Bills Committee on Air Pollution Control (Amendment) (No. 2) Bill 2013

Follow-up actions required of the Administration

(as at 6 November 2013)

The Administration's response to the information requested by members at the meeting on 5 November 2013:

1. In relation to Chinese medicine –

- (a) if a proprietary Chinese medicine contains any kind of asbestos or asbestos containing material in the medicine's formula, whether such information will be expressly stated on the drug label of the medicine concerned;
- (b) the demand for proprietary Chinese medicines and Chinese herbal medicines which contain asbestos or asbestos containing material in Hong Kong; and
- (c) whether there are substitutes to the medicines that are mentioned in paragraph (b) above.
- The Department of Health has advised that according to section 26(2) of the Chinese Medicines Regulation (Cap. 549F), except as otherwise provided in section 26(3) and (4), a label on a package of a proprietary Chinese medicine (pCm) to be sold in Hong Kong, whether being the outermost package to be sold or distributed to an ultimate user of the medicine or otherwise, shall include the following particulars, at least in Chinese
 - (a) the name of the medicine;
 - (b) if
 - (i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredients; or
 - (ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients;
 - (c) the name of the country or territory in which the medicine is produced;
 - (d) the registration number of the medicine as specified in its certificate of registration;
 - (e) if the package –

- (i) is the outermost package, the name of the holder of the certificate of registration of the medicine as specified in the certificate; or
- (ii) is not the outermost package, either the particulars set out in paragraph (e)(i) or the name of the manufacturer who produces the medicine;
- (f) its packing specification;
- (g) its dosage and method of usage;
- (h) its expiry date; and
- (i) its batch number.

Hence, if a pCm is composed of less than 3 kinds of active ingredients with asbestos containing material being one of active ingredients, the name of the asbestos containing active ingredient shall appear on the label.

On the other hand, if a pCm is composed of 3 or more kinds of active ingredients, the name of the asbestos containing active ingredient may or may not appear on the label as the registration holder only have to show the names of more than half of the total number of active ingredients.

1(b) 'Tremolitum' (陽起石) and 'actinolitum' (陰起石) are the two types of Chinese herbal medicines (Chm) that are asbestos-containing ingredients.

As of 11 Nov 2013, there are a total of 36 pCm containing 'tremolitum'(陽起石) registered in Hong Kong. There is no record of registered pCm that has 'actinolitum' (陰起石).

The Department of Health does not have information on the trading or sales volume of the pCm.

1(c) According to the literature, e.g.《中華本草》, the functions of both 'tremolitum' (陽起石) and 'actinolitum' (陰起石) are to warm kidney and strengthen yang (温腎壯陽).

Regarding Chm, some other kinds of yang-replenishing (補陽藥) Chm, such as 淫羊藿、巴戟天、杜仲、莬絲子、補骨脂 and 鹿茸 etc., would have similar functions. Chinese Medicine Practitioners may consider using these substitutes during prescription.

Regarding pCm, 'tremolitum' has been used as one of the active ingredients in traditional formulation for long. There is no Chinese medicine theory to support replacing 'tremolitum'(陽起石) with other Chm in the traditional formulary, and there is a lack of scientific support including comparison studies for such replacement. In addition, different diseases may come with different mechanisms despite presenting similar symptoms, and hence the treatment should involve corresponding medications. A comparable substitution therefore may not be possible.

2. Apart from proprietary Chinese medicine, whether any asbestos or asbestos containing material can be found in the formulae of other types of medicine (such as Chinese herbal medicine) or pharmaceutical products which can be legally supplied or consumed in Hong Kong.

The Department of Health has advised that as of 11 Nov 2013, there is no pharmaceutical product registered under the Pharmacy and Poisons Ordinance (PPO) (Cap. 138) that contains asbestos or asbestos containing materials.

