and physical exertion, helps temporarily restore mental alertness or wakefulness when experiencing fatigue or drowsiness,
- Do not consume more than X cans per day. “X” will be the number specific to the individual product.

Currently, there are approximately 190 products on the market with exemption numbers, some of which do not meet these requirements. Some of these products do not disclose caffeine content (5-hour Energy, #EN-140564, 140566).

6. The Panel notes that this is a safety concern and recommends that Health Canada ensure that all products meet strict labeling requirements and fully disclose the exact caffeine concentration (mg) prior to receiving an exemption number. Without caffeine amounts consumers are unable to abide by Health Canada’s recommendation on caffeine consumption.

QUESTION #1:

Does the current medical and scientific evidence, including the strength of the signal, warrant additional risk management strategies further to Health Canada’s current requirements? Please explain/provide the rationale for your recommendation(s).

Panel Response:

Caffeine is the most widely consumed psychoactive or central nervous stimulant in the world, widely recognized to increase wakefulness, and readily available to all ages.

Four sets of potential health problems have been identified:
1. There are known side effects, and withdrawal associated problems, in adults as a result of concentration levels of the drug caffeine found in different stimulant drug containing drinks.

Caffeine is known to cause the following side effects at lower doses:

- restlessness,
- anxiety,
- nervousness,
- insomnia, and
- irritability.

Caffeine is known to cause the following, more serious effects at higher doses (IOM 2001, Sawynok 1995, Greden 1974, Bigard 2010):

- delirium,
- emesis,
- neuromuscular tremors, and
- convulsions.

Caffeine is also known to affect blood pressure and heart rate (Arciero PJ, Ormsbee MJ- Appl Physiol Nutr Metab. 2009 34(4):754-62.) with varying effects depending on age and fitness. Withdrawal, even from moderate use, has long been known to produce symptoms of headache, fatigue, and anxiety (Sawynok 1995).

Large safety data for energy drinks in children and adolescents is lacking. Very large surveillance studies would be needed to assess rare adverse events. In this case, active pharmacovigilance strategies would be the most feasible tool.

2. Adverse drug reactions (ADRs) relating to caffeine stimulant drug containing drinks have been reported to Health Canada. A total of 61 ADRs relating to “energy” drinks have been reported to Health Canada: 32 serious and 29 nonserious. Of the 32 serious ADRs, 15 involved the cardiovascular system and 7 of the 32 occurred in adolescents. However, in the absence of utilization data (including the age distribution of the users), inferences about effect modification by age cannot be made. Following standard causality review based on World Health Organization (WHO) standards, 4 serious ADRs were graded as probably related to the caffeine stimulant drug containing drinks and 8 as possibly related. There are 3 ADRs including two deaths that could not be assessed due to incomplete information.

The Panel noted that these cases, following causality assessment, constituted a case series that leads to a safety signal. More confirmatory studies are required however to evaluate such risk.

A recent small placebo controlled trial found that 1 hour after consumption of a caffeine stimulant drug containing drink containing caffeine (80 mg), taurine (1000 mg), and glucuronolactone (600 mg), there are objective cardiovascular changes characterized by an increase in blood pressure, an increase in platelet aggregation,

Caffeine overdose is a rare but reported cause of sudden death (Reissig et al., 2009). It is usually as a result of pill-format overdose, with blood levels ranging from 130mg/L to 1560 mg/L (Garriott et al., 1985; Kerrigan and Lindsey, 2005: Mrvos, 1989).

Caffeine stimulant drug containing drinks are marketed as enhancers of sports performance, yet physiologic studies indicate that caffeine reduces myocardial reserve (Bottcher et al., 1995; Namdar et al., 2006). Thus, the cardiac ADRs reported to Health Canada, the findings of the Worthley et al. study noted above, along with published case reports of sudden deaths following consumption of such beverages, should raise concerns about the potential for serious adverse events with these products.

In addition to the serious cardiac ADRs, the Panel also drew attention to the cases of seizures that have also been observed. Caffeine is known at high doses to cause seizures but, whether it can cause seizures in those with lower seizure thresholds in certain conditions is not well established. Neither is it clear if these seizures were cardiac related. The ADRs where alcohol might be a contributing factor are also of importance given the increasing number of reports of concomitant use of stimulant drug containing drinks. This area needs more research and documentation of co-consumption rates, and risk factors that can be mitigated.

