Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Reference materials for the Code of Practice/Code of Conduct and the proposed requirement of the written order of drugs

At the meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") on 4 July 2014, Members inquired about the background information relating to the Codes of Practice / Code of Conduct and the proposed requirement of placing drug orders in written form. The Administration now provides the relevant reference materials for Members' reference.

Codes of Practice ("COPs")/ Code of Conduct ("COC")

2. In response to recommendations no. 11, 21 and 32 in the report of the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("Review Committee"), we propose to empower the Pharmacy and Poisons Board ("the Board") to promulgate corresponding COPs and COC in order to provide practical guidance to different licensed traders and traders subject to registration requirement (including manufacturers, wholesalers and retailers), as well as registered pharmacists; and enhance the monitoring of the conduct of their activities. The Board has a well-established mechanism in place for consultation with the trade and relevant stakeholders in drafting, issuing and revision of any COPs/COC.

3. As a matter of fact, some existing ordinances also empower relevant authorities to issue COPs, for examples:

(i) section 26 of the Supplementary Medical Professions Ordinance (Cap. 359);
(ii) section 6 of the Chiropractors Registration Ordinance (Cap. 428);
(iii) section 6 of the Veterinary Surgeons Registration Ordinance (Cap. 529);
(iv) section 3 of the Broadcasting Ordinance (Cap. 562); and
(v) section 29 of the Unsolicited Electronic Messages Ordinance (Cap. 593)

The relevant provisions of the above ordinances are at **Annex 1**.

The requirement to place drug orders in written form

4. The proposed requirement will be added to the COPs of relevant licensed traders. As the Administration has repeatedly pointed out, the Hong Kong Medical Association ("HKMA") reviewed the Good Dispensing Practice Manual ("GDP Manual") in 2007 and recommended that the ordering of drugs from suppliers should be made in writing and the written orders should be kept for verification upon delivery of the drugs and for future reference (extract at **Annex 2A**). A sample drug ordering form has also been provided in the GDP Manual to serve as a reference for practising doctors (extract at **Annex 2B**) As recommended by the Medical Council of Hong Kong in the Code of Professional Conduct (extract at **Annex 2C**), all practising doctors should comply with the GDP Manual.

5. We wish to emphasise that the acceptable means of placing drug orders in written form, in addition to mail and fax, **also include various kinds of retainable electronic records** (e.g. e-mails and textual messages). To facilitate the trade to adapt to the relevant requirement, the Board is considering implementing the requirement by phases. For instance, in the initial stage of implementation, the requirement would only apply to antibiotics, dangerous drugs, and drugs in Part I of the Poisons List of the Poisons list Regulations (Cap. 138B). The Board will later consider extending the requirement to drugs with lower risk, such as drugs in Part II of the Poisons List and drugs not included in the Poisons List.

6. We consider that the relevant requirement would assist the entire drug supply chain (i.e. every step from the source of supply to patients) to establish a complete set of movement records of drugs, in order to facilitate the tracing of the sources of drugs and minimise errors in the delivery and receipt of drugs. In fact, in the "Good Distribution Practice of medicinal products for human use" distributed by the European Commission, it is pointed out that good documentation constitutes an essential part of the quality system, and that written documentation should prevent errors from spoken communication and permit the tracking of relevant operations during the distribution of medicinal products. Besides, it is also pointed out in the "Good Distribution Practice for Pharmaceutical Products" issued by the World Health

Organization that written instructions and records which document all activities relating to the distribution of pharmaceutical products should be available.