As mentioned above, 'tremolitum' (陽起石) and 'actinolitum' (陰起石) are the only two types of Chm that are asbestos containing materials. 'Tremolitum' (陽起石) is listed on Schedule 2 to the Chinese Medicine Ordinance (CMO) (Cap. 549). On the other hand, 'actinolitum' (陰起石) is not listed on either Schedule 1 or 2 to the CMO and is therefore not subject to regulation under the CMO.

The Chinese Medicine Council of Hong Kong recommended to ban the use and prescribing of 'tremolitum' (陽起石) and 'actinolitum' (陰起石) in Chm but does not consider it necessary to ban pCm containing these ingredients.

3. The recent statistics in Hong Kong on the quantity of goods in transit and transshipment which contained asbestos materials.

The Census and Statistics Department provides import and export statistics of asbestos containing materials (mainly including asbestos cement products, fabricated clothing and friction products) but has not compiled statistics on goods in transit and transhipment which contain asbestos materials.

The import and export of asbestos containing materials have declined in

the past five years as shown below:

	2008	2009	2010	2011	2012
Import (Tonnes)	250.8	37.3	35.4	48.2	21.1
Export (Tonnes)	6	63.5	0.3	0.1	0.15

- 4. In relation to qualified asbestos professionals, including asbestos consultants, contractors and supervisors who are registered under the Air Pollution Control Ordinance (Cap. 311) ("APCO")
 - (a) the requirements for being such qualified professionals;
 - (b) the number of such professionals in Hong Kong who are qualified to engage in the demolition works of building structures involving asbestos containing materials;
 - (c) the range of fees for carrying out the aforesaid demolition works; and
 - (d) whether the duration of carrying out such works, including the time which the Administration may spend on handling any relevant plans submitted by any of such qualified professionals, is regulated by legislation.
- 4(a) The Environmental Protection Department (EPD) has advised that the requirements for being such qualified professionals are as follows:

For <u>registered asbestos consultants</u>, the requirements include a recognized bachelor degree in science, engineering, architecture, building or building surveying or other recognized qualification; not less than 12 months' recognized working experience in asbestos abatement and management work since obtaining the abovementioned qualification; completed a recognized course of training in asbestos investigation, management planning and project design, or recognized equivalent training. The consultants must also have demonstrated to the satisfaction of the Asbestos Administration Committee that they are competent to perform the duties and functions of asbestos investigation, management and supervision of asbestos works.

For <u>registered asbestos contractors</u>, the requirements include at least one registered asbestos supervisor under their employment at any one time; possessing high efficiency particulate air filtered

appliances, personal protective gear and other tools and equipment in such number and type and with such specifications as to be able to perform effectively asbestos abatement work in a pressure environment; possessing gauge managerial and technical skills as to be able to support effective maintenance of equipment and facilities and provision of materials necessary for execution of asbestos management plans, asbestos abatement plans or works involving the use and handling of asbestos containing material on site; and providing continued and professional in-house training to workers for maintenance of a high standard of work. The contractors must also be able to demonstrate to the satisfaction of the Asbestos Abatement Committee that they are competent to perform the duties and functions of carrying out asbestos abatement work in accordance with relevant codes of practice and asbestos abatement plan, maintaining good working practices and housekeeping at work site, maintaining specialized equipment in good working condition, maintaining a maintenance programme for the specialized equipment and keep records and usage logs, handling and disposing of asbestos wastes in accordance with relevant codes of practice and legislation, provide continued and professional in-house training to workers, and maintain records of medical surveillance programme and training programme for workers.

For registered asbestos supervisors, the requirements include having been educated to Form 5 or above and not less than 12 months' recognized working experience in asbestos abatement work, and having completed a recognized course of training comprising lectures and practical sessions in the nature and use of asbestos, legislation and codes of practice relating to asbestos, personal protection, abatement methods and the use and maintenance of equipment relating to asbestos. They must also have demonstrated to the satisfaction of the Asbestos Administration Committee that they are competent to perform the duties and functions of supervising the carrying out of an asbestos abatement work in accordance with relevant codes of practice and asbestos abatement plan, providing training to workers, maintaining specialized equipment in good working condition, and handling and disposing of asbestos wastes in accordance with relevant code of practice and legislation.