3. Known drug interactions between caffeine stimulant drug containing drinks and alcohol leading to behavioural changes: this interaction has not been studied as an ADR but evidence is mounting that this is a serious problem especially among adolescents and young adults (recent review by Bigard AX- Risks of energy drinks in youth Archives de Pédiatrie 2010;17:1625-31; and research findings by Arria AM et al. Alcohol Clin Exp Res. 2010 Nov 12. doi: 10.1111/j.1530-0277.2010.01352 and Arria et al. Addict Med. 2010;4(2):74-80.) This will need a different strategy to determine risk, frequency of occurrence, and outcomes compared to ADRs where the drugs have been prescribed for a medical indication.

4. Unknown potential drug interactions between caffeine and the other biological and pharmaceutical components of different stimulant drug containing drinks: there is limited data on the potential interaction of caffeine and other biological and pharmaceutical components of different stimulant drug containing drinks. Given that some herbs are well known to interact with other drugs in terms of metabolism, adverse effects and, efficacy, these studies are warranted.

*Panel Recommendations:*
7. Since serious adverse event signals (cardiac events, and to a lesser extent seizures) have been detected, Health Canada should, in collaboration with the provinces and territories, consider steps to investigate further and mitigate these risks:

a) Contact the Provincial Chief Coroners across the country to determine if there is pediatric death review data where stimulant drug containing drinks have been consumed that Health Canada has not had access to.

b) Alert the Provincial Chief Coroners and their review committees that Health Canada has detected a signal. Propose the inclusion of a question regarding the ingestion of stimulant drug containing drinks when data is being collected systematically on cases.

c) Alert practitioners that a signal has been detected. Although practitioners may not be prescribing stimulant drug containing drinks, they may see adverse events and need to report them.

d) Consider setting up an active surveillance system, possibly in collaboration with PHAC, in sentinel emergency rooms across the country to actively search for serious ADRs following the consumption of stimulant drug containing drinks with and/or without alcohol and other products. The system could be modeled on the long running IMPACT system which actively carries out surveillance for serious adverse events following immunization ([http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/00vol26/dr2615ea.html](http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/00vol26/dr2615ea.html), [http://www.cps.ca/English/surveillance/impact/impact.htm](http://www.cps.ca/English/surveillance/impact/impact.htm)).

e) Examine the data on fatal car crashes and the relationship with the consumption of stimulant drug containing drinks taken concurrently with alcohol. In addition, consider the examination of blood samples from these cases for both alcohol and caffeine concentration. This work might be done in collaboration with the Provincial Chief Coroners.

f) Conduct a utilization study of stimulant drug containing drinks in both adults and underage youth, and co-consumption rates with alcohol.

g) Health Canada considers contracting with Health Evidence Canada at McMaster University to do a systematic review of the published and gray literature on adverse events of caffeine, caffeine-alcohol interactions, and outcome and caffeine interactions with other biologicals and pharmaceuticals in stimulant drug containing drinks.

QUESTION #2

Intended subpopulation:
a) Does the current scientific evidence warrant that restrictions be required for the adolescent subpopulation? If so, should these restrictions be based on body weight as opposed to age? Please explain/provide the rationale for your recommendation(s).

b) Should the labelling of these products include defining the term "adult use only" (i.e., should adult be defined as "Y years of age or older")? Please explain/provide the rationale for your recommendation(s).

Panel Response:

Substantive safety data for stimulant drug containing drinks are lacking, especially for adolescents. The disproportionate number of serious ADRs in adolescents to that of adults in the domestic signal, the recognized increase in the combination of stimulant drug containing drinks with alcohol by young people, and the associated behavioural problems are of concern (see above). It is not clear if the disproportionate number of serious ADRs in adolescents is a reflection of a large denominator of users, an indication that adolescents may be intrinsically at an increased risk for severe events, or a reflection of an excess in per dose consumption. Thus, the Panel does not see adequate evidence to expand age groups for intended population for the current dosage, nor to provide “safe” dosing amounts for these stimulant drug containing drinks for children or adolescents. The panel reviewed information on the amounts of caffeine in stimulant drug containing drinks/products which is available in Appendix E.

