Observatório Europeu da
Droga e da Toxicodependência

Distribuído pelos Srs. Deputados. —
Lx. 28/09/2012

Exmo. Senhor
Dr. Fernando Negrão
Presidente da Comissão de Assuntos Constitucionais,
Direitos, Liberdades e Garantias
Assembleia da República
Palácio de São Bento
1249-068 Lisboa

Ref: DIR/GF/rdn (12) D 124
Date: 26 de setembro de 2012

Exmo. Senhor,

Em resposta ao V/ofício n° 1239/XII/1.ª – CACDLG/2012 do passado dia 20 de setembro, venho por este meio remeter a V. Exa a informação mais recente do OEDT disponível em Português sobre as soluções existentes a nível europeu para fazer face ao problema das novas substâncias psicoativas.

A questão das novas drogas está na linha da frente das preocupações das instituições europeias e dos Estados-membros da União Europeia, estando o OEDT a investir uma parte considerável dos seus recursos na monitorização, identificação e difusão dos riscos associados ao consumo das mesmas. Só no ano passado, foram oficialmente notificadas 49 novas substâncias psicoativas através do sistema de alerta rápido da EU – que o OEDT gere em conjunto com a Europol – tendo este número já sido ultrapassado em 2012.

Assim, das diversas publicações editadas pelo OEDT sobre esta temática, envio em anexo a esta carta as mais recentes disponíveis em Português:

- edição n° 22 do boletim 'Drogas em destaque' sobre o tema 'Responder às novas substâncias psicoativas' (dezembro/2011);
- comunicado de imprensa por ocasião do lançamento do Relatório Anual do OEDT-Europol sobre as novas substâncias psicoativas, bem como o próprio relatório que só existe em Inglês (abril/2012); e
- excerto do Relatório Anual 2012 do OEDT, seção 'Legislações nacionais no que respeita a novas substâncias psicoativas' (novembro/2012) – Relativamente a este último elemento, gostaria de chamar a atenção que se trata de informação ainda não publicada – o relatório será oficialmente lançado à imprensa no dia 15 de novembro – pelo que peço e agradeço o especial favor de manter este documento sob estrito embargo até à referida data.

Para além destes elementos, o OEDT está à disposição de V. Exa. e da Comissão dos Assuntos Constitucionais, Direitos, Liberdades e Garantias da Assembleia da República para prestar quaisquer outros esclarecimentos adicionais: seja através de envio de mais documentação, seja através da participação em qualquer reunião em que o contributo do OEDT sejam tido por necessário.

Com os melhores cumprimentos, de muita estima e pessoal.

Wolfgang Götz
Diretor

Anexos: 3

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Nº Único 443509
Entrado/Saído nº 988 Data 28/09/12

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Drogas em destaque 22

Nota do Observatório Europeu da Droga e da Toxicodependência

ISSN 1681-6374

Responder às novas substâncias psicoactivas

Dado que as legislações penais devem definir claramente as substâncias sujeitas a controlo, a descoberta de uma substância psicoactiva que não esteja controlada por lei pode permitir que os seus fornecedores obtenham lucros, expondo a saúde dos consumidores a um risco desconhecido. Estas substâncias podem ser subsequentemente identificadas pelas autoridades e adicionadas à lista das substâncias controladas, iniciando-se um novo ciclo. Os recentes progressos que permitem sintetizar substâncias químicas orgânicas a baixo custo, conjugados com o intercâmbio de informações e as possibilidades de comercialização oferecidas pela Internet, têm levado a que as novas substâncias psicoactivas fiquem amplamente disponíveis e com uma rapidez sem precedentes. Estas substâncias podem ser comercializadas através de lojas especializadas em material diverso para o consumo de drogas, situadas nos centros das cidades e em sítios *web* fáceis de criar e capazes de difundir rapidamente o consumo de uma nova droga no interior de cada país e a nível internacional. A rapidez com que as novas substâncias psicoactivas podem surgir e ser distribuídas actualmente, põe em causa o procedimento de adopção de legislação para controlar uma substância estabelecido em cada país. Os fornecedores obtêm lucros substanciais durante os meses necessários ao controlo penal de uma nova substância e enquanto os riscos associados ao seu consumo não são determinados. Os decisores políticos exigem novas formas, mais rápidas e eficazes, de submeter as drogas a controlo, que protejam a saúde pública e, se possível, impeçam os fornecedores de encontrar novas substâncias para continuarem o ciclo.

É necessário que os Estados-Membros tenham capacidade para identificar rapidamente e avaliar cientificamente as novas substâncias, cada vez mais diversas e complexas, que surgem no mercado. Os seus mecanismos de resposta devem ser optimizados de modo a protegerem a saúde pública de forma eficaz e eficiente, minimizando ao máximo as consequências adversas; o controlo ao abrigo da legislação em matéria de droga é uma de várias opções que permitem atingir esse objectivo.

Wolfgang Götz,
director do OEDT

Definição

Nova substância psicoactiva: um novo estupefaciente ou um novo psicotrópico, puro ou numa preparação, que não seja controlado pela Convenção Única das Nações Unidas de 1961 sobre os estupefacientes, nem pela Convenção das Nações Unidas de 1971 sobre substâncias psicotrópicas, mas que possa constituir uma ameaça para a saúde pública comparável à das substâncias enumeradas nessas convenções (Decisão 2005/387/JAI do Conselho).

Resumo das questões-chave

1. As novas substâncias psicoactivas não são facilmente detectáveis e identificáveis pelos laboratórios de polícia científica. A realização de testes para detectar substâncias desconhecidas ou inesperadas é morosa, complexa e cara, o que dificulta aos legisladores e às forças policiais a definição de respostas direccionadas e rápidas.

2. Juridicamente, não é possível criminalizar a distribuição não autorizada de todas as substâncias psicoactivas e, por isso, a legislação, em vez de ser proactiva, apenas pode reagir às substâncias à medida que elas vão surgindo.

3. As novas substâncias psicoactivas podem pôr em risco a saúde individual e pública, além de gerarem riscos sociais, que afectam a comunidade em geral. Porém, quando surgem pela primeira vez no mercado, não há informação sobre os riscos que lhes estão associados.

4. O processo legislativo necessário para submeter uma substância a medidas de controlo ao abrigo da legislação em matéria de droga exige tempo, em alguns países mais de um ano.