For <u>registered asbestos laboratories</u>, the requirements include accreditation for the relevant asbestos tests by the Hong Kong Laboratory Accreditation Scheme (HOKLAS) managed by the

Commissioner for Innovation and Technology on behalf of the Government or by a scheme with which HOKLAS has a mutual recognition agreement. They must also satisfy the Asbestos Administration Committee that they are competent to perform the duties and functions required of registered asbestos laboratories, that is being able to carry out sampling of substances suspected to be asbestos containing materials, identifying asbestos in bulk samples and production of test report for inclusion in an asbestos investigation report, carrying out sampling of asbestos air-borne fibres and dust, in accordance with instructions and air sampling plan from a registered asbestos consultant, etc.

- 4(b) As of 7 November 2013, there are 37 Asbestos Consultants, 9 Asbestos Contractors, 49 Asbestos Supervisors and 2 Asbestos Laboratories, totalling 97 asbestos professionals that are qualified and registered with the EPD to engage in asbestos abatement works.
- The cost of an asbestos removal work is determined by the market. 4(c) The actual costs vary with the size and complexity of the work. For the more common removal work involving asbestos corrugated asbestos cement sheets (CACS), the cost could be significantly reduced if the owners in the same building join together to hire one registered asbestos contractor for the work. As an indicative reference, it may cost about \$6,000 per flat to remove a typical canopy or cage with CACS not longer than 5 metres in length, provided that scaffolding is available and there are more than ten such flats in the same building. Removal of a CACS canopy or cage for a single flat will be more expensive, at around \$10,000 as the individual owner needs to bear all the overhead costs. It is always advisable to approach a few of the registered asbestos contractors to obtain and compare the quotations before commissioning the work.
- According to section 69 of the Air Pollution Control Ordinance (APCO), if one needs to carry out asbestos abatement work, he must employ a registered asbestos consultant to conduct an asbestos investigation and prepare an asbestos investigation report (AIR) and an asbestos abatement plan (AAP), and submit the AIR and AAP to EPD at least 28 days before he starts the asbestos abatement work. According to sections 73 and 75 of the APCO, he must also notify EPD in writing of the date of commencement of the asbestos work at least 28 days in advance and employ a registered asbestos contractor to carry out the asbestos work in accordance with the asbestos abatement plan. The EPD may

consider relaxation of the said notification periods on individual merits. The considerations involved are avoidance of interruption to public service, avoidance of impact to public health, etc.

- 5. In relation to section 78 of the APCO and the proposed section 78, the Administration's considerations with respect to
 - (a) the amendments as stated in the proposed section 78(1)(b); and
 - (b) the addition of the proposed section 78(2).
- 5(a) The EPD and Department of Justice (DoJ) have advised that section 78(1)(b) of the APCO is as follows
 - "A person does not commit an offence under section 77 if he adduces evidence that shows—

. . .

(b) he did not know and could not have reasonably known of the presence of <u>asbestos</u> <u>containing material</u> at the time when he carried out the work, or caused or permitted the work to be carried.".

The new section 78 reads –

"(1) It is a defence for a person charged under section 77 in respect of any work in the premises or any part of the premises if the person establishes that—

. . .

(b) the person did not know and could not have reasonably known of the presence of <u>asbestos</u> <u>containing material</u> in the premises or that part of the premises at the time when the person carried out the work, or caused or permitted the work to be carried out."

The key difference between the extant provision and the revised provision is the deletion of the words "asbestos or".

