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**A Dose of Reality: The Medicinal Products Regulations 2015**  
**20 December 2016**  
**Peter O’Sullivan**

Dear Editor,

Given the recent events involving a pharmacist on Grafton Street, Dublin who administered a life-saving EpiPen to a girl in anaphylaxis,<sup>1</sup> it seems an opportune time to write to you to discuss the legislative framework controlling the supply of an emergency medicine without a corresponding prescription. It is important to note at the outset of this letter that none of the new laws discussed below amend or repeal the current provisions relating to the protection of ‘good Samaritan’ in Irish law.<sup>2</sup>

The Medicinal Products (No 2) Regulations 2015<sup>3</sup> was passed last year following the tragic death of Emma Sloan in 2013.<sup>4</sup> This came into force on the 15th of October 2015 and amends the Medical Products Regulations 2003.<sup>5</sup> Although some of the 2003 legislation is amended, its provisions pertaining to ‘Exemptions for Emergency Supply’ have not in fact been amended.<sup>6</sup> These provide that a pharmacist must interview the individual concerned and satisfy him/herself that:

- (i) there is an immediate need for the medicine to be supplied;
- (ii) the substance has previously been prescribed;
- (iii) the dose of the medicine can be safely specified.<sup>7</sup>

The wording of the provisions in the 2003 Regulation is very similar to those currently found in the law regulating this area in the UK.<sup>8</sup> While these provisions do address the issue of the supply of emergency medicines to an extent, it is to be welcomed that the previous Government passed the new legislation, giving this matter a more comprehensive and focused assessment.

The new legislation again allows for prescription-only medicines to be supplied in an *emergency* situation without the necessary prescription by trained non-medical individuals or pharmacists.<sup>9</sup> An emergency situation occurs when the ‘physical state of an individual reasonably leads another to suspect that the first individual is experiencing a life-threatening event that requires the provision of immediate care to assist the physiological functioning of that person’.<sup>10</sup>

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<sup>1</sup> Mark Hilliard, ‘Nut Allergy Emergency: Woman Recovers after Grafton Street Injection’ *The Irish Times* (Dublin, 6 October 2016) <<http://www.irishtimes.com/news/health/nut-allergy-emergency-woman-recovers-after-grafton-st-injection-1.2819783>> accessed 19 December 2016.

<sup>2</sup> Civil Law (Miscellaneous Provisions) Act 2011, s 3.

<sup>3</sup> Medicinal Products (Prescription and Control of Supply) (Amendment) (No 2) Regulations 2015, SI 2015/449.

<sup>4</sup> Arlene Harris, ‘I didn’t know what anaphylaxis meant until my daughter died’ *The Irish Times* (Dublin, 6 May 2014) <<http://www.irishtimes.com/life-and-style/the-health-centre/i-didn-t-know-what-anaphylaxis-meant-until-my-daughter-died-1.1784296?mode=sample&auth-failed=1&pw-origin=http%3A%2F%2Fwww.irishtimes.com%2Flife-and-style%2Fthe-health-centre%2Fi-didn-t-know-what-anaphylaxis-meant-until-my-daughter-died-1.1784296>> accessed 19 December 2016.

<sup>5</sup> Medicinal Products (Prescription and Control of Supply) Regulations 2003, SI 2003/540.

<sup>6</sup> *ibid* reg 8.

<sup>7</sup> *ibid* reg 8(2)(a).

<sup>8</sup> Human Medicines Regulations 2012, SI 2012/1916 (UK), reg 225(2).

<sup>9</sup> Regulations 2015 (n 3), reg 4, which inserts reg 4C and reg 4B to Regulations 2003.

<sup>10</sup> *ibid* reg 3(a).

The emphasis of this letter is predominantly on supply by pharmacists, but trained non-medical individuals will now be briefly mentioned for completeness. These are individuals employed or engaged by ‘listed organisations’ (eg an organisation, body, person or group in control of a place of work, sports venue, a commercial aircraft, a local authority, fire service etc)<sup>11</sup> who have completed an accredited course on administering emergency medicines.<sup>12</sup> The Health Products Regulatory Authority will be responsible for maintaining an online register containing the details of all ‘listed organisations’ permitted to obtain and administer these emergency medicines.<sup>13</sup> It is advisable for pharmacists to check this register before supplying emergency medicines to organisations.

The 2015 Regulations now permit pharmacists to provide emergency medicines ‘in the course of their professional practice’ (ie inside or outside the pharmacy premises) to a patient, even if they cannot ascertain whether or not the medication was previously prescribed.<sup>14</sup> The pharmacist must however first complete a training course approved by the Pharmaceutical Society of Ireland on the administration of these medicines and the management of any adverse reactions which may occur.<sup>15</sup> Schedule Eight lists the medicines which are permitted to be used in these emergency situations by pharmacists. These include:

Adrenaline EpiPens - treatment of anaphylaxis

Glucagon - reverse hypoglycaemia

Naloxone - reversal of opioid adverse effects

Salbutamol - acute asthmatic attacks

Glycerol trinitrate - angina.<sup>16</sup>

There are further requirements for a record to be kept detailing the particulars of the medicine administered, and for it to be subsequently furnished to the patient’s general practitioner.<sup>17</sup>

As with any other medical procedure, the patient should give informed consent to the proposed treatment.<sup>18</sup> However, the 2015 Regulation recognises that in emergency circumstances obtaining explicit consent may not be an easy endeavour. Consequently, it is permissible to obtain, where possible, consent from the patient’s representative (ie family or friend) or to assume consent through interaction with the patient concerned when clinical circumstances deem the administration of the emergency medicine necessary.<sup>19</sup>

As the legislation is not drafted in a mandatory manner, it is an entirely voluntary on the part of pharmacies to choose to train their pharmacists in the supply of emergency medicines without a

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<sup>11</sup> *ibid* reg 3(c).

<sup>12</sup> *ibid* reg 4, which inserts reg 4C.

<sup>13</sup> HPRRA, Check the Register (*HPRRA*) <<https://www.hpra.ie/homepage/medicines/emergency-medicines/emergency-medicines-search>> accessed 19 December 2016.

<sup>14</sup> Regulation 2015 (n 3), reg 4.

<sup>15</sup> *ibid*.

<sup>16</sup> *ibid* sch 8.

<sup>17</sup> *ibid* reg 8, which inserts reg 10C.

<sup>18</sup> See further on the issue of ‘informed consent’, Deirdre Madden, *Medicine, Ethics and the Law* (2nd edn, Bloomsbury Professional 2011) 384-388.

<sup>19</sup> Regulation 2015 (n 3), reg 7(e).

prescription. One difficulty caused by this is that an individual who requires such medical assistance may not know which pharmacies in a particular area actually offer these emergency medicines. The legislation is silent on this issue and it is hoped that the Pharmaceutical Society of Ireland will provide some guidance in this respect. In Britain, Community Pharmacy Scotland has undertaken an ‘anaphylaxis campaign’ by requesting its members to stock emergency EpiPens for children and adults. This campaign was backed by former Liberal Democrat MP Jo Swinson, who herself suffered a severe anaphylactic reaction.<sup>20</sup> In order for the public to be able to identify which pharmacies have signed up to this, they must display an orange cross logo stating that anaphylaxis treatment is available in their pharmacy.<sup>21</sup>

In Ireland, between the years 2007 and 2013, 16,722 people died after a heart attack from multiple causes, 359 died from an acute asthma attack, 17 from hypoglycemia and 4 from severe allergic reactions.<sup>22</sup> It is hoped that many pharmacies in Ireland will train their pharmacists in line with the new Regulations, as there is great potential here to save lives.

It has only been one year since the amended law commenced, and already a pharmacy in Grafton Street, which trained its pharmacists in line with the Regulations, has been praised in the media for saving the life of a 17 year old girl suffering from anaphylaxis.<sup>23</sup> The Pharmaceutical Society of Ireland has recently released a guidance document on interpreting the legislation,<sup>24</sup> and highlight the importance of pharmacists educating their patients on the use of emergency medicines, and of carrying these medicines with them at all times. This in itself, they state, will help reduce the possibilities of these emergency situations arising.<sup>25</sup>

In conclusion, even though the topic of emergency medicines was already addressed by the legislature, it is submitted that the new legislation gives a more pragmatic and coherent approach to the supply of prescription-only medicines when an emergency arises.

Is mise le meas,

Peter O’Sullivan

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<sup>20</sup> BBC News, ‘Allergy MP Jo Swinson Backs Anaphylaxis Treatment Scheme’ (*BBC News Glasgow and West Scotland*, 9 August 2013) <<http://www.bbc.com/news/uk-scotland-glasgow-west-23632366>> accessed 19 December 2016.

<sup>21</sup> Community Pharmacy Scotland, ‘Anaphylaxis Campaign’ (*Community Pharmacy Scotland*, 2016) <<http://www.communitypharmacyscotland.org.uk/news,-policy-and-publications/policy/anaphylaxis-campaign/anaphylaxis-campaign/>> accessed 19 December 2016.

<sup>22</sup> Paul Cullen, ‘Public to be Allowed to Administer More Emergency Medicines’ *The Irish Times* (Dublin, 15 October 2015) <<http://www.irishtimes.com/news/health/public-to-be-allowed-administer-more-emergency-medicines-1.2392206>> accessed 19 December 2016.

<sup>23</sup> Hilliard (n 1).

<sup>24</sup> Pharmaceutical Society of Ireland, ‘Guidance for Pharmacists on the Safe Supply and Administration of Prescription-Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency’ (Pharmaceutical Society of Ireland, February 2016)

<[http://www.thepsi.ie/Libraries/Folder\\_Pharmacy\\_Practice\\_Guidance/Guidance\\_for\\_Pharmacists\\_on\\_Supply\\_and\\_Administration\\_of\\_Medicines\\_in\\_an\\_Emergency\\_Final.sflb.ashx](http://www.thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/Guidance_for_Pharmacists_on_Supply_and_Administration_of_Medicines_in_an_Emergency_Final.sflb.ashx)> accessed 19 December 2016.

<sup>25</sup> *ibid* 9.