5. Controlar uma nova substância psicoactiva pode ter consequências imprevistas e indesejadas. Pode, nomeadamente, estimular a procura e a distribuição de uma substância não controlada, eventualmente ainda mais nociva do que a anterior.

6. Outras opções de controlo, embora mais rápidas, carecem das sanções necessárias para transmitir as mesmas mensagens de dissuasão e de risco para a saúde, além de poderem ser ineficazes para prevenir ou impedir a comercialização e distribuição de uma nova substância.

1. Sistemas de alerta rápido

Na Europa, os sistemas de alerta rápido para as novas substâncias psicoactivas funcionam simultaneamente ao nível da UE e ao nível nacional. O sistema europeu de alerta rápido, criado em 1997, é implementado pelo OEDT e pelo Europol e baseia-se nos sistemas nacionais. Trata-se de uma rede pluridisciplinar, que recolhe, analisa e divulga rapidamente as informações sobre as novas drogas e os seus componentes. Nos últimos dois anos, um número recorde de novas substâncias foi identificado pela primeira vez na Europa – 24 em 2009 e 41 em 2010 (ver gráfico). Actualmente estão a ser monitorizadas pela UE cerca de 150 substâncias.

Os sistemas nacionais de alerta rápido têm estruturas e componentes diferentes em função das necessidades e prioridades nacionais específicas, embora também satisfaçam as necessidades do sistema europeu. Na Europa, os sistemas nacionais de alerta rápido diferem em muitos aspectos, nomeadamente quanto à base jurídica, ao seu posicionamento na estrutura governamental (nos organismos de saúde ou responsáveis pela aplicação da lei), à cobertura (local, regional ou nacional) e aos recursos que lhes são atribuídos. Podem ainda ter composição e capacidade diferentes: por exemplo, há sistemas de alerta rápido que incluem redes sólidas de polícia científica e peritos em toxicologia, outros monitorizam amostras recolhidas junto dos consumidores e outros ainda estão ligados a um mecanismo de resposta rápida. Os sistemas nacionais de alerta rápido podem ser reforçados através da utilização de indicadores quantitativos de monitorização das drogas, da investigação qualitativa e do recurso a fontes de informação pluridisciplinares, como prestadores de cuidados de saúde, organismos responsáveis pela aplicação da lei e investigadores independentes. Podem tirar partido dos últimos avanços analíticos e tecnológicos e beneficiar de um intercâmbio de informações eficiente e oportuno entre todos os parceiros.

2. Controlo proactivo

As substâncias psicoactivas controladas ao abrigo da legislação penal devem ser claramente definidas. O princípio subjacente, consagrado na Convenção Europeia dos Direitos do Homem e em algumas constituições nacionais, é de que ninguém pode ser condenado por uma infracção que não era criminalizada na altura em que foi cometida. Com base neste princípio, o Tribunal Europeu dos Direitos do Homem decidiu que o direito penal deve especificar o que classifica como infracção. Em consequência, as substâncias que não estejam enumeradas na legislação em matéria de droga não são por ela controladas.

A jurisprudência do Tribunal Europeu dos Direitos do Homem permite, no entanto, que alguns elementos da infracção sejam clarificados e incluídos na definição inicial da infracção. A Irlanda e o Reino Unido utilizam as definições genéricas das famílias químicas das substâncias controladas. Nas substâncias análogas ou derivadas de drogas controladas podem incluir-se as substâncias com estruturas ou efeitos semelhantes, abrangendo, assim, uma gama de substâncias mais vasta do que a definição genérica; estas classificações podem ser aplicadas a todas as substâncias sob controlo da legislação em matéria de droga (como acontece na Bulgária e na Noruega), a categorias seleccionadas (Letónia e Malta), ou apenas a um pequeno grupo de substâncias (Luxemburgo). Contudo, alguns Estados-Membros indicaram que teriam dificuldade em aplicar uma definição genérica, por isso exigir alterações da legislação primária ou ser contrária aos princípios constitucionais. Em 2010, a Irlanda adoptou legislação que proíbe a venda de todas as substâncias psicoactivas para consumo humano que sejam nocivas ou causem dependência e a Polónia proibiu a comercialização de drogas de substituição. Mas ainda é demasiado cedo para avaliar globalmente esta abordagem.

3. Avaliação dos riscos

Na maioria dos Estados-Membros da UE, existem sistemas nacionais para avaliar os riscos das novas substâncias psicoactivas, que analisam os riscos sociais e para a saúde colocados pelas novas substâncias nas várias etapas, desde a produção até ao tráfico para consumo. Podem avaliar também o potencial envolvimento da criminalidade organizada, e as consequências das eventuais medidas de controlo. Dos 26 países com informações disponíveis, seis não mencionaram a existência de um sistema de avaliação dos riscos no âmbito do procedimento legal de controlo. A legislação em matéria de droga de seis países refere directamente um sistema de avaliação dos riscos; em sete países esse sistema encontra-se semi-formalizado, e noutros sete a avaliação é realizada caso a caso. Na maioria dos países, é efectuada pela administração do Estado, mas em quatro é confiada a um organismo científico independente (Hungria, Países Baixos, Áustria e Reino Unido).

Cerca de metade dos Estados-Membros da UE distingue juridicamente as substâncias com base na sua nocividade, podendo a avaliação dos riscos contribuir para classificar com exactidão os seus possíveis danos e divulgá-los. A informação transmitida nos meios de comunicação social sobre potenciais danos pode pressionar no sentido de um controlo legislativo antes de alguns dados fundamentais serem conhecidos. Porém, havendo indícios de que relativamente poucas pessoas consomem as novas substâncias psicoactivas, há que ter cuidado para não perder a credibilidade exagerando os seus riscos. Aparentemente, são poucos os países que reexaminam *à posteriori* a exactidão da classificação feita, quando há novas informações disponíveis.