Section 78 of the APCO is a defence provision in relation to an offence under section 77 of APCO. The offences under section 77 of the APCO are –

- "(1) A person who implements or causes the implementation of an asbestos management plan or asbestos abatement plan contrary to section 74 commits an offence.
- (2) A person who implements or causes the implementation of an asbestos management plan or carries out or causes the carrying out of work involving the use or handling of **asbestos containing material** contrary to section 75 commits an offence.
- (3) A person who carries out or causes the carrying out of the sampling, measurement or analysis of a substance containing or suspected to contain <u>asbestos containing</u> <u>material</u> contrary to section 76 commits an offence.
- (4) A person who does not follow the specifications, steps or measures specified in an asbestos management plan or an asbestos abatement plan and any additional measures or steps stipulated by the Authority and any conditions imposed on the plan by the Authority commits an offence."

The offences under section 77(1) and (4) of the APCO are related to an asbestos management plan or asbestos abatement plan. Section 71(1) of the APCO provides for matters concerning an asbestos management plan, and section 69(1) of the APCO provides for matters concerning an asbestos abatement plan. Both provisions mention asbestos containing material only but not asbestos. The offences under section 77(2) and (3) of the APCO are also related to asbestos containing material only. Since the offences under section 77 are all related to asbestos abatement work which do not relate to raw asbestos in mineral form, the words "asbestos or" in the extant section 78(1)(b) of the APCO are proposed to be removed in the new section 78(1)(b) of the APCO.

5(b) The EPD and Department of Justice (DoJ) have advised that section 78 of the APCO is to provide a defence to the offences created under section 77 of the APCO. The policy intent is to

impose an evidential burden instead of a legal (or persuasive) burden on the defendant in relation to a fact that needs to be established for the defence. The new section 78(2) of the APCO provides that the defendant is taken to have established any fact that needs to be established for a defence under section 78(1) if there is sufficient evidence to raise an issue with respect to the fact, and the contrary is not proved by the prosecution beyond reasonable doubt. The new section 78(2) is added to the APCO to reflect the policy intent and make it explicit that merely an evidential burden is imposed on the defendant. This is in line with paragraph 6.2.18 of the Guide to Styles and Practices published by the Law Drafting Division. Also, since the new section 78(2) would expressly provide that section 78 of the APCO merely imposes an evidential burden on the defendant, it makes it clear that the offence is compatible with the right to be presumed innocent guaranteed by article 87(2) of the Basic Law, and article 11(1) of the Hong Kong Bill of Rights. Similar provisions to the new section 78(2) of the APCO can be found in section 4(5) of the Prevention of Child Pornography Ordinance (Cap. 579). Other precedents include section 43Q(5) of the Employment Ordinance (Cap. 57); section 44(6) of the Mandatory Provident Fund Schemes Ordinance (Cap 485) and section 141(5) of the Lifts and Escalators Ordinance (Cap 618).

6. In relation to the proposed sections 80, 82 and 83 –

- (a) with respect to the term "exempted person" which appears in section 82 and in the light of the Chinese Medicine Ordinance (Cap. 549) ("CMO"),
 - (i) the persons who are exempted under section 158(1) of the CMO from the application of section 119 of the CMO;
 - (ii) the Administration's considerations in proposing that the proposed section 80 would not be applicable to any such person.
- (b) with respect to the proposed sections 82(3) and 82(4), given that the term "asbestos" does not appear in the two respective subsections, it seems that the proposed section 80 (which concerns both asbestos and asbestos containing material) would be applicable to an exempted person for a proprietary Chinese medicine who conducts any of the activities stated in the said subsections in relation to asbestos

but not to such person who conducts the same kinds of activities in relation to asbestos containing material. In the light of the aforesaid, the Administration's considerations in drafting the said subsections;