Food and Health Bureau
16 July 2014

Provisions of existing legislation on empowering the regulation authorities to issue codes of practice and codes of conduct

(i) SUPPLEMENTARY MEDICAL PROFESSIONS ORDINANCE（Cap. 359） section 26

Section:	26	**Boards may prepare Codes of Practice**		30/06/1997

(1) A board may prepare and revise Codes of Practice which shall not be inconsistent with this Ordinance or any regulations made thereunder for the relevant profession for the purposes of this Ordinance- (Amended 70 of 1989 s. 8)

(a) prescribing standards of conduct and practice for persons practising that profession, for the employers of persons practising that profession and the directors of any company carrying on the business of practising that profession;

(b) regulating the activities of persons practising that profession including the activities of such persons in the supervision and control of unqualified persons assisting such persons in the practice of the profession; and

(c) regulating the activities of persons-

(i) who are required to be supervised in the practice of their profession by regulations made under this Ordinance, in the practice of the profession; and

(ii) in the supervision of persons referred to in subparagraph (i), (Added 70 of 1989 s. 8)

and the Codes of Practice may prohibit specified activities.

(1A) Where, under subsection (1), a board-

(a) prepares a Code of Practice, it shall inform the Council in writing that such a Code of Practice has been prepared and serve a copy thereof on the Council; and

(b) revises a Code of Practice, it shall inform the Council in writing of any changes made thereto and serve a copy of the revision on the Council. (Added 70 of 1989 s. 8)

(1B) Any Code of Practice prepared under subsection (1) or any revision of such a code shall not come into operation until the expiration of-

(a) the period of 6 months from the date the Council receives a copy of the Code of Practice or, as may be appropriate, any revision of such a code, served pursuant to subsection (1A); or

(b) such shorter period as may be agreed by the Council and the board concerned. (Added 70 of 1989 s. 8

(2) The secretary of the board shall cause a copy of a Code of Practice and each revision thereof to be served upon each person registered in respect of the profession to which the Code of Practice or revision applies.

(3) A person, who contravenes any Code of Practice prepared or revised under subsection (1) and applicable to his profession, may be subject to inquiries held by a board; but the fact that any matters are not mentioned in a Code of Practice, shall not preclude the board from judging a person to be guilty of unprofessional conduct by reference to those matters. (Amended 67 of 1985 s. 12; 68 of 1995 s. 35)

(ii) CHIROPRACTORS REGISTRATION ORDINANCE（Cap. 428）section 6

Section	6	**Powers of the Council**		30/06/1997

The Council may-

(a) create and appoint members of committees to advise the Council on the carrying out of the powers and functions of the Council;

(b) issue a Code of Practice and make rules for the professional conduct and discipline of registered chiropractors;

(c) make such further rules as may be required by, or by virtue of, this Ordinance

(iii) VETERINARY SURGEONS REGISTRATION ORDINANCE（Cap. 529）section 6

Section	6	**Powers of the Board**	E.R. 2 of 2012	02/08/2012

The Board may-

(a) create, and appoint members of, committees to advise the Board on the carrying out of the powers and functions of the Board;

(b) issue a Code of Practice and make rules for the professional conduct and discipline of registered veterinary surgeons;

(c) make such further rules as may be required by, or by virtue of, this Ordinance.

(iv) BROADCASTING ORDINANCE（Cap. 562）section 3

Section	3	**Approval of codes of practice by Authority***	E.R. 2 of 2012	02/08/2012

Note： * (Amended 17 of 2011 s. 28)

(1) Subject to subsection (8), for the purpose of providing practical guidance for licensees in respect of any requirements under this Ordinance imposed on licensees or in respect of licence conditions, the Authority may- (Amended 17 of 2011 s. 28)

(a) approve and issue such codes of practice (whether prepared by it or not) as in its opinion are suitable for that purpose; and

(b) approve such codes of practice issued or proposed to be issued otherwise than by it as in its opinion are suitable for that purpose.

(2) Where a code of practice is approved under subsection (1), the Authority shall, by notice in the Gazette- (Amended 17 of 2011 s. 28)

(a) identify the code concerned and specify the date on which its approval is to take effect; and

(b) specify for which of the requirements under this Ordinance or licence conditions the code is so approved.

(3) The Authority may- (Amended 17 of 2011 s. 28)

(a) from time to time revise the whole or any part of any code of practice prepared by it under this section; and

(b) approve any revision or proposed revision of the whole or any part of any code of practice for the time being approved under this section,

and the provisions of subsection (2) shall, with the necessary modifications, apply in relation to the approval of any revision under this subsection as they apply in relation to the approval of a code of practice under subsection (1).

