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## PRINCIPLES OF PHARMACEUTICAL PRESENCE AND DUTY ROSTERS

All pharmaceutical acts must be performed under the actual control of a pharmacist<sup>1</sup>. Each pharmacist must practise his/her profession personally<sup>2</sup>, certain operations cannot be outsourced<sup>3</sup>. In this respect, the Chief Pharmaceutical Officer (CPO) is wholly and entirely responsible for the pharmaceutical activities performed within his/her company. In his/her organisation, the CPO can delegate certain operations to other pharmacists placed under his/her responsibility<sup>4</sup> who meet the conditions for practising pharmacy and whose minimum number is laid down by the Public Health Code<sup>4</sup>.

The pharmaceutical duty roster<sup>5</sup> is a principle which derives from the principle of the continuity of care incorporating the appropriate, continuous supply of medicines in the interests of the patient.

**Pharmaceutical duty roster:** within the framework of his/her whole and entire responsibility **the Chief Pharmaceutical Officer (CPO) or the pharmacist who has received a delegation from the CPO** must be available and must be able to ensure the continuity of pharmaceutical operations, including outside the site's opening hours, and in the event of an emergency (advertising<sup>5</sup>, batch recall, issues on the production line, pharmacovigilance cases<sup>6</sup>, etc.). He /she shall ensure the maintenance, the durability and the regularity of the essential activities of the pharmaceutical establishment concerned. The pharmaceutical duty roster shall be organised on the basis of the presence of a pharmacist or pharmacists during opening hours and on the basis of on-call duty outside opening hours. The Chief Pharmaceutical Officers (or the Acting Chief Pharmaceutical Officer in the absence of the CPO) shall constitute the single contact point forming a permanent link with the authorities<sup>7</sup>.

**Pharmaceutical replacement:** if the Chief Pharmaceutical Officer or the Delegate Pharmacist is absent or incapacitated, the latter shall ensure that another qualified pharmacist (Acting Chief Pharmaceutical Officer, Acting Delegate Pharmacist or Assistant Pharmacist replacing the Delegate) shall perform an actual control of the pharmaceutical acts guaranteeing the continuity and safety of the pharmaceutical operations<sup>8</sup>.

**Pharmaceutical presence:** intervention and action of a pharmacist (Chief Pharmaceutical Officer or **a pharmacist who has received delegation from the CPO**) physically present in the establishment in which he/she performs his/her activity for the execution of the required pharmaceutical operations intervention.

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<sup>1</sup> Articles R. 5124-19 and R. 5124-23 (CPO/Acting CPO) of the Public Health Code

<sup>2</sup> Articles L. 5124-4 and R. 4235-13 of the Public Health Code

<sup>3</sup> Articles L. 5124-47 of the Public Health Code

<sup>4</sup> Articles L. 5124-2 and R. 5124-38 and 40 of the Public Health Code

<sup>6</sup> Article R. 5122-2 of the Public Health Code

<sup>7</sup> Article R. 5121-164 of the Public Health Code

<sup>8</sup> Articles L. 5124-49, R. 5124-55 of the Public Health Code

<sup>9</sup> Articles L. 5124-4, R. 5124-23 and 30 of the Public Health Code

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Based on an analysis of risk, the Chief Pharmaceutical Officer shall map out the pharmaceutical operations by identifying those operations which can be performed/controlled at a distance or those which require an onsite presence; those which must be controlled in real time or those which can be performed upstream or downstream of the operation. This analysis of risk shall be regularly revised in line with the changes which have occurred in the organisation.

During the establishments' opening hours, a minimum, physical pharmaceutical presence shall be determined in line with the results of an analysis of risk (cyclical and structural) which shall be reviewed regularly to reflect the context. The minimum number of assistant pharmacists per establishment shall be defined by the CPO's provisions<sup>4</sup>.

**Pharmaceutical premises:** an authorised pharmaceutical establishment shall be given material reality by a physical place with an address, infrastructures, equipment, specific layouts and qualified personnel enabling the company to perform pharmaceutical acts. These premises shall be situated in one and the same place whose continuity shall not be interrupted by the presence of other premises occupied by third parties<sup>9</sup>.

**Actual control**<sup>10</sup>: all the organisational resources (staffing levels and number of pharmacists<sup>11</sup>), technical or operational resources (emergency plans<sup>13</sup>) implemented by the Chief Pharmaceutical Officer and his/her team to ensure the monitoring, regularity/compliance and validation of the company's pharmaceutical acts.

The actual control of a pharmaceutical act shall not be necessarily defined by the physical, pharmaceutical presence but by the implementation of a system providing for this control on the basis of an analysis of risk (see Pharmaceutical Presence).

**Unannounced inspection:** An inspection conducted by a State-authorized, competent authority of control without prior notice being given to the Chief Pharmaceutical Officer of the pharmaceutical establishment concerned by the inspection.

The Chief Pharmaceutical Officer shall set up an organisation ensuring that the inspection team is received and that the inspection is performed satisfactorily. The Chief Pharmaceutical Officer or, in his/her absence, the Acting CPO shall ask to be contacted as soon as the inspector arrives. The Chief Pharmaceutical Officer, the Acting CPO, the Delegate CPO or the Acting Delegate shall therefore be able to go to the site within a reasonable timeframe or, if required, be in a position to facilitate the inspection at a distance, in whole or in part (videoconferencing tools, etc.).

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<sup>10</sup> Article R. 5124-7 of the Public Health Code

<sup>11</sup> Article R. 5124-19 of the Public Health Code

<sup>12</sup> Article R. 5124-40 of the Public Health Code

<sup>13</sup> Article R. 5124-60 of the Public Health Code