- (c) with respect to the proposed section 82, information on whether any asbestos, in its pure form, can be used as a medication or pharmaceutical product which can be legally supplied or consumed in Hong Kong;
- (d) with respect to the proposed section 82 and in the light of Schedule 2 to the Hazardous Chemicals Control Ordinance (Cap. 595) ("HCCO"), whether the Administration considers it necessary to extend the scope of the proposed section 82 to cover any asbestos or asbestos containing material which satisfies any of the provisions as stated in paragraph 2 of Part 2 of Schedule 2 to HCCO and the relevant considerations of the Administration; and
- (e) with respect to the proposed section 83, the factors which the Authority will take into account in deciding whether the requirements as stated in the proposed section 83(1)(a) and (b) have been satisfied.
- The Department of Health has advised that it is an offence under section 119 of the CMO to sell or possess any pCm which is not registered. An exemption could be granted under section 158(1) of the Ordinance to a person or institution concerned with **education or scientific research** from the application of section 119 if the pCm in question is required for the purposes of education or scientific research. As such, it is proposed that the proposed section 80 also provides the exemption to any such person.
- 6(b) The EPD and DoJ have advised that the exemptions under the proposed sections 82(3) and 82(4) only apply in relation to asbestos containing material (as opposed to pure asbestos minerals) that is a proprietary Chinese medicine.

Under section 2 of the CMO, a proprietary Chinese medicine must be a "proprietary <u>product</u>" which is <u>formulated in a finished dose form</u>. A proprietary Chinese medicine is therefore a "product" that can only be classified as asbestos containing material. This is the reason for qualifying "proprietary Chinese medicine" solely by "asbestos containing material" in the proposed section 82(3) and

- 6(c) The Department of Health has advised that there is no pCm registered under the CMO or pharmaceutical product registered under the Pharmacy and Poisons Ordinance (Cap. 138) that contains asbestos in its pure form.
- The EPD has advised that the Hazardous Chemical Control 6(d) Ordinance (HCCO) (Cap. 595) has been enacted in the local context by transposing the requirements of the Stockholm Convention on Persistent Organic Pollutants or the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The HCCO introduces a permit system to regulate the hazardous chemicals listed in the aforementioned international conventions. Paragraph 2 of Part 2 of Schedule 2 to HCCO lists out the conditions (e.g., if the chemical is or is a part of manufactured products, pesticides, foods, additive, pharmaceutical products, etc.) that the permit system does not apply to type 2 chemicals, which include asbestos. For the control of asbestos, the scope of the HCCO is more limited than that of APCO as the former does not apply to manufactured products, pesticides, foods, additive, pharmaceutical products, etc.. Hence, some common asbestos containing materials such as corrugated asbestos cement sheets are controlled under the APCO but not the HCCO.

The policy intention of the Air Pollution Control Ordinance (Amendment)(No. 2) Bill 2013 is to ban all asbestos and asbestos containing materials (e.g. manufactured products) except goods in transit, pCm and work carried out in an industrial undertaking as stated in the proposed section 82. Extension of the scope of exemption in the Bill to cover any asbestos or asbestos containing material which satisfies any of the provisions as stated in paragraph 2 of Part 2 of Schedule 2 to HCCO will result in the exemption of some common asbestos containing materials such as corrugated asbestos cement sheets under the APCO. Such proposal is against the policy intention of the Bill.

6(e) The EPD has advised that the proposed section 83(1) is as follows:

"On application, the Authority may exempt a person from a prohibition imposed under section 80(1) if the Authority considers that the exemption –

(a) is warranted; and

(b) would be unlikely to lead to a health risk to the community.".

In consideration of whether the proposed section 83(1)(a) have been satisfied, i.e. whether the exemption is warranted, the Authority will take into account of the following factors:

- (1) whether an asbestos free substitute is available,
- (2) whether there will be serious disruption to a public service if the application for exemption is not granted; and
- (3) whether there will be serious safety problem or risk to human life if the application for exemption is not granted.

In consideration of whether the proposed section 83(1)(b) have been satisfied, i.e. whether the exemption would be unlikely to lead to a health risk to the community, the Authority will take into account of the following factors:

- (1) the quantity of the asbestos or asbestos containing material (ACM) involved;
- (2) the precautionary measures to be taken to prevent release of asbestos into the air;
- (3) the location and activity involved; and
- (4) the likelihood the asbestos or ACM involved will be disturbed.

Environment Bureau/Environmental Protection Department 18 November 2013