To mitigate the risk of excessive caffeine consumption per dosage unit, the Panel discussed the need for caffeine consumption dose standardization for stimulant drug containing drinks: maximum dose per single unit container, maximum concentration per mL, and a maximum per day dose.

Given the misperception by the general public that stimulant drug containing drinks are foods, labeling for these products must be clear: that these are drugs, what the dose is per container, the maximum dose per mL, and the maximum daily dose for all caffeine sources.

Panel Recommendations:

8. Health Canada should maintain stimulant drug containing drinks for use only in adults age ≥ 18 years. No expansion of age groups.

9. Health Canada needs to specify (for adults):
   - maximum dose per single dose container of 80 mg of caffeine.
   - maximum of 0.32 mg caffeine/mL if in a beverage format.
   - total maximum caffeine per day of no more than 400 mg/day from ALL caffeine sources.
the frequency of caffeine stimulant drug containing drink use of only every 3 to 4 hours.

10. Health Canada, in collaboration with the provinces and territories, needs to support the development of education programs that will allow the public to easily identify the amount of caffeine in different foods and stimulant drug containing drinks, the maximum caffeine per day, and the interval. Collaboration with school boards across the country was suggested as a means to access the youth population. Social networking strategies such as “YouTube” and other techniques need to also be considered.

QUESTION #3:
Cardiovascular events:

a) Does the current medical and scientific evidence warrant cautionary labeling with respect to events of a cardiovascular nature (e.g. arrhythmia, palpitations, etc.) such as "May cause increased or irregular heart rate. Consult a health care practitioner if this occurs."? Please explain/provide the rationale for your recommendation(s).

b) What additional risk mitigation strategies should be implemented regarding the cardiovascular events (e.g. arrhythmia, palpitations, etc.)? Please explain/provide the rationale for your recommendation(s).

Panel Response:
The evidence on cardiovascular risk was discussed by the Panel both in terms of sudden death (ADRs, literature cases, etc.) and potential biological mechanisms (arrhythmias, myocardial infarction etc.) (see above). The Panel noted that caffeine does have an effect on the QT interval (the time between the start of the Q wave and the end of the T wave in the heart’s electrical cycle) in in vitro studies, but does have an effect at the extreme concentration that would be seen in intentional overdoses (5mM, 970 mg/L) (Cockerill & Mitcheson, J. Pharmacol. Exp. Ther., 2005).

The Panel noted that palpitations are commonly reported by the public with caffeine products. The Panel reiterated that any patient with symptoms suggestive of an arrhythmia needs to be seen by a health practitioner and to desist from using these stimulant drug containing drinks until clarity of risk has been assessed for that individual. Individuals with palpitations are generally advised to have assessment by a medical professional (Zitenbaum et al., NEJM, 1998; Giada et al., G Ital Cardiol (Rome). 2010). Similarly, syncope can be due to cardiac arrythmias and require assessment by a health provider (Moya et al., 2009 [Joint Guidelines] European Heart Journal). The Panel noted that it is very hard to identify in advance those groups that are at increased risk for cardiovascular adverse events. The relationship to exercise confounds the causality.
assessment as well. The Panel would like to draw attention to similar sudden death risk data that had arisen and presented to Health Canada through Adderall XR New Drug Committee Report (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/new-drug-com-nouvelle-droge/ndca_rep_cnma_rap_2005-08-25-eng.php). In comparison to the Adderral XR review, the days of exposure for stimulant drug containing drinks would appear to be much less, yet two deaths (albeit, so far, unassessable due to limited information) have occurred, and deaths have been reported in other jurisdictions. In order for adults in the general public to be able to make an informed choice on whether to consume or not consume a stimulant drug containing drink, it will require not only accurate and fulsome labeling on the products but also a public education program about stimulant drug containing drinks.

**Panel Recommendations:**

11. Health Canada requires labels for stimulant drug containing drinks include the following:

- That the product is NOT recommended for children or adolescents under the age of 18 years.
- Clearly indicate the concentration of caffeine from all sources in mg. As this is a drug of known concentration, the variability of drug should not exceed 10% (in contrast to the 120% currently allowable as a natural health product).
- Maximum daily caffeine dose from all sources and the interval for dosing.
- That caffeine is addictive even with moderate dosing.
- The known adverse reactions to caffeine including: insomnia, anxiety, palpitations, arrhythmias, allergic reaction, and symptoms with withdrawal.
- A caution that if sustained palpitations or fainting occur, to discontinue use and consult a health practitioner.
- That these products should NOT be used with alcohol (N.B.: This point demands much education and should be highlighted in all education materials for the general public).
- Those serious adverse events, including death, have been seen with these products, possibly due to cardiac events.
- All information that is printed on the container be in a font size that is easily readable by an adult.
- All information to be presented in appropriate language for the general public.

12. Education programs be developed that:

- Enhance the public’s ability to discern that stimulant drug containing drinks are drugs, not foods, and that these products differ from electrolyte replacement beverages.
These products are not for children or adolescents under the age of 18 years.

- Describe common side effects of caffeine, including withdrawal symptoms, even after short intervals with only moderate doses.
- Clearly describe the risk of imbibing on stimulant drug containing drinks concurrently with alcohol.
- Enhance knowledge of what foods contain caffeine, maximum dosing of caffeine per day, and per interval.
- Is tailored to meet the needs of different populations and risk groups including underage users and marginalized populations.
- Focus not only on enhanced public knowledge about risks of stimulant drug containing drinks but also on mitigation of behaviours that can further increase risk for adverse events or adverse behavioural problems.

These education programs need to be developed and carried out in collaboration with public health in the provinces and territories and/or school boards.

QUESTION #4

Other Risk Management strategies:

a) Given the information presented to the panel, what additional risk management strategies do you recommend that Health Canada, Industry and Health Care Practitioners consider in order to further mitigate the potential risks associated with the use of caffeinated energy drinks and allow Canadians to make informed choices with respect to these products (including address areas of uncertainty in the scientific data, ingredient interactions and educational activities, etc.)? Please explain/provide the rationale for your recommendation(s).

b) Are there additional steps that should be taken to strengthen the vigilance of caffeinated energy drinks and related population health effects? Please explain/provide the rationale for your recommendation(s).

Panel Response:

These products are drugs, therefore, must be dealt with as a drug which includes meeting the requirements that other drugs must meet. Caffeine in tablet form (100-200mg/pill format, DIN ID#) are sold as a regulated drug and scheduled on the National Association of Pharmaceutical Regulatory Authorities (NAPRA) under Schedule III (i.e., over-the-counter in the pharmacy under the direct supervision of the pharmacist). In comparison, an equivalent dosing of caffeine in a stimulant drug containing drink does not fall under the same regulation. These products are regulated as a natural health product. At present, there are no restrictions on where these stimulant drug containing beverages can be sold even though the dosing of caffeine in a stimulant drug containing drink is at a higher
dosage than found in a caffeine tablet classified and regulated as a drug. While other countries have dealt with these as food products for approval and the EU now requires that they be sold in food stores, etc. (Norway had to make this move in 2009), this should not preclude Canada from dealing with them as drugs, a classification the Panel believes these products should be under.

Post-marketing surveillance has been required for new drugs that are licensed for several years in order to enhance detection of rare adverse drug related events. This requirement should apply to all stimulant drug containing drinks as these are, in reality, drug delivery systems in a beverage format.

Given the lack of data on consumption available in Canada (only data on purchases) there is a knowledge gap on who is using these products, where, why, how much, and if they are being consumed with other caffeine or alcohol containing products.

**Panel Recommendations:**

13. Health Canada require post-marketing surveillance for the detection of rare serious adverse events for stimulant drug containing drinks, which is currently required for other drugs. Detection of such events, if causally assessed to be due to the contents of the stimulant drug containing drinks, could lead to withdrawal of licensure, a change in the label, as well as further education programs.

14. Health Canada review to ensure that stimulant drug containing drinks are not being advertised to children and youth given that these are only licensed for those 18 years and over. The penalty for improper advertising must be stiff given the high volume of these products currently being sold.

15. Given that these are drugs, Health Canada must ensure that companies do not give out free samples as this is precluded for drugs. The penalty for giving out free samples must be stiff given the high volume of these products currently being sold. The distinction between ‘sampling’ and ‘free distribution’ needs to be very clear. Both practices need to be prohibited.

16. Health Canada, in collaboration with the provinces and territories, develop a communication strategy for dissemination of risk information on stimulant drug containing drinks to a wide audience. In order to optimize the reach to work not only with public health in the provinces and territories, but also with professional groups such as:
   - Canadian Paediatric Society
   - Canadian Nurses Association
   - Canadian Medical Association
   - Canadian College of Family Physicians
   - Mothers Against Drunk Drivers
   - Canadian Association of Emergency Physicians
• Canadian Nurse Practitioners Association
• Canadian School Boards Association
• Canadian Home and School Association
• Youth sport coaching associations

17. Given that stimulant drug containing drinks contain active drugs and are not prescribed for health indications, they need to be treated like a drug and a change in allowable point of sale to NAPRA schedule III needs to be considered. This would more formally signal to the general public that these are drug products, not foods. Label information alone is unlikely to rectify this confusion.

18. The Panel also expressed concern to Health Canada on the large number of stimulant drug containing drink products on the market without a licence due to backlog. Given the huge volume of sales, and the potential health risks, this situation needs to be addressed quickly in order to mitigate risk.

Panel Priority Recommendations:

1. Health Canada to provide the recommendation of moving stimulant drug containing drinks to NAPRA Schedule III as they are drugs.

2. Health Canada specify caffeine from all sources be clearly listed
   • maximum dose per single dose (80 mg per single dose caffeine in a single use container or a maximum of 0.32 mg caffeine /mL if in a beverage)
   • total maximum caffeine per day of no more than 400 mg/day from all caffeine
   • the frequency of caffeine use of only every 3 to 4 hours

3. Health Canada licence stimulant drug containing drinks only for those over the age of 18 years.

4. Health Canada in collaboration with the provinces and territories ensure that the general public is knowledgeable that stimulant drug containing drinks are drugs in a beverage format, not a food, through appropriate education channels.

5. Health Canada move to prevent further confusion with newer stimulant drug containing preparations where there is increased blurring of the drug food boundaries due to the addition of
electrolytes etc. Any stimulant drug containing drink that contains added caffeine in dosing noted in 2 regardless of the other additives must remain classified as a drug.
Appendix A

EXPERT PANEL ON ENERGY DRINKS (the Panel)
DRAFT TERMS OF REFERENCE

The Expert Panel on Energy Drinks (the Panel) will provide Health Canada (HC) with expert advice on the most appropriate way to mitigate safety concerns related to caffeinated energy drinks currently being marketed in Canada.

1. MANDATE

The objective of the Panel is to provide recommendations on questions relating to the appropriate risk mitigation strategies for energy drink natural health products, as a result of potential safety concerns identified by the HPFB. These concerns are based on an assessment of the current available literature and evidence surrounding the safety and efficacy of these products, as well as data from adverse reaction events.

The Panel’s role is advisory. That is, the Panel will provide Health Canada with advice and recommendations, but related decision-making responsibility remains with Health Canada.

2. REPORTING STRUCTURE

The Panel will report to the Director General (DG), Natural Health Products Directorate (NHPD) or designate, who acts as the Executive Secretary to the Panel.

3. MEMBERSHIP

The Panel will consist of six to eight individuals, chosen based on their knowledge, expertise, and experience. Panel members are expected to consider all information provided by departmental representatives and stakeholders objectively, and views expressed should not represent their respective firms, organizations, professions or affiliations. These members serve on the Panel as knowledgeable individuals in their own right, and in the best interest of Canadians.

Panel members will be selected by the DG of NHPD based on recommendations by Health Canada’s Energy Drinks Working Group, who will incorporate into their decision such factors as availability, breadth of representation, and (primarily) scientific/medical expertise pertinent to the mandate of the Panel and covering the following areas of expertise:

- regulatory affairs;
- public health;
- paediatrics;
- pharmacology;
The Chairperson will be selected by the DG of the NHPD. Health Canada staff may not serve as members. External guests may be invited to provide supplementary expertise.

4. SECURITY CLEARANCE, CONDUCT AND CONFLICT OF INTEREST

Panel members are expected to conduct themselves in an appropriate manner, i.e. the use of their position cannot be reasonably construed to be for their private gain or that of any other persons or organization. All members are expected to protect and maintain as confidential any trade secret or privileged information divulged during the work of the Panel. Members must not discuss this information with persons not on the Panel, or divulge information obtained from the work of the Panel, including presentations made to it, until such time as this information has been officially released for public distribution.

Furthermore, as a condition of serving on the Panel, members will be required to submit to the Executive Secretary declarations of their Affiliations or Interests to determine if there are any potential conflicts. An internal review committee will examine the declarations to judge if any circumstances may place, or may be seen to place the member in a real, potential or perceived conflict of interest. As a condition of appointment, members will allow Health Canada to publish on its website a Summary of Expertise, Experience and Affiliations and Interests. The Summary will be prepared by NHPD and members will be asked to review the content for accuracy before its release.

Members are also required to undergo a security clearance to the level of ‘reliability status’, and are expected to ensure that confidential or protected documents are securely stored, at all times, and disposed of properly.

5. INDEMNIFICATION AND LEGAL ASSISTANCE

To be determined pending decision by HC Legal Services relating to recent Treasury Board revocation of the Government of Canada Volunteer Policy

6. COMPENSATION

Members are compensated for travel and accommodation expenses according to Treasury Board guidelines.
7. MANAGEMENT AND ADMINISTRATION

The Panel is tentatively scheduled to meet in October, 2010.

The Secretariat will develop the meeting agenda for approval by the DG in consultation with the Chair. Members will receive meeting materials as far in advance as possible prior to the meeting.

Discussion during the meetings shall be open, frank, and free-flowing. All members of the Panel shall have equal status during the discussion.

Advice of the Panel consists of recommendations to the DG of NHPD, which are reached by consensus. When a consensus is not possible, the meeting record will reflect the diversity of opinions.

A report will be published after the meeting in both official languages and will comply with Treasury Board’s Common Look and Feel Guidelines, Health Canada’s Guidelines for Presentation of Reports and Publications, and Health Canada’s Guidelines for Presentation of Public Involvement Activities and Consultations. There will be no references to comments made by individual Members or the public.

8. REFERENCES

Appendix B

Expert Panel On Caffeinated Energy Drinks: Oct 2010

Dr. Robert Hamilton
Section Head, Electrophysiology, Division of Cardiology
Hospital for Sick Children
Toronto, ON

Dr. Richard Hill
Manager, Pharmacovigilance Service
World Health Organization
Uppsala, Sweden

Mr Majlinda Lanahiatis
Unit Supporting the Panel on Food and Nutrient Sources
European Food Safety Authority
Parma, Italy

Dr. Noni MacDonald
Professor of Pediatrics
Dalhousie University
Halifax, NS

Ms. Patricia Malloy
Clinical Nurse Specialist, Tuberculosis Clinic
Hospital for Sick Children
Toronto, ON

Ms. Yola Moride
Associate Professor
Faculty of Pharmacy, University of Montreal
Montreal, QC

Dr. Jane Shearer
Assistant Professor
Faculty of Kinesiology
University of Calgary
Calgary, AB

Mr Tobin Robinson
Emerging Risks Unit
Unit European Food Safety Authority
Parma, Italy
Appendix C
Expert Panel on Caffeinated Energy Drinks

Meeting Agenda
October 26, 2010
Les Suites Hotel, 133 Besserer Street, Garden Suite, Ottawa, Ontario

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| 1) 8h30 – 8h45 | Opening Remarks  
|             | • Nancy Richards, A/Director General, Natural Health Products Directorate  
|             | • Dr. Noni MacDonald, Chair                                              |
| 2) 8h45 - 9h45 | Health Canada Presentations  
|             | Natural Health Products Directorate  
|             | • Katherine Vandyk, Assessment Officer, Product Assessment Division     
|             | • Alison Ingham, Manager, Product Assessment Division                   |
| 3) 9h45 – 10h15 | Questions                                                               |
| 4) 10h15 – 10h30 | Health Break                                                            |
| 5) 10h30 – 11h30 | Health Canada Presentations  
|             | Marketed Health Products Directorate  
|             | • David Cunningham, Medical Evaluator, Marketed Biologicals, Biotechnology and Natural Health Products Bureau  
|             | • Mano Murty, Manager, Clinical Section, Marketed Biologicals, Biotechnology and Natural Health Products Bureau  |
| 6) 11h30 – 12h00 | Questions                                                               |
| 7) 12h00 – 13h00 | Lunch                                                                   |
| 8) 13h00 – 16h00 | Panel Discussion and Formulation of Recommendations for Health Canada |
| 9) 16h00 – 16h15 | Closing Remarks  
|             | • Dr. Noni, MacDonald                                                    |

Appendix D
## Scientific Expert Panel on Caffeinated Energy Drinks

- **Information Package –**

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<td>1</td>
<td>Panel Questions for Discussion</td>
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| 2      | Draft Caffeinated Energy Drink Labeling Standard  
  - Research on abbreviated labeling standard;  
  - Abbreviated labeling standard evidence. |
| 3      | Informal Letters to Licensees and Applicants  
  - Letters;  
  - Informal Letter Response Evidence;  
  - Informal Letter Response Summary. |
| 4      | Stakeholder Information |
| 5      | International Summary |
| 6      | Pharmacovigilance overview of Energy drinks |
| 7      | Core Review Documents  
  A. Summary of all domestic serious adverse reactions case reports with energy drinks;  
  B. Causality assessments of all domestic serious adverse reaction case reports with energy drinks;  
  C. Signal assessment: The potential risks associated with energy drink consumption in the adolescent population |
| 8      | Appendices  
  A. Summary domestic cardiac adverse reaction serious case reports with energy drinks;  
  B. Summary domestic adolescent adverse reaction case reports with energy drinks;  
  C. Summary domestic non recommended use serious case reports with energy drinks |
energy drinks;
D. Canada Vigilance search results for all domestic adverse reactions associated with energy drinks to July 20, 2010;
E. Case reports of all domestic serious adverse reactions associated with energy drinks;
F. Summary of industry submitted domestic adverse reactions;
G. Health Canada’s risk communications with energy drinks:
   o It’s Your Health;
   o Canadian Adverse Reaction Newsletter;
H. Marketed Health Products Directorate’s Standard Operation Procedures
   o Causality Assessment
   o Signal Assessment
Appendix E.1

**Figure Legend**
- SoBe No Fear (NHP Licensed)
- SoBe Adrenaline Rush (NHP Licensed)
- Full Throttle (NHP Licensed)
- Health Canada – Recommended Limit (2.5mg/kg)
- Tea
- Coca-Cola
- Brewed coffee

**Figure 1.** Energy drink caffeine dose (mg/kg) per container. Body mass values represent the 50th percentile based on Center for Disease Control (Weight for age percentiles for children, 2000). The red line indicates the current recommended caffeine intake of children set by Health Canada (2.5mg/kg). Many products exceed Health Canada’s limits in a single container. The current status of each product (NHP License, Exemption, or Illegally Sold) is indicated by each product. All products were sold in Canada, regardless of status.
Appendix E.2

Caffeine Containing Energy Shots - Boys

Caffeine Containing Energy Shots - Girls

Figure Legend
- 5 Hour Energy (NHP Exemption)
- NOS Powershot (Illegally Sold in Canada)
- Red Bull Energy Shot (NHP License)
- Talon Blood Punch Shot (Illegally Sold in Canada)
- 6 Hour Energy (NHP Exemption)
- 5150 Juice (Illegally Sold in Canada)
- Health Canada -- Recommended Limit (2.5mg/kg)

Figure 2. Energy shot caffeine dose (mg/kg) per container. Body mass values represent the 50th percentile based on Center for Disease Control (Weight for age percentiles for children, 2000). The red line indicates the current recommended caffeine intake of children set by Health Canada (2.5mg/kg). The majority of products exceed Health Canada’s limits in a single container. The current status of each product (NHP License, Exemption, or Illegally Sold) is indicated by each product. All products were sold in Canada, regardless of status.