4. Processos mais céleres — mas supervisionados

O período de tempo necessário para submeter uma nova substância a medidas de controlo depende do procedimento seguido, do tipo de legislação e do nível de aprovação exigido. Por exemplo, um procedimento complexo para alterar uma lei parlamentar que exija a aprovação do chefe de Estado demora mais do que um procedimento simples para alterar um regulamento assinado por um único ministro. Para ultrapassar atrasos processuais, a Alemanha e os Países Baixos criaram sistemas de emergência que permitem submeter temporariamente uma substância a medidas de controlo durante um ano, com a aprovação de um ministro e não de todo o governo; se o procedimento de controlo permanente não for aplicado no prazo de um ano, essa restrição prescreve. Outros países têm procedimentos rápidos para submeter

substâncias a medidas de controlo permanente reduzindo os prazos de consulta durante o processo legislativo. Na Suécia, uma lei específica, a lei sobre os produtos perigosos para a saúde, permite classificar rapidamente uma substância submetendo-a a sanções penais graves por venda ou posse, enquanto as autoridades verificam se ela corresponde à definição de «droga», sendo, em caso afirmativo, incluída na lista das substâncias controladas. A Directiva 98/34/ /CE do Parlamento Europeu e do Conselho exige um pré-aviso de três meses para as acções nacionais que limitem as trocas comerciais intracomunitárias, mas esse procedimento pode não ser aplicado por razões graves de saúde ou segurança públicas.

5. Consequências indesejadas das medidas de controlo

O procedimento de avaliação dos riscos da UE tem em conta as eventuais consequências das medidas de controlo, nas quais se podem incluir a substituição de uma substância recentemente sujeita a controlo por outra não controlada – por vezes, com efeitos mais graves. Por exemplo, o controlo do GHB (ácido gama-hidroxibutírico) poderá ter causado um aumento do consumo do seu precursor químico e metabólico GBL (gama-butirolactona), uma substância pelo menos tão perigosa como o GHB. Após a imposição de medidas de controlo sobre cogumelos alucinogénios que contêm psilocina, alguns retalhistas começaram a vender o cogumelo *amanita muscaria*, que tem grandes riscos de toxicidade. Quando a mefedrona foi submetida a medidas de controlo na Europa, os vendedores online começaram a publicitar a nafirona como substituta. Contudo, em lugar da nafirona, muitas amostras continham uma ou mais catinonas controladas, ou outras substâncias sem relação química com a nafirona.

A manutenção de uma vigilância apertada às novas drogas pode ser muito dispendiosa, uma vez que é necessário identificar um número crescente de novas substâncias e investigar os seus riscos associados e respostas. Além disso, submeter novas substâncias psicoactivas a medidas de controlo ao abrigo da legislação em matéria de droga exige afectar recursos para a execução da lei. Os países que aplicam esta abordagem de forma sistemática correm o risco de sobrecarregar o seu sistema nacional. Tendo isto em conta, peritos de avaliação de riscos dos Países Baixos e do Reino Unido opuseram-se ao controlo penal da oferta de determinadas substâncias (cogumelos alucinogénios e khat, respectivamente), preferindo, em seu lugar, os programas de prevenção.

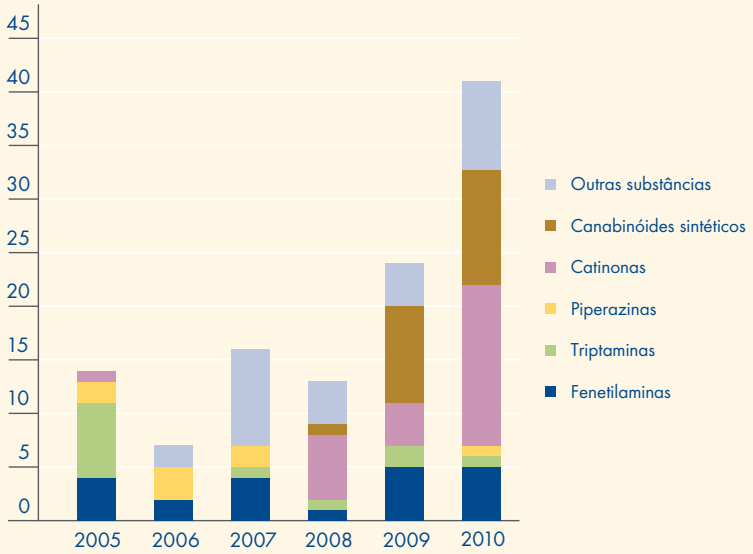
6. As outras leis são eficazes?

Alguns países europeus têm utilizado com êxito outras leis para impedir a distribuição livre de novas drogas. São leis baseadas em definições harmonizadas ao nível da UE, que devem estar operacionais em todos os Estados-Membros. A regulamentação relativa à obrigatoriedade de todos os produtos e géneros alimentícios em venda indicarem claramente no rótulo a utilização a que se destinam tem sido invocada para apreender produtos «spice» não rotulados na língua nacional (Itália) e a mefedrona rotulada como sais de banho ou fertilizantes de plantas (Reino Unido). Aplicando a definição de medicamento harmonizada ao nível da UE às novas substâncias psicoactivas, as agências de medicamentos nacionais podem proibir a sua importação, comercialização ou distribuição não autorizadas. Em 2009, a Áustria classificou os produtos «spice» ao abrigo da legislação não penal relativa aos medicamentos, conseguindo assim pôr termo à venda e distribuição livres do «spice» na Áustria, sem criminalizar os consumidores. As proibições de importação aplicadas na Áustria («spice») e no Reino Unido (mefedrona) contribuíram para impedir a livre distribuição dessas substâncias.

O acesso dos jovens a novas substâncias pode ser reduzido através da imposição de restrições ao licenciamento dos pontos de venda ou de limites de idade para a venda dos produtos. Estas medidas podem ser idênticas às que regulam a venda de álcool e de tabaco, mas há outros exemplos, como os «coffee shops» dos Países Baixos e a venda de butano e de produtos solventes no Reino Unido.

Todas estas abordagens seguem as recomendações recentemente formuladas pelo Gabinete das Nações Unidas contra a Droga e o Crime para enfatizar a aplicação das leis que protegem a saúde e reprimem os fornecedores, em vez de criminalizar todos os consumidores.

Número de novas substâncias psicoactivas notificadas ao sistema europeu de alerta rápido nos termos da Decisão 2005/387/JAI do Conselho



N.B.: A Decisão 2005/387/JAI do Conselho entrou em vigor em 21 de Maio de 2005.
Fonte: Sistema europeu de alerta rápido.