(4) The Authority may at any time withdraw its approval from any code of practice approved under this section. (Amended 17 of 2011 s. 28

(5) Where under subsection (4) the Authority withdraws its approval from a code of practice approved under this section, it shall, by notice in the Gazette, identify the code concerned and specify the date on which its approval of it is to cease to have effect. (Amended 17 of 2011 s. 28.

(6) References in this Ordinance to a ***Code of Practice*** are references to that code as it has

effect for the time being by virtue of any revision of the whole or any part of it approved under this section.

(7) The power of the Authority under subsection (1)(b) to approve a code of practice issued or proposed to be issued otherwise than by it shall include power to approve a part of such a code and, accordingly, in this Ordinance ***Code of Practice*** may be read as including a part of such a code. (Amended 17 of 2011 s. 28)

(8) The Authority shall, before approving a code of practice under subsection (1) or any revision or proposed revision of the code under subsection (3), consult with- (Amended 17 of 2011 s. 28)

(a) such bodies representative of licensees to which the code or the code as so revised, as the case may be, will apply (whether in whole or in part), (Amended 17 of 2011 s. 28)

(b) (Repealed 17 of 2011 s. 28)

as it thinks fit.

(9) For the avoidance of doubt, it is hereby declared that different codes of practice may be approved under subsection (1) for different classes of licensees, and may be so approved for the same or different requirements mentioned in that subsection or licence conditions

(Amended 17 of 2011 s. 28)

(v) UNSOLICITED ELECTRONIC MESSAGES ORDINANCE(Cap. 593)section 29

Section	29	**Authority may approve codes of practice***	E.R. 2 of 2012	02/08/2012

Note： * (Amended 17 of 2011 s. 28)

(1) Subject to subsection (3), for the purpose of providing practical guidance in respect of the application or operation of any provision of this Ordinance, the Authority may —

(Amended 17 of 2011 s. 28)

(a) approve and issue such codes of practice (whether prepared by it or not) as in its opinion are suitable for that purpose; and

(b) approve such codes of practice issued or proposed to be issued otherwise than by it as in its opinion are suitable for that purpose.

(2) A code of practice —

(a) may consist of a code, standard, rule, specification or any other documentary form of practical guidance prepared by the Authority or other body or authority; and

(b) may apply, incorporate or refer to any document that has been formulated or published by a body or authority either as in force at the time the document is approved by the Authority or as amended, formulated or published from time to time.

(3) Where a code of practice is approved under subsection (1), the Authority shall, by notice published in the Gazette — (Amended 17 of 2011 s. 28)

(a) identify the code concerned and specify the date on which its approval is to take effect; and

(b) specify the provision or provisions of this Ordinance for which the code is so approved.

(4) The Authority may — (Amended 17 of 2011 s. 28)

(a) from time to time revise the whole or any part of any code of practice prepared by it under this section; and (Amended 17 of 2011 s. 28)

(b) approve any revision or proposed revision of the whole or any part of any code of practice for the time being approved under this section.

5) The provisions of subsection (3) shall, with the necessary modifications, apply in relation to any revision or approval under subsection (4) as they apply in relation to the approval of a code of practice under subsection (1).

(6) The Authority may at any time withdraw its approval from any code of practice approved under this section. (Amended 17 of 2011 s. 28)

(7) Where under subsection (6) the Authority withdraws its approval from a code of practice approved under this section, it shall, by notice published in the Gazette, identify the code concerned and specify the date on which its approval is to cease to have effect. (Amended 17 of 2011 s. 28)

(8) References in this Ordinance to an approved code of practice are references to that code as approved under this section and as it has effect for the time being, including by virtue of any revision of the whole or any part of it approved under this section.

(9) The power of the Authority under subsection (1)(b) to approve a code of practice issued or proposed to be issued otherwise than by it shall include the power to approve a

part of such a code and, accordingly, in this Ordinance, ***code of practice*** may be read as including a part of such a code. (Amended 17 of 2011 s. 28)

(10) A code of practice approved under this section and a notice published under subsection (3) or (7) are not subsidiary legislation

(Amended 17 of 2011 s. 28)

5 STORES PROCUREMENT AND STOCK MANAGEMENT

Stores procurement

The Doctors in-charge are responsible for the requisition of pharmaceutical stores. It is recommended that the ordering of drugs from suppliers be made in writing, the written order to be kept for checking by the doctor against the drugs delivered and for future reference. (A sample order form is attached on P.16 for reference.)

Stock management

The purpose of good stock management is to bring about a safe and effective dispensing service. Over-stocking of stores should be avoided and optimum stock quantities should be maintained to ensure a continuous supply. To ensure proper stock management, the following measures are recommended:

1. To ensure that the correct medicine is received:
   a. The medicine label, including the expiry date, should be checked before receiving stores.
   b. Unlabelled medicines should be rejected and the supplier should be informed of it.
2. To avoid mixing-up of medicines:
   a. Medicines for internal use should be stored separately from medicines for external application.
   b. External products should be distinctively labeled with the cautionary statement "For External Use Only".
   c. The label of a medicine should be checked before putting it on the shelf.
   d. Similar looking medicines should be stored separately from each other.
   e. Different strengths of the same medicine should be highlighted appropriately to avoid mixing-up.
   f. Staff should be notified if the shape and/or colour of any medicine has been changed.
   g. Expired medicines should be labeled properly and put aside for proper disposal as chemical waste according to the guidelines of the Environmental Protection Department.
3. To avoid product deterioration:
   a. Medicines should be stored in a clean and good condition.
   b. The temperature of the store and the refrigerator should be regularly checked.
4. To ensure effective use of stock:
   a. Stock rotation should be carried out right after stores receiving.
   b. The expiry dates of medicines should be regularly monitored.
5. To ensure safe custody of Dangerous Drugs:
   a. Dangerous Drugs should be stored separately under lock and key.

MEDICAL PRODUCTS ORDER FORM

From : Dr _____

To : _____

Date : _____

This is to place an order for the following medical product(s):

1. _____

2. _____

3. _____

4. _____

Please confirm by replying to Dr / Ms _____

Tel : _____ or _____

Fax : _____

_____

(Signature / Chop)

Dr _____

not be presented in such a way that it furthers the professional interests of the doctors concerned, or attracts patients to their care.

7. Specialist title

7.1 Only doctors on the Specialist Register are recognized as specialists, and can use the title of "specialist in a specialty". A specialist can claim himself as a specialist only in the specialty under which he is included in the Specialist Register but not other specialties.

7.2 Doctors who are not on the Specialist Register cannot claim to be or hold themselves out as specialists. A non-specialist is not allowed to use any misleading description or title implying specialization in a particular area (irrespective of whether it is a recognized specialty), such as "doctor in dermatology" or "皮膚醫生".

8. Information about medical innovations

8.1 Doctors who directly or indirectly release information to the public on new discoveries, inventions, procedures, or improvements should ensure beforehand that:-

(a) the relevant medical innovation has been adequately tested;

(b) the value of the innovation is evidence-based;

(c) the evidence-based research has been properly documented and completed with peer approval. It is the duty of the author to seek peer approval from the relevant professional or academic bodies;

(d) the ethical guidelines under sections 5.2.1 and 22 are observed; and

(e) it is not implied that the doctor may be consulted by individual patients.

C. DRUGS

9. Prescription and labelling of dispensed medicines

9.1 A doctor may prescribe medicine to a patient only after proper consultation and only if drug treatment is appropriate.

9.2 A doctor who dispenses medicine to patients has the personal responsibility to ensure that the drugs are dispensed strictly in accordance with the prescription and are properly labelled before they are handed over to the patients. The doctor should establish suitable procedures for ensuring that drugs are properly labelled and dispensed. Doctors are advised to observe the provisions of the Good Dispensing Practice Manual issued by the Hong Kong Medical Association.