SPECIAL ACCESS PROGRAMME

FORM B – FUTURE USE REQUEST

SECTION A: PRACTITIONER INFORMATION		
Practitioner's Name:		
Hospital or Clinic Name: (if applicable)		
Address: (shipping address only)		
City:	Province:	Postal Code:
Contact Person: (if other than practitioner)		Send Drug c/o: In-patient Hospital Pharmacy Practitioner's Office Nuclear Medicine Blood Bank
Contact Telephone #:		
Contact Fax #:		
Contact's Email Address: (optional)	Practitioner's Email Address: (optional)	

SECTION B: DRUG AND MANUFACTURER INFORMATION	
Trade Name: DIMAVAL	Other Name: DMPS (2,3-dimercapto-1-propane sulfonate)
Manufacturer: Heyl (www.heyl-berlin.de)	PO#:
Route of Administration: ORAL ☐ I.V. ☒ I.M. ☒ TOPICAL ☐ S.C. ☐ OTHER:	
Dosage Form: TAB ☐ CAP ☐ LIQUID ☒ POWDER ☐ CREAM ☐ OINT. ☐ PATCH ☐ OTHER:	

SECTION C: PATIENT-PRODUCT TRACKING INFORMATION

INDICATION _____ **STRENGTH**_____ **QUANTITY**_____
(I.E. SPECIFIC NUMBER OF VIALS/TABS)

1ST FUTURE USE REQUEST: YES X NO ☐

IF NO,

1. PLEASE PROVIDE A LIST OF PATIENTS WHO RECEIVED THE PREVIOUS SUPPLY IN THE TABLE BELOW.

2. IF REPLACING EXPIRED STOCK PLEASE CHECK HERE ☐

PATIENT INITIALS (E.G. A.B.C.)	DOB (DD/MM/YYYY)	GENDER	INDICATION FOR USE OF DRUG	NEW OR REPEAT PATIENT VIA THE SAP FOR THIS DRUG?	QUANTITY RELEASED (E.G. ## TABS)	DATE ADMINISTERED (DD/MM/YY)
	/ /	M ☐ F ☐		N ☐ R ☐		/ /
	/ /	M ☐ F ☐		N ☐ R ☐		/ /
	/ /	M ☐ F ☐		N ☐ R ☐		/ /

SECTION D: CLINICAL RATIONALE
1a) Please specify the circumstances in which the drug will be used including information on conventional therapies considered, failed or that are unavailable to achieve an adequate response. Explain why this product is needed on a future use basis.
DMPS would be used in the setting of acute heavy metal poisoning (ie. lead Pb encephalopathy, mercuric Hg salt poisoning or inorganic arsenic As poisoning). In lead encephalopathy, a seizing patient cannot wait for treatment. In mercuric salt or inorganic arsenic poisoning, a vomiting patient is unable to tolerate an oral chelator.) The only metal chelator approved for use for Pb, Hg and/or As is BAL, which 1. Is known to mobilize lead TO the brain and so, without another chelator could make a patient worse, 2. Has poor absorption from muscle in a hypotensive patient with GI corrosion from Hg or As 3. Is formulated as a deep IM injection in peanut oil when there is significant peanut allergy in the population would potentially leave a heavy metal patient without any therapy while a Special Access application was forwarded and approved. BAL has been on back order in the recent past. b) What specifically about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s)? Please explain.
DMPS is a heavy metal chelator available by compounding in the US and by approval in Europe for the treatment of acute heavy metal poisoning. DMPS can be given intravenously for reliable absorption. DMPS has an efficacy profile that includes best results (increased heavy metal mobilization) when given early following clinical suspicion of exposure (within 6 hours) as compared to mobilization when given even as late as 24 hours after an exposure. Heavy metal levels are NEVER available to the clinician at the time that the exposure has occurred and can take days to weeks for results. DMPS has a safety profile that is superior to that of the chelator currently approved for sale in Canada (BAL) and is not formulated in peanut oil avoiding potential peanut allergy problems. DMPS can bridge to treatment with the oral chelator DMSA when the patient is stabilized enough to take medications by mouth and when DMSA can be obtained through Special Access.
2) Please provide **specific** data, references and/or resources in your possession, with respect to the use safety and efficacy that support your decision to prescribe this drug. For citations please include journal/article titles, author(s), volume, issue, date and page information. Check here if reference(s) is/are attached ☐
Bjorklund G, Mutter J, Aaseth J. Metal chelators and neurotoxicity: lead, mercury and arsenic. Arch Toxicol. 2017: 91; 3787-97. Chisolm JJ, Thomas DJ. Use of 2,3-dimercaptopropane-1-sulfonate in treatment of lead poisoning in children. J Pharm Exper Therapeutics. 1985: 235(3); 665-9. Kosnett MJ. The role of chelation in the treatment of arsenic and mercury poisoning. J Med Toxicol. 2013: 9; 347-54.

Dimaval is available in 5 mL ampules, each containing 250 mg of DMPS-Na. The usual dose, depending on the severity of the poisoning would be 250 mg IV slowly over 5 minutes, q6-8h. The maximum adult daily dose would be 2000 mg per day.

SECTION E: PRACTITIONER ATTESTATION	
I, the practitioner, am accessing this non-marketed drug for use in the emergency treatment of a patient under my care in accordance with the *Food and Drug Regulations* C.08.010.	
I, the practitioner, am aware that by accessing this drug through the SAP, the sale of the drug is exempt from all aspects of the *Food and Drugs Regulations* including those respecting the safety, efficacy and quality.	
I, the practitioner, agree to provide a report on the results of the use of the drug including information on Adverse Drug Reactions and, on request, to account for quantities of the drug received.	
Practitioner's Signature:	**License #:**
	Date:

Special Access Programme Therapeutic Products Directorate c/o Health Canada AL 3105 A Tunney's Pasture Ottawa, ON K1A 0K9	**FAX all requests to (613) 941-3194** For urgent requests requiring immediate attention please follow up with a call to the SAP at: **(613) 941-2108**	**AUTHORIZATION ONLY VALID WITH SIGNATURE & SAP STAMP**
website: http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index_e.html **email: sapdrugs@hc-sc.gc.ca**		