Drogas em destaque é uma série de notas sobre políticas publicadas pelo Observatório Europeu da Droga e da Toxicodependência (OEDT), de Lisboa. São publicadas regularmente nas 23 línguas oficiais da União Europeia e em norueguês e turco. Versão original: inglês. Reprodução autorizada mediante citação da fonte.

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TD-AD-11-002-PT-C

Conclusões e considerações de carácter político

1. **Detectar e identificar as novas substâncias psicoactivas à medida que vão surgindo no mercado é o primeiro passo para avaliar os riscos das novas drogas potencialmente perigosas e para as submeter a medidas de controlo. A capacidade de realizar esta tarefa é um elemento essencial dos sistemas de alerta rápido.**

2. **Os sistemas de avaliação dos riscos podem fornecer evidência para apoiar o processo legislativo. Os seus resultados permitem transmitir ao público uma mensagem precisa e credível sobre o perigo associado à substância. A investigação orientada é essencial para dar à avaliação de riscos e às medidas de controlo uma fundamentação científica sólida.**

3. **Encontrar o equilíbrio adequado entre a rapidez da resposta às novas substâncias, por um lado, e a evidência científica e a supervisão legislativa suficientes, por outro lado, constitui um importante objectivo político.**

4. **A legislação em matéria de droga deve abordar as substâncias que representem ameaças graves para a saúde e para a sociedade. É possível usar medidas de outro tipo, em conjunto com os programas de prevenção, a fim de dissuadir o consumo de substâncias não controladas, que não são necessariamente seguras.**

5. **É importante analisar se outras leis já disponíveis, como as relativas à protecção dos consumidores e aos medicamentos, poderão atingir o objectivo desejado; a rapidez de reacção pode ser mais importante do que a severidade. As proibições de importação podem reduzir a pressão sobre os mecanismos locais de aplicação da lei.**

6. **A Comissão Europeia, em cooperação com alguns países da UE, o OEDT e a Europol, está a trabalhar na elaboração de nova legislação para melhor responder ao controlo das novas substâncias psicoactivas a nível da UE.**

Principais fontes

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Informação na Internet

Perfis sobre drogas do OEDT:

BZP e outras piperazinas [BZP and other piperazines]
http://www.emcdda.europa.eu/publications/drug-profiles/bzp

Canabinóides sintéticos e «spice» [Synthetic cannabinoids and 'Spice']
http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cannabinoids

Catinonas sintéticas [Synthetic cathinones]
http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cathinones

Derivados sintéticos da cocaína [Synthetic cocaine derivatives]
http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cocaine-derivatives

Decisão 2005/387/JAI do Conselho relativa ao intercâmbio de informações, avaliação de riscos e controlo de novas substâncias psicoactivas

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:127:0032:0037:PT:PDF

Serviço das Publicações

EDITOR OFICIAL: Serviço das Publicações Oficiais da União Europeia

DIRECTOR: Wolfgang Götz
AUTORES: Brendan Hughes, Ana Gallegos e Roumen Sedefov
REDACTOR: Peter Fay
CONCEPÇÃO GRÁFICA: Dutton Merryfield Ltd, Reino Unido
Printed in Belgium

Observatório Europeu da
Droga e da Toxicodependência

COMUNICADO da agência da UE de informação sobre droga, Lisboa

OEDT DISTINGUE ESCRITA CIENTÍFICA NUMA CERIMÓNIA ANUAL REALIZADA EM LISBOA

Prémio de escrita científica 2012 do OEDT revela investigação inovadora no domínio da droga

(24.9.2012, LISBOA) Os três vencedores do **prémio de escrita científica 2012 do OEDT** serão distinguidos esta semana, em Lisboa, na cerimónia anual organizada pela **agência da UE de informação sobre droga** ([1]). Este ano, os resultados refletem o lado feminino da ciência, uma vez que os três autores distinguidos são mulheres. As laureadas — da Alemanha, Suécia e Reino Unido — receberão no dia 26 de setembro um prémio não monetário atribuído pelos seus contributos, à margem da cerimónia de abertura do encontro anual do **International Society of Addiction Journal Editors**, que decorrerá nessa semana no **OEDT** ([2]).

O prémio, atribuído pela primeira vez em 2011 pelo **OEDT** e pelo seu **Comité Científico** ([3]), distingue a escrita científica e a elevada qualidade da investigação no domínio das drogas ilícitas. Num novo formato adotado este ano, foram convidados quatro grupos para a nomeação de artigos: sociedades de investigação europeias, membros do Comité Científico do OEDT, os pontos focais nacionais da rede Reitox e revistas científicas europeias, especializadas na área da droga.

De acordo com os critérios de admissão, todos os artigos foram publicados em 2011 em revistas científicas especializadas, sendo o autor principal proveniente de um Estado-Membro da UE, Croácia, Turquia ou Noruega. Os trabalhos podiam ser submetidos para diversas categorias, incluindo: investigação de base no domínio biológico, neurobiológico e comportamental; estudos epidemiológicos baseados em amostras populacionais e redução da procura e da oferta. Os trabalhos premiados em 2012 são:

- «Diminished gray matter in the hippocampus of cannabis users: possible protective effects of cannabidiol» (Diminuição de massa cinzenta do hipocampo nos consumidores de canábis: possíveis efeitos protetores do canabidiol), **Dr.ª Traute Demirakca, Dipl. Psych.** (Alemanha).
  Publicado em *Drug and alcohol dependence,* 114 (2011) 242-245.

- «Long-term effects of a community-based intervention: five-year follow-up of 'Clubs against Drugs'» (Efeitos a longo prazo de uma intervenção numa comunidade: cinco anos de acompanhamento dos «Clubes contra Drogas»), **Dr.ª Johanna Gripenberg, PhD** (Suécia). Publicado em *Addiction,* 106, 1997-2004.

- «The impact of needle and syringe provision and opiate substitution therapy on the incidence of hepatitis C virus in injecting drug users: pooling of UK evidence» (Impacto do fornecimento de seringas e agulhas e da terapia de substituição de opiáceos sobre a incidência do vírus da hepatite C em consumidores de drogas injetáveis: compilação de dados do Reino Unido), **Dr.ª Katy M.E. Turner, PhD** (Reino Unido). Publicado em *Addiction,* 106, 1978-1988.

Este ano, foram recebidas cerca de 30 candidaturas elegíveis, as quais foram analisadas com base nos seguintes critérios: originalidade científica; qualidade científica; clareza e qualidade de redação; e relevância para a UE. Fizeram parte do júri membros do **Comité Científico do OEDT** e **especialistas científicos** da agência. Os resumos dos trabalhos premiados serão disponibilizados no sítio Web da agência em inglês, com traduções para alemão e francês, num esforço para promover a divulgação dos resultados em países não anglófonos. Este ano estará igualmente disponível a lista completa dos artigos que, em cada categoria, receberam as pontuações mais elevadas.

Comentando a iniciativa, a **Presidente do Comité Científico do OEDT, Dr.ª Marina Davoli**, disse que o prémio de escrita científica do OEDT foi concebido com o objetivo de refletir a importância das publicações

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científicas e de constituir um canal para a divulgação dos resultados da investigação a nível europeu junto dos decisores políticos e dos profissionais de saúde. “Felicito os premiados de 2012 pela sua contribuição positiva para o nosso conhecimento no domínio da droga e da toxicodependência”.

Notas

([1]) A cerimónia de entrega dos prémios terá lugar às 17h30 do dia 26 de setembro, no OEDT (endereço abaixo) e será **aberta à imprensa**. Para mais informações sobre a cerimónia e os resumos dos trabalhos laureados: www.emcdda.europa.eu/news/2012/6
([2]) Para mais informações sobre a reunião do ISAJE: www.parint.org/isajewebsite
([3]) Para mais informações sobre o Comité Científico do OEDT: www.emcdda.europa.eu/about/sc

European Monitoring Centre for Drugs and Drug Addiction

EUROPOL

EMCDDA–Europol 2011 Annual Report on the implementation of Council Decision 2005/387/JHA

In accordance with Article 10 of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances

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Overview

This report presents the activities implemented by the EMCDDA and Europol in 2011 in support of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances (hereinafter referred to as the Decision) ([1]).

In 2011, 49 new psychoactive substances were officially notified for the first time in the European Union through the information exchange mechanism, the Early-warning system (EWS), which was set up by the Decision. This represents the largest number of substances ever reported in a single year, considerably up from 2010 (41 substances) and 2009 (24 substances). Thus the number of substances identified in the period 2009–11 accounts for more than two thirds of the total number of substances notified under the terms of the Council Decision since 2005.

As in 2010, the list of newly notified substances was dominated by synthetic cannabinoids ([2]) (23) and synthetic cathinones (8); these two chemical families represented about two thirds of the total number of substances reported in 2011 (see Annex 1 and Annex 3). The list also included five phenethylamines and a large number of diverse compounds belonging to an expanding range of chemical families that are relatively new or for which a small number of representatives had been previously reported — two aminoalkylbenzofurans, a thiophene derivative of methamphetamine, an aminoindane, and a substituted piperidine. The report also highlights the emergence of seven substances that are medicines, metabolites or precursors of medicines or that could be described as 'designer medicines'.

A brief follow-up on the increasingly diverse family of synthetic cannabinoids and on mephedrone — the synthetic cathinone risk assessed and subsequently controlled in 2010 — is also included in the report.

In 2011, 'legal highs' (see definition in Annex 2) continued to receive high priority and political interest as evidenced by several initiatives at national level on awareness raising, new legislative formulations, as well as inclusion of new psychoactive substances in general population surveys. In 2011, representative studies were conducted for the first time on the prevalence of 'legal highs' and new psychoactive substances. The results indicate that prevalence levels are not substantial but there is a potential for rapid rise of use in certain sub-populations. Furthermore, new drugs appear to be widely accessible and some substances emerge both on the 'legal highs' and illicit markets. Furthermore, the online availability of 'legal highs' as revealed by the EMCDDA Internet snapshots conducted in 2011–12 has continued to increase.

Finally, the conclusions of the assessment of the Council Decision 2005/387/JHA carried out by the European Commission ([3],[4]) in the framework of the EU drugs action plan for 2009–12 ([5]) are also highlighted.

([1]) OJ L 127, 20.5.2005, p. 32.

([2]) A more precise term for these compounds is 'synthetic cannabinoid receptor agonists', however, the term 'synthetic cannabinoids' has been widely accepted and is therefore used throughout the report.

([3]) European Commission (2011), 'Report from the Commission on the assessment of the functioning of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances', Brussels, 11.7.2011, COM(2011) 430 final.

([4]) European Commission (2011), Commission staff working paper on the assessment of the functioning of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances, Brussels, 11.7.2011, SEC(2011) 912 final.

([5]) EU drugs action plan for 2009–12 (2008/C 326/09) [Official Journal of the European Union C 326/7 IV, 20.12.2008].

1. Introduction and background

The Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances establishes a mechanism for the rapid exchange of information on new psychoactive substances that may pose public health and social threats, including the involvement of organised crime. This allows European Union institutions and Member States to act on all new narcotic and psychotropic substances that appear on the European Union drug scene (see definitions in Annex 2). The Decision also provides for an assessment of the risks associated with these new substances, so that measures applicable in the Member States for the control of narcotic and psychotropic substances can also be applied to new psychoactive substances ([6]).

The EMCDDA and Europol, in close collaboration with their networks, the Reitox National Focal Points (NFPs) and Europol National Units (ENUs) respectively — are assigned a central role in detecting and reporting new psychoactive substances (Article 4 of the Decision). Furthermore, in cooperation with the European Medicines Agency (EMA), the two organisations may collect, analyse and present information on a new psychoactive substance in the form of a joint report (Article 5). The joint report provides evidence-based advice to the Council and the Commission on the need to request a risk assessment on a new psychoactive substance. Such a risk assessment examines the health and social risks posed by the use of, manufacture of, and traffic in a new psychoactive substance, the involvement of organised crime and the possible consequences of control measures. In order to carry out the risk assessment, the EMCDDA convenes a special meeting under the auspices of its Scientific Committee (Article 6).

To ensure transparency in the implementation of the Decision, Article 10 stipulates that: 'The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The report shall, in particular, include experience relating to coordination between the system set out in this Decision and the Pharmacovigilance system.'

In compliance with the above provision, the EMCDDA and Europol herewith present the seventh Annual Report on the implementation of the Decision for the period January to December 2011. The report outlines the results of the implementation, describes key issues arising from accumulated experiences and also serves as a monitoring tool.

The report is written as a stand-alone document with its annexes kept to a minimum. The report frequently refers to articles of the Decision; therefore, to facilitate its reading, the full text of the Decision is appended (Appendix 1). When describing the notified new psychoactive substances, the report presents sufficiently detailed information, while avoiding highly technical descriptions (the complete list of newly notified psychoactive substances, which includes detailed information on the chemical names, the reporting Member State and date of notification is presented in Annex 1). More comprehensive information on the new substances described in the report is available from the EMCDDA and Europol. Furthermore, definitions on new drugs used throughout the report are presented in Annex 2, and an overview of the main groups of new psychoactive substances monitored by the EWS is provided in Annex 3.

([6]) In compliance with the provisions of the 1961 UN Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances.

2. Implementation arrangements and cooperation with the EU Pharmacovigilance system

2.1 Specific implementation arrangements

2.1.1 Assistance to national EWSs

The EWS is frequently consulted by the Member States, individual experts, scientists and, increasingly, the media in relation to various new psychoactive substances. The EMCDDA regularly provides support to partners from the national EWSs assisting them in the identification of new substances. This is done by providing analytical data, exchanging data between forensic laboratories, cross-checking information from national databases and facilitating the exchange of drug samples where this is possible. Such activities prove to be useful for the identification of new psychoactive substances in the absence of reference materials, or where limited resources are available at national level.

In 2011, the quality of chemical analytical data exchanged on new psychoactive substances has continued to improve. In addition to the data in picture format (.jpg, .pdf) already collected, gas chromatography coupled with mass spectrometry (GC/MS) data in zipped Chemstation format and nuclear magnetic resonance (NMR) data, etc., have also been regularly provided. This facilitates considerably the work of forensic scientists by allowing them to import directly raw data into their GC/MS libraries and promotes the use of more selective detection methods.

Currently, the EMCDDA is finalising a compendium describing all EU national Early-warning systems, which will present a comprehensive overview of these systems, promote best practices and enhance the exchange of experiences.

In the context of the project for Pre-Accession Assistance (IPA) beneficiaries ([7]), the EMCDDA facilitates the establishment of a drug information system at national level compatible with EMCDDA standards. In 2011, a Reitox Academy on new psychoactive substances and the early–warning system was organised in Tirana with the participation of Europol. The main objective was to provide the knowledge and skills necessary to participate in the EWS network and to provide a basis to establish and/or strengthen the respective national systems.

2.1.2 Annual meeting of the Reitox EWS network and First international multidisciplinary forum on new drugs

In 2011, the *11th Annual meeting of the Reitox Early-warning system network* was organised in Lisbon, followed by the *First international multidisciplinary forum on new drugs* ([8]).The purpose of the forum was to take stock of the state-of-the-art in the area of new drugs, anticipate future challenges and identify common anchor points that can inform future actions. Discussions charted how the new drugs phenomenon has developed over the last ten years, and explored through case studies differing national approaches.

Participants included representatives from more than 40 countries (the 30 EMCDDA member countries plus Australia, Belarus, Canada, Hong Kong SAR, Israel, Japan, New Zealand, Russia, Switzerland, Ukraine and the United States). Furthermore, major international organisations such as the Inter-American Drug Abuse Control Commission (CICAD), the Pompidou Group of the Council of Europe, the United Nations Office on Drugs and Crime (UNODC) and the World Health Organization (WHO) as well as the European Commission, Europol and the European Medicines Agency also participated. The contributing experts came from various disciplines and included epidemiologists, forensic scientists, clinicians, law-enforcement officials, as well as technical staff from EU and international institutions selected for their technical expertise and research in the field of new psychoactive substances.

([7]) Participating countries: Bosnia and Herzegovina, Serbia, Montenegro, the Former Yugoslav Republic of Macedonia, Kosovo (under UNSCR 1244/99), Turkey and Croatia.

([8]) Meeting documents available at: http://www.emcdda.europa.eu/events/2011/new-drugs-forum

A general conclusion from the forum was that there had been a paradigm shift in the drugs field, reflecting broader social processes. The speed at which the new drug phenomenon develops calls for a re-evaluation of the information sources used and the ways in which we disseminate information to inform policy, practice and the general public. Furthermore, the forum highlighted the need to better understand the possible acute and chronic health implications of the use of these new substances and to identify and monitor patterns and trends in their use. A starting point would be: to map out the future research agenda, particularly focusing on developing common concepts, terminology and instruments; to invest in forensic science research and the detection of new substances available on the market; to take a more holistic analysis to understand better the interplay between established illicit drugs and new psychoactive substances; and to develop theoretical models that could help predict the substances that may pose particular risks or have the potential to become established. ([9])

In view of the importance of international cooperation in this area and the high interest from all international partners, the US National Institute on Drug Abuse (NIDA) decided to partner with the EMCDDA in co-organising the *Second interdisciplinary forum on new and emerging psychoactive substances* in 2012 ([10]).

2.1.3 Structured monitoring of the Internet — online availability of 'legal highs'

To complement the main EWS data sources such as seizures and reports on use and toxicity, the EMCDDA actively monitors the online availability of unregulated psychoactive substances and products. One of the main potentials for the EMCDDA to be of added value in this area lies in the multilingual approach and the utilisation of sound methodology over time ([11]).

EMCDDA Internet monitoring is carried out in the form of snapshots, which are performed during a short time window on one or more substances and/or products. In 2011, two multilingual, wide-scope EMCDDA snapshots were carried out on the same substances as the 2010 annual snapshot. Furthermore, at the beginning of 2012 a snapshot was conducted in 20 EU languages plus Ukrainian, Russian and Norwegian.

The total number of online drugs shops offering at least one psychoactive substance/product rose from 170 in January 2010 to 314 in January 2011. The increase continued with 630 shops identified in July 2011 and 690 in January 2012. In general, these sites more often sell new drugs under names such as 'herbal highs' or 'research chemicals' than under the term 'legal highs'. The main increase seems to be due to a rise in the number of 'US shops' although establishing the country of origin of online shops is difficult. In 2011, mephedrone continued to be available on the Internet through online shops although at fewer sites and at higher prices.

Some Member States carry out additional Internet snapshots in their own languages. For example, in January and February 2011 the Hungarian NFP carried out an Internet snapshot on the online sale of MDPV, JWH-018, GBL and mefildronon (a fictitious compound), identifying 19 online shops offering at least one of the four substances. In Italy, France, Slovakia and Romania the online sales are also monitored.

Test purchasing of new psychoactive substances and forensic studies have shown that the contents of products are variable — they may contain controlled substances, the composition may vary from sample to sample, and a psychoactive substance can be sold under different product names. In this context, the EMCDDA has launched a specific project — 'Match' — that attempts to relate products' names to their content. The data integrated in this searchable tool include

([9]) EMCDDA (2011), 'Concluding remarks of the First international multidisciplinary forum on new drugs'. Available at: http://www.emcdda.europa.eu/news/2011/new-drugs-forum-conclusion

([10]) 2012 NIDA International Forum, *New and emerging psychoactive substances: second interdisciplinary forum,* June 8–11, 2012, Palm Springs, California, USA. Information available at: http://www.cvent.com/events/2012-nida-international-forum/event-summary-993dab44351348b1874d61aba460c8e5.aspx

([11]) EMCDDA briefing paper (2011), 'Online sales of new psychoactive substances/'legal highs': summary of results from the 2011 multilingual snapshots' at: http://www.emcdda.europa.eu/publications/scientific-studies/2011/snapshot

information from Reporting Forms, national test purchases, scientific literature, and Internet snapshots. By end of 2011, the 'Match' tool comprised more than 300 product/substance(s) entries thereby providing an insight into the most commonly sold products/substances. This project, however, needs to be further conceptualised and automatised.

2.2 Cooperation with the EMA and the Pharmacovigilance system

The European Medicines Agency (EMA) is a key partner in the implementation of the system set up by the Decision. The EMCDDA and EMA have established a mechanism for bilateral exchange of information on the basis of data available through the Early-warning system and the European Union Pharmacovigilance system. Electronic tools such as the existing databases — EudraVigilance, EMA and the European Database on New Drugs (EDND), EMCDDA — are being used to enable a rapid and reliable exchange of information. The regular information exchange between the EMCDDA and EMA includes formal reports on new psychoactive substances through Reporting Forms, as well as *ad hoc* reports on misused medicines in order to complement the reporting via the EU Pharmacovigilance system.

The EMA is currently preparing a *Good vigilances practice* (GVP) guide to formalise and cover the provisions of Regulation (EU) 1235/2010 ([12]). Pursuant to Article 28c of the Regulation, in 2011 a draft implementation proposal was prepared by the EMA and the EMCDDA. The draft proposal foresees that EMA EudraVigilance queries will provide to the EMCDDA, on request, data on relevant preferred terms (PTs) from the standardised MedDRA ([13]) queries (SMQs) 'drug abuse, dependence and withdrawal'.

In 2011, consultations and exchange of information between EMCDDA and EMA took place on two substances:

- 5-HTP or oxitriptan (INN) — a widely marketed off-the-shelf food (dietary) supplement, which can be used as a precursor to 5-hydroxytryptamine. The EMA reported 32 specific adverse reactions, which were extracted from EudraVigilance.

- phenazepam — an internationally non-controlled benzodiazepine used for the treatment of epilepsy, alcohol withdrawal syndrome, insomnia and anxiety in Russia and some neighbouring countries. Two cases related to phenazepam were found in EudraVigilance: one of them reporting hallucination (PT), and the other one reporting respiratory depression, asthma, headache and toxicity to various agents.

([12]) Article 28c, of Regulation (EU) 1235/2010 stipulates that the EMA and the EMCDDA 'shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs'. The Regulation will apply as of 2 July 2012.

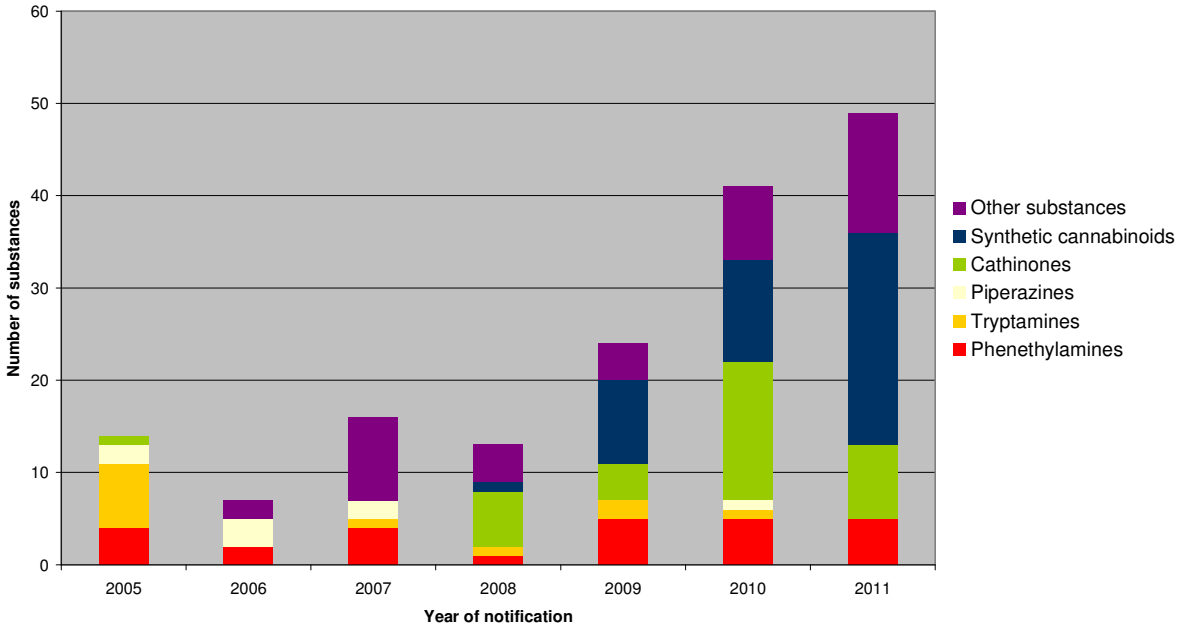
([13]) Medical Dictionary for Regulatory Activities.

3. Results achieved in 2011

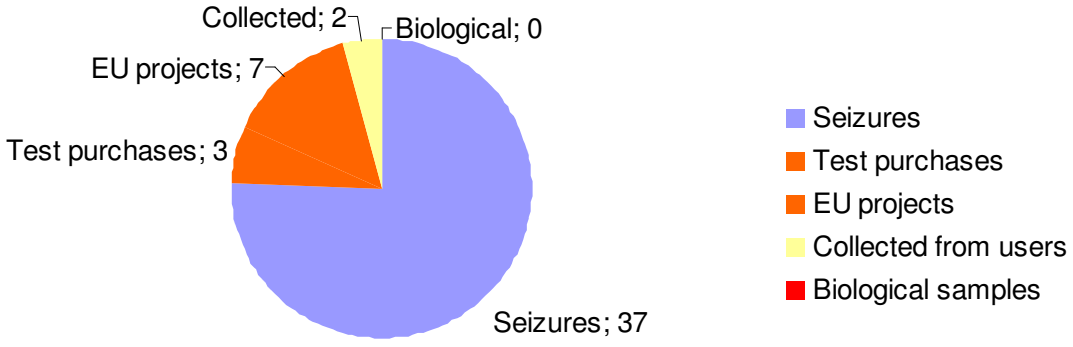
3.1 New psychoactive substances notified in 2011

During 2011, a total of 49 new psychoactive substances were officially notified for the first time in the European Union via the EWS (see Annex 1 and Graph 1). This is the largest number of substances ever reported in a single year. The marked increase in the number of substances notified takes place in the context of a continuous development of the 'legal highs' phenomenon and probably reflects both the number of substances available in the EU as well as the improved reporting capacities of national Early-warning systems due to increased awareness about new drugs among various professionals and high interest at national level. Some of the newly identified substances have been actively sought through test purchases of 'legal highs' products on the Internet and from specialised shops (see Graph 2).

Graph 1. Number of new psychoactive substances notified in 2005–11, by year



Graph 2. Source of new psychoactive substances notified in 2011, by type of notification



Of the newly identified substances, synthetic cannabinoids and cathinones represented about two thirds of the number of substances notified in 2011 (but also of the total number of substances reported under the terms of the Council Decision), thus becoming two of the largest drug families monitored by the EWS. The 23 new synthetic cannabinoid receptor agonists reported ([14]) belonged to different sub-families (see 3.3 below). Furthermore, eight new synthetic cathinones ([15]) and five substances belonging to the phenethylamine chemical family ([16]) were reported.

There were also compounds belonging to an expanding range of chemical families that are relatively new or for which a small number of representatives had been previously reported — 2 aminoalkylbenzofurans (cp. Annex 1, substances 22 and 23), a thiophene analogue of methamphetamine (cp. Annex 1, substance 3), and aminoindane (cp. Annex 1, substance 9), and a substituted piperidine (cp. Annex 1, substance 37). Also included are seven substances, which are medicines, metabolites or precursors of medicines or that could be described as 'designer medicines' ([17]).

From the above list, it is worth noting the appearance of several derivatives of controlled drugs:

- two aminopropylbenzofuran (APB) positional isomers — unsaturated benzofuran derivatives of APDB compounds and deoxygenated derivatives of the controlled drug methylenedioxiamphetamine (MDA) — which act as serotonin (5-HT(2c)) agonists;

- methylthienylpropamine, a thiophene analogue of methamphetamine;

- 4-MeO-PCP, a derivative of phencyclidine (PCP);

- methoxyphenamine, a positional isomer of para-methoxymethamphetamine (PMMA);

- and 4-benzylpiperidine, a substituted piperidine structurally very close to benzylpiperazine (BZP).

The aminoindane 5-iodo-2-aminoindane (5-IAI) already anticipated in 2010 by an Internet snapshot) was also identified in 2011.

The list of substances with medicinal properties or 'designer medicines' (substances designed to mimic the effects of known medicines by slightly altering their chemical structure) included derivatives and metabolites of several medicines:

- Phenazepam and etizolam, two benzodiazepines used in some countries. Phenazepam is scheduled in Finland and Norway, furthermore, in 2011, the Advisory Council on the Misuse of Drugs published advice to Government in relation to phenazepam, recommending that the substance be brought under the control in the UK;

- Ethylphenidate, a derivative and metabolite of methylphenidate (Ritalin), a CNS stimulant used in the treatment of attention deficit hyperactivity disorder (ADHD);

- Camfetamine, a derivative of fencamfamine (Reactivan) used for the treatment of depressive daytime fatigue, lack of concentration and lethargy, in individuals with chronic medical conditions;

- 5-hydroxytryptophan (Oxitriptan), a chemical precursor as well as metabolic intermediate in the biosynthesis of the neurotransmitters serotonin and melatonin from tryptophan;

([14]) Annex 1, substances 1, 4, 6–8, 10, 13–16, 18, 21, 24, 26–32, 43, 45 and 48.

([15]) Annex 1, substances 12, 33–36, 38, 39 and 47.

([16]) Annex 1, substances 5, 11, 19, 40 and 49.

([17]) Annex 1, substances 2, 17, 20 25, 41, 42, 44 and 46.

- 3-amino-1-phenyl-butane, a metabolite and a precursor of Labetalol, an alpha/beta adrenergic antagonist used to treat high blood pressure and angina pectoris; and

- Ostarine, a tissue-selective androgen receptor modulator (SARM) under development for the prevention and treatment of muscle wasting in patients with cell lung cancer (see section 4.4).

Following the formal notifications, new substance profiles were created in the European Database on New Drugs (EDND). In addition, the EMCDDA implements longer-term monitoring through biannual EWS reports. Based on the information collected and analysed, the list of all notified substances is reviewed regularly by the EMCDDA and Europol in order to identify those with a potential to trigger a joint report. At the time of writing this report, no substance merited the production of a joint report. However, the EWS remains vigilant as there are a few substances of concern that need to be proactively followed up on (see subsection 3.4.1).

3.2 Synthetic cannabinoids and follow-up on mephedrone

3.2.1 Synthetic cannabinoids

In 2011, 23 new synthetic cannabinoid receptor agonists were reported via the EWS, bringing the total number of synthetic cannabinoids reported to 45, the largest drug family monitored by the EMCDDA.

The synthetic cannabinoid compounds reported between 2008 and 2010 belonged to five different chemical groups — naphthoylindoles, cyclohexylphenols, tricyