

Competency based training in Irish psychiatry

Izu Nwachukwu

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The goal of undertaking postgraduate training in psychiatry is to become a competent specialist, and the educational model under which one is trained and assessed is crucial in achieving this goal. Over the years, traditional training models have emphasised what trainees know, over a given period of time, with outcomes assessed mainly by simple recall of knowledge.¹ While these traditional approaches have met with varying levels of success, they are less than optimal when the goal is to train individuals to perform specific, job-related skills.² This recognition has led to a global move towards competency based training models³⁻⁵ where the focus of training and assessment is the mastery of specific knowledge and skills as well as the conduct of the doctor in day-to-day clinical situations. In this article, a general overview of competency-based training in psychiatry is followed by a review of recent developments in Ireland in a global context.

The concept of competency based training

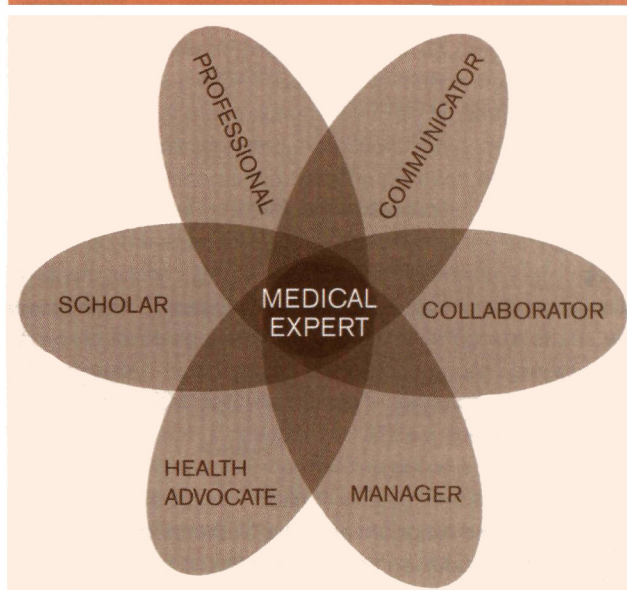
One definition of competency is a combination of related knowledge, skills and attitudes that are necessary for the performance of a major task or function in the work setting. Competence must be demonstrable. It correlates with performance; can be measured against well-accepted standards; and can be improved via training and development.⁶ Competency based training seeks to ensure that trainees completing their programme have achieved learning outcomes that correlate with the ability to provide competent care. The focus is on performance rather than simple recall of knowledge. All core domains of knowledge, skills and attitudes as well as other aspects of the doctor-patient relationship that underpin professionalism are taught and assessed. Under this model, the trainee remains in training until they have been shown to have the required knowledge and skills and can apply them independently.⁷ Compared with traditional approaches, competency-based training potentially leads to an individualised flexible training, transparent standards, and increased public accountability.⁴

*Izu Nwachukwu, MB.BS, MRCPsych, Senior Registrar, St Vincent's University Hospital, Dublin 4, Special Lecturer, UCD Department of Psychiatry & Mental Health Research, Dublin. Chair, Trainees' Committee, College of Psychiatry of Ireland. Chair, Competence-Based Training Working Group, European Federation of Psychiatric Trainees (EFPT). Member of Core Working Group on Competence-Based Training, European Board of Psychiatry. Email: izunwachukwu@hotmail.com.

*Correspondence

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Figure 1: The CanMEDS framework⁹



Evolution of competency based training

Competency-based training as presently conceptualised can be traced back to the vocational training movement of the 1980s. Building training around defined competencies aided the development of measurable outcomes based on performance, and made quality assurance easier. This move towards outcomes in medical education was inspired by the work of Prof Ralph Tyler of the University of Chicago who, in 1949, stressed that the success of educational activities should be judged by how well students achieved measurable outcomes.⁸ Medical core competencies thus, grew out of this 'outcomes movement' and was pioneered by the Royal College of Physicians and Surgeons of Canada with the CanMEDS Framework⁹ in the 1990s (see *Figure 1*).

It was also within this context, in 1997, that the Accreditation Council for Graduate Medical Education (ACGME) in the US made a commitment to learning outcomes as an educational tool. Their 'outcome project' led to the identification of six core competencies that formed the basis of competency based training curricula for all medical specialties in the United States.¹⁰ Of note, both the Canadian and American frameworks were products of extensive and iterative consultation processes that involved all stakeholders in mental healthcare provision in those countries.

Building on these developments in Canada and the United States, competency based training has recently been introduced into postgraduate training on a nationwide scale in other countries.⁵ Australia and New Zealand have defined medical core competencies and have designed their curricula based on them. Also, European countries like Sweden,

Table 1: Common core competencies in selected countries

Canada	United States	Australia/ New Zealand	EU	United Kingdom	Denmark	Sweden	Netherlands
(RCPSC CanMEDS)	(ACGME/ABMS)	(RANZCP Goals of Training)	(UEMS – Profile of a psychiatrist)	(GMC – Good Medical Practice)	(CanMEDS revised)		(Dutch Central College of Medical Specialities)
Medical Expert/ Clinical Decision Maker	Patient Care	Medical Expert/ Clinical Decision Maker	Medical Expert/ Clinical Decision Maker	Good Clinical Care	Medical expert	Medical Competence	Medical Performance
Communicator	Medical Knowledge	Communicator	Communicator	Maintaining Good Clinical Practice	Communicator	Communication	Communication
Collaborator	Interpersonal and Communication Skills	Collaborator	Collaborator	Teaching and training, appraising and assessing	Collaborator	Leadership	Collaboration
Manager	Practice-based Learning and Improvement	Manager	Manager	Relationships with Patients	Manager and administrator	Medical Science and Quality Enhancement	Knowledge & Science
Health Advocate	Professionalism	Health Advocate	Health Advocate	Working with Colleagues	Health promoter		Community Performance
Scholar	Systems-Based Practice	Scholar	Scholar	Probity	Academic		Management
Professional		Professional	Professional	Health	Professional		Professionalism

Denmark, United Kingdom and The Netherlands are all well underway to introducing competency-based curricula in their postgraduate medical training^{5,11} based on defined core competencies (see Table 1).

Drivers for change

The focus on outcomes in medical education grew out of society's increasing demands for accountability in professional training standards. A rapidly evolving body of medical knowledge and growing awareness and expectations of patients and society has fast eroded the once omnipotent view of physicians. Third party healthcare providers, governments and advocacy groups now demand transparency in the process of certification, re-certification and maintenance of certification of doctors. Besides, when doctors are found negligent, it has not only been on the basis of lack of clinical knowledge but also on the basis of deficiencies in those other generic (softer) skills and attitudes that underpin our professionalism. The medical profession has therefore moved to monitor itself, as the establishment of external agencies to do so might otherwise be inevitable.

The advent of competency-based training in medical education is not aimed at radically changing the training of doctors. The difference is that while traditional medical education articulated competence around core medical expertise, the CanMEDS framework and all other similar frameworks also emphasise those aspects of traditional medical education that have not been previously explicit, therefore promoting the development and assessment of these broader competencies. Thus, in these frameworks, medical expertise becomes the central role around which these other softer competencies are developed, preserving the holistic view of the role of a doctor (see Figure 1).

Impact on European psychiatry

Increasing mobility of labour across an expanding common European market has driven a need for a common sense of European professional identity. Harmonisation and mutual recognition of training programmes across Europe has therefore become inevitable. It is in this context that the Union of European Medical Specialists (UEMS) Board of Psychiatry, responsible for stipulating minimum training requirements in psychiatry in Europe, set up a permanent working group on competency-based training. This group is tasked with developing a competency based curriculum framework as a benchmark model for training across Europe. They have produced 'The Profile of a Psychiatrist'¹² which sets out seven core competencies that define a specialist in Psychiatry from a European perspective (see Table 1). Their work has been adapted largely from the CanMEDS framework, and is similar to the models adopted by Australia, New Zealand and the United States. Irish psychiatry is represented in this group through their representative at the European Federation of Psychiatric Trainees (EFPT). Table 1 illustrates some of the international frameworks derived to date.

The Irish perspective

Background

Until recently, the Irish Psychiatric Training Committee (IPTC) was the statutory body regulating psychiatric training in Ireland. Alongside the IPTC, the Royal College of Psychiatrists (through its Irish division) provided accreditation and educational approval to training schemes and programmes. The educational programme has been based on traditional methods that are focused on syllabic contents and the time spent in the programme. There are currently 12 training schemes with approximately 500 trainees in Ireland. Training

comprises three to four years of basic training as SHO/ registrar, followed by another three to four years of higher training as senior registrar leading to the award of Certificate of Satisfactory Completion of Training (CSCT) and entry onto the specialist register of the Irish Medical Council.

In recent years, several reports and assessments of the state of medical education in Ireland have been published. In 2006, the Fottrell report¹³ called for urgent and structured reforms in undergraduate medical education in Ireland. It recommended outcome-based curricula built on identified core competencies, as well as a programme structure that outlines how these outcomes are to be achieved and assessed. It also called for in-built quality assurance mechanisms in the educational programmes of all medical schools.

Focusing on postgraduate medical education, the Buttimer report¹⁴ also published in 2006 advised the facilitation of trainees to address skills deficits that hinder entry onto the specialist register. One of their key recommendations was the development of a governance structure to drive reform in medical education with an emphasis on effectiveness and efficiency.¹⁴

Another landmark report on the future of Irish psychiatry (*A Vision for Change*) recommended reform and increased investments in medical education and research.¹⁵ The new Medical Practitioners' Act 2007 also emphasises the development and maintenance of professional competence and the promotion of lifelong learning across all medical specialties.

The Irish society has experienced unprecedented changes in socio-cultural and demographic dynamics in the last decade. The current economic downturn has put even more pressures on finite healthcare resources. Psychiatric trainees in Ireland must therefore be competent to deliver an effective service to this diverse population, within the budgetary constraints that apply.

On-going changes in postgraduate training structure

On January 1, 2009, a new College of Psychiatry with statutory responsibility to regulate training in Ireland came into being. The emergence of this new college has set postgraduate psychiatric training in Ireland on a new direction, providing an opportunity for needed reforms to be implemented. In recognition of recent advances in medical education, ongoing developments in European psychiatry and local policy initiatives and recommendations, Irish psychiatry has embraced the concept of competency-based training. Different steering groups are currently and separately developing curriculum and assessment frameworks for basic specialist training (BST).

The curriculum for the first year of BST has been completed and is designed around clinical and non-clinical competencies with defined educational outcomes. The curriculum for the rest of the basic training years is now being developed, and will follow the same model. Plans are also underway to develop a curriculum for the National Higher Specialist Training (HST) Scheme. The steering group on assessments is currently developing a robust system, expected to assess what trainees know (knowledge); can do (competence); and actually do in the work setting (performance). Under this project, a set of workplace-based assessments is currently being piloted, and an indigenous membership examination that is expected to be in place in the next few years is

being developed. Furthermore, one of the three 'pillars' of the college has been dedicated to promoting Continued Professional Development (CPD) and is currently defining core competencies for the various sub-specialities in psychiatry, upon which a programme of lifelong learning and performance evaluation will be built.

Irish developments in a global context

It is a welcome development that Irish psychiatry is embracing the concept of competency-based training. As discussed above, development of curriculum and assessment programmes for various levels of training designed around educational outcomes is well advanced. However, some have argued that a competency based training programme is only as effective as the process used in identifying the essential job skills and competencies as well as for setting guidelines for its implementation and evaluation.²

It is widely recognised that the process of defining core competencies should involve consultation and consensus building with specialties, profession leaders, service users and providers as well as carer and advocacy groups. As described above, the CanMEDS framework and similar projects involved extensive and iterative consultations with stakeholders. It is on the basis of these core competencies that curricula are designed, along a continuum of certification and maintenance of certification. To date, there have been no studies on what core competencies define a psychiatrist from an Irish perspective. While it is likely that any findings will not be very different from what obtains elsewhere, seeking a consensus with stakeholders in Irish psychiatry may be a step in the right direction.

One other result of the increasing demand for accountability in medical education is that every training programme must document whether trainees are achieving the objectives mandated by agreed standards. This requires developing dependable methods of assessing performance within these set competencies. The idea that assessment drives learning is now well recognised, and has led to assessment systems becoming integral parts of the curriculum.¹⁶

Developing curriculum and assessment systems separately as appears to be occurring in Ireland must therefore be re-examined. On the other hand, given that developing valid and reliable competency based assessment tools *de novo* can be a monumental task, the approach to adopt and pilot tools developed elsewhere seems very reasonable. Besides the issue of curriculum design, trainees in the UK and Netherlands have highlighted the need for adequate information to be made available to trainers, trainees and other stakeholders about the implementation of competency-based training, its assessment and potential benefits.¹⁷ This should therefore be addressed in the Irish project. The role of a regulator and a process for reviewing the curriculum and assessments in the future should also be considered as part of the programme development.

Competency based training is not without potential limitations. If applied inappropriately, it can lead to demotivation and a focus on minimum acceptable standards.⁴ It has huge resource implications, which in the current economic downturn is significant. Training the trainers and providing them with administrative support and protected time for training would be expensive, yet indispensable. Considerable consultants'

and trainees' time would also be spent away from direct patient care during assessment and feedback sessions.¹⁷ Adequate organisational and infrastructural support must be secured and funds ring-fenced to support training and research. Careful planning will also be needed to relieve the present tension between pressures of service provision and the delivery of the highest standards of training.

The creation of academic consultant posts for teaching may be needed in all approved training centres or schemes. Creating a faculty of academic psychiatry in the College should also be considered. This special interest group would be made up of psychiatrists with expertise, experience and interest in medical education. The overall aim would be to promote the ethos of evidence based medical education in Irish psychiatry. They would take a longitudinal view of education in psychiatry in Ireland across undergraduate, postgraduate and continued professional development levels. They would facilitate collaboration between the various groups involved in describing and assessing competencies across all levels of training and expertise, and advise the College council on medical education matters.

Conclusion

It is now widely recognised that competency based training is a more effective method of medical education, compared to traditional methods. That Irish psychiatry has embraced it as the cornerstone of its postgraduate psychiatry training and continued professional development is a welcome development.

Great care and attention to detail must be ensured at the design, delivery and evaluation stages to ensure maximum effectiveness and overcome its potential limitations. There will be cost in terms of time and other resources but hopefully, these will compare favourably with the benefits that

competency based training and assessments bring to the learning experience.

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Declaration of Interest: None.

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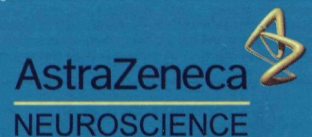
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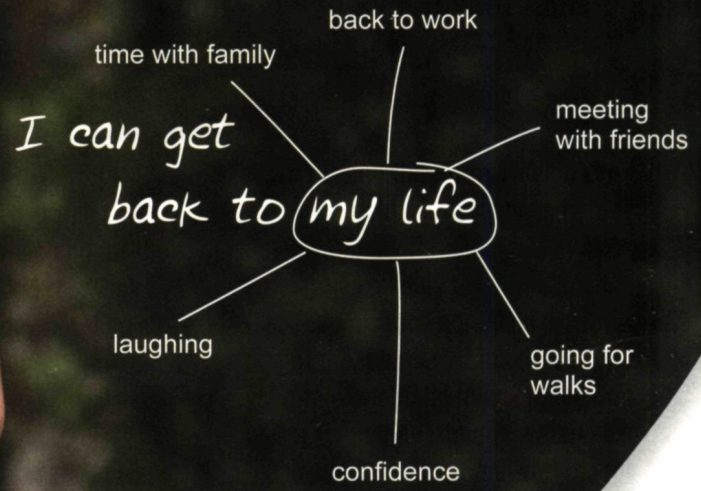
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The daily dose at the start of therapy is 300mg on Day 1 and 600mg on Day 2 and up to 800mg after Day 2. The dose should be adjusted within the effective dose range of 400mg to 800mg per day depending on clinical response and tolerability. Recommended daily dose is 600mg daily. For maintenance therapy in schizophrenia no dosage adjustment is necessary. Treatment of depressive episodes associated with bipolar disorder: Treatment should be prescribed by physicians experienced in treating bipolar disorder. Should be administered at bedtime. Daily dose for the first four days is: 50mg [Day 1], 100mg [Day 2], 200mg [Day 3] and 300mg [Day 4]. Recommended daily dose is 300mg but may be titrated up to 600mg, depending on response. **Elderly:** Use with caution. Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. Patients should be started on 50mg/day and can be increased in increments of 50mg/day to an effective dose. Efficacy & safety not evaluated in patients > 65 years with depressive episodes in framework of bipolar disorder. **Children & Adolescents:** Not evaluated. **Renal Impairment:** No dose adjustment required. **Hepatic Impairment:** Use with caution. Patients should be started on 50mg/day and can be increased in increments of 50mg/day to an effective dose, depending on response and tolerability. **Contra-indications:** Hypersensitivity to quetiapine fumarate or excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone. **Precautions and warnings:** Suicide/suicidal thoughts or clinical worsening: Depression in bipolar disorder is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide related events); patients should be closely monitored until significant remission occurs. Somnolence: quetiapine has been associated with somnolence and related symptoms, such as sedation. In clinical trials for bipolar depression onset was usually within the first 3 days of treatment and was predominantly mild to moderate intensity. If somnolence intensity is severe, patients may need more frequent contact for a minimum of 2 weeks after onset or until symptoms improve. Treatment discontinuation may need to be considered. Known cardiovascular disease (consider slower titration), cerebrovascular disease, or other conditions predisposing to hypotension. Possible initial orthostatic hypotension during the dose titration period (if it occurs consider lower dose or slower titration). Caution is recommended in patients with a history of seizures. In clinical trials, quetiapine was associated with an increased incidence of extrapyramidal symptoms (EPS) versus placebo in patients treated for major depressive episodes in bipolar disorder. If signs and symptoms of tardive dyskinesia appear dose reduction or discontinuation should be considered. In the event of neuroleptic malignant syndrome discontinue treatment and give appropriate medical treatment. Severe neutropenia has been uncommonly observed in clinical trials – discontinue quetiapine if neutrophil count < 1.0 x 10⁹/L. Observe patients for signs/symptoms of infection and follow neutrophil counts until they exceed 1.5 x 10⁹/L. Hepatic enzyme inducers – see interactions. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported – monitoring advised in patients with diabetes or risk factors for developing diabetes. Increases in triglycerides and cholesterol observed in clinical trials – manage lipid increases as clinically appropriate. QT prolongation was observed with overdose. As with other antipsychotics, caution should be exercised when quetiapine is prescribed in patients with cardiovascular disease or family history of QT prolongation, and when quetiapine is prescribed with medicines known to increase QTc interval and concomitant neuroleptics, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia. Acute withdrawal symptoms such as insomnia, nausea, headache, diarrhoea, vomiting, dizziness and irritability have been described after abrupt cessation of quetiapine. Gradual withdrawal (over at least 1–2 weeks) is advisable. Not approved for the treatment of patients with dementia – related psychosis. Use with caution in patients with risk factors for stroke. Contains lactose, patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice (concomitant use not recommended). Hepatic enzyme inducers such as phenytoin & carbamazepine can significantly increase quetiapine clearance – refer to SPC. Thioridazine. Observe caution when used concomitantly with drugs known to cause electrolyte imbalance or to increase QTc interval. **Pregnancy & lactation:** Safety and efficacy not established. **Effects on ability to drive:** Patients should be advised not to drive or operate machinery until individual susceptibility is known. **Undesirable effects.** Very Common: Dizziness, somnolence, headache, dry mouth, withdrawal (discontinuation) symptoms, elevations in serum triglyceride levels, elevations in total cholesterol (predominantly LDL cholesterol) Common: Leucopenia, syncope, extrapyramidal symptoms, tachycardia, vision blurred, orthostatic hypotension, rhinitis, constipation, dyspepsia, mild asthenia, peripheral oedema, weight gain, elevations in serum transaminases (ALT, AST), decreased neutrophil count, blood glucose increased to hyperglycaemic levels, abnormal dreams and nightmares. **For a full list of undesirable effects refer to SPC. 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CYMBALTA[®] (DULOXETINE) REPUBLIC OF IRELAND ABBREVIATED PRESCRIBING INFORMATION Presentation Hard gastro-resistant capsules, 30mg or 60mg of duloxetine. Also contains sucrose. **Uses** Treatment of major depressive episodes. Treatment of generalised anxiety disorder. Treatment of diabetic peripheral neuropathic pain (DPNP) in adults. **Dosage and Administration Major Depressive Episodes** Starting and maintenance dose is 60mg once daily, with or without food. Doses up to a maximum dose of 120mg per day, administered in evenly divided doses, have been evaluated from a safety perspective in clinical trials. However, there is no clinical evidence suggesting that patients not responding to the initial recommended dose may benefit from dose up-titrations. Therapeutic response is usually seen after 2-4 weeks. After establishing response, it is recommended to continue treatment for several months, in order to avoid relapse. **Generalised Anxiety Disorder** The recommended starting dose in patients with generalised anxiety disorder is 30mg once daily, with or without food. In patients with insufficient response the dose should be increased to 60 mg, which is the usual maintenance dose in most patients. In patients with co-morbid major depressive episodes, the starting and maintenance dose is 60mg once daily. Doses up to 120mg per day have been shown to be efficacious and have been evaluated from a safety perspective in clinical trials. In patients with insufficient response to 60mg, escalation up to 90mg or 120mg may therefore be considered. After consolidation of the response, it is recommended to continue treatment for several months, in order to avoid relapse. Abrupt discontinuation should be avoided. When stopping treatment with Cymbalta the dose should be gradually reduced over at least one to two weeks to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, continue decreasing the dose, but at a more gradual rate. **Diabetic Peripheral Neuropathic Pain** Starting and maintenance dose is 60mg daily, with or without food. The plasma concentration displays large inter-individual variability. Hence, some patients that respond insufficiently to 60mg may benefit from a higher dose. The medicinal response should be evaluated after 2 months treatment. Additional response after this time is unlikely. The therapeutic benefit should regularly be reassessed. **Contra-indications** Hypersensitivity to any of the components. Combination with MAOIs. Liver disease resulting in hepatic impairment. Use with potent inhibitors of CYP1A2, eg, fluvoxamine, ciprofloxacin, enoxacin. Severe renal impairment (creatinine clearance <30ml/min). Should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Breast-feeding is not recommended. Initiation in patients with uncontrolled hypertension that could expose patients to a potential risk of hypertensive crisis. **Precautions** Do not use in children and adolescents under the age of 18. No dosage adjustment is recommended for elderly patients solely on the basis of age. However, as with any medicine, caution should be exercised. Data on the use of Cymbalta in elderly patients with generalised anxiety disorder are limited. Use with caution in patients with a history of mania, bipolar disorder, or seizures. Caution in patients with increased intra-ocular pressure or those at risk of acute narrow-angle glaucoma. Duloxetine has been associated with an increase in blood pressure and clinically significant hypertension in some patients. In patients with known hypertension and/or other cardiac disease, blood pressure monitoring is recommended as appropriate, especially during the first month of treatment. Use with caution in patients whose conditions could be compromised by an increased heart rate or by an increase in blood pressure. For patients who experience a

sustained increase in blood pressure while receiving duloxetine, consider either dose reduction or gradual discontinuation. Caution in patients taking anticoagulants or products known to affect platelet function, and those with bleeding tendencies. Hyponatraemia has been reported rarely, predominantly in the elderly. Caution is required in patients at increased risk for hyponatraemia, such as elderly, cirrhotic, or dehydrated patients, or patients treated with diuretics. Hyponatraemia may be due to a syndrome of inappropriate anti-diuretic hormone secretion (SIADH). It is general clinical experience that the risk of suicide may increase in the early stages of recovery from depression. Other psychiatric conditions for which Cymbalta is prescribed can also be associated with an increased risk of suicide-related events. Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal thoughts prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicidal behaviour, and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old. Close supervision of patients, and in particular those at high risk, should accompany drug therapy, especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts, and unusual changes in behaviour, and to seek medical advice immediately if these symptoms present. Since treatment may be associated with sedation and dizziness, patients should be cautioned about their ability to drive a car or operate hazardous machinery. Cases of akathisia/psychomotor restlessness have been reported for duloxetine. In patients who develop these symptoms, increasing the dose may be detrimental. Duloxetine is used under different trademarks in several indications (major depressive episodes, generalised anxiety disorder, stress urinary incontinence, and diabetic neuropathic pain). The use of more than one of these products concomitantly should be avoided. Cases of liver injury, including severe elevations of liver enzymes (>10-times upper limit of normal), hepatitis, and jaundice have been reported with duloxetine. Most of them occurred during the first months of treatment. Duloxetine should be used with caution in patients with substantial alcohol use or with other drugs associated with hepatic injury. **Interactions** Caution is advised when taken in combination with other centrally acting medicinal products and substances, including alcohol and sedative medicinal products; exercise caution when used in combination with antidepressants. In rare cases, serotonin syndrome has been reported in patients using SSRIs concomitantly with serotonergic products. Caution is advisable if duloxetine is used concomitantly with serotonergic antidepressants like SSRIs, tricyclics, St John's Wort, venlafaxine, or triptans, tramadol, pethidine, and tryptophan. Undesirable effects may be more common during use with herbal preparations containing St John's Wort. **Effects on other drugs:** Caution is advised if co-administered with products that are predominantly metabolised by CYP2D6 (risperidone, tricyclic antidepressants [TCAs], such as nortriptyline, amitriptyline, and imipramine) particularly if they have a narrow therapeutic index (such as flecainide, propafenone, and metoprolol). **Anticoagulants and antiplatelet agents:** Caution should be exercised when duloxetine is combined with oral anticoagulants or antiplatelet agents due to a potential increased risk of bleeding. Increases in INR values have been reported when duloxetine was co-administered with warfarin. **Undesirable Effects** The majority of common adverse reactions were mild to moderate, usually starting early in therapy, and most tended to subside as therapy continued.

Those observed from spontaneous reporting and in placebo-controlled clinical trials in depression, generalised anxiety disorder, diabetic neuropathic pain, and fibromyalgia at a rate of $\geq 1/100$, or where the event is clinically relevant, are: *Very common* ($\geq 1/10$): Nausea, headache, dry mouth, somnolence, fatigue, insomnia, dizziness, and constipation. *Common* ($\geq 1/100$ and $< 1/10$): Weight decrease, palpitations, tremor, paraesthesia, dysgeusia, lethargy, blurred vision, tinnitus, yawning, diarrhoea, vomiting, dyspepsia, flatulence, sweating increased, rash, night sweats, musculoskeletal pain, muscle tightness, muscle spasm, decreased appetite, flushing, abdominal pain, chills, erectile dysfunction, agitation, libido decreased, anxiety, orgasm abnormal, abnormal dreams, sleep disorder. Clinical trial and spontaneous reports of anaphylactic reaction, hyperglycaemia (reported especially in diabetic patients), mania, hyponatraemia, SIADH, hallucinations, dyskinesia, serotonin syndrome, extra-pyramidal symptoms, convulsions, akathisia, psychomotor restlessness, glaucoma, mydriasis, syncope, tachycardia, supra-ventricular arrhythmia (mainly atrial fibrillation), syncope, hypertension, hypertensive crisis, epistaxis, gastritis, haematochezia, dysuria gastro-intestinal haemorrhage, hepatic failure, hepatitis, acute liver injury, angioneurotic oedema, Stevens-Johnson syndrome, trismus, and gynaecological haemorrhage have been made. Cases of suicidal ideation and suicidal behaviours have been reported during duloxetine therapy or early after treatment discontinuation. Cases of aggression and anger have been reported particularly early in treatment or after treatment discontinuation. Discontinuation of duloxetine (particularly abrupt) commonly leads to withdrawal symptoms. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), fatigue, agitation or anxiety, nausea and/or vomiting, tremor, headache, irritability, diarrhoea, hyperhidrosis, and vertigo are the most commonly reported reactions. The heart rate-corrected QT interval in duloxetine-treated patients did not differ from that seen in placebo-treated patients. No clinically significant differences were observed for QT, PR, QRS, or QTcB measurements between duloxetine-treated and placebo-treated patients. In clinical trials in patients with DPNP, small but statistically significant increases in fasting blood glucose were observed in duloxetine-treated patients compared to placebo at 12 weeks. There was a small increase in fasting blood glucose and in total cholesterol in duloxetine-treated patients compared with a slight decrease in the routine care group. There was also an increase in HbA_{1c} in both groups, but the mean increase was 0.3% greater in the duloxetine-treated group. For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at <http://www.medicines.ie/>. **Overdose** Cases of overdoses, alone or in combination with other drugs, with duloxetine doses of 4800mg were reported. Some fatalities have occurred, primarily with mixed overdoses, but also with duloxetine alone at a dose of approximately 1000mg. **Legal Category** POM. **Marketing Authorisation Numbers and Holder** EU/1/04/296/001 EU/1/04/296/002 EU/1/04/296/003 EU/1/04/296/004 Eli Lilly Nederland BV Grootslag 1-5 NL-3991 RA Houten The Netherlands. **Date of Preparation or Last Review** July 2008. **Full Prescribing Information is Available From** Eli Lilly and Company Limited Lilly House, Priestley Road Basingstoke, Hampshire, RG24 9NL Telephone: Basingstoke (01256) 315 999 or Eli Lilly and Company (Ireland) Limited Hyde House, 65 Adelaide Road Dublin 2, Republic of Ireland Telephone: Dublin (01) 661 4377. **CYMBALTA** (duloxetine) is a trademark of Eli Lilly and Company. **Date of preparation** January 2009. **Reference:** 1. Zimmerman M, McClinchey JB, et al. *Am J Psychiatry* 2006; 163:148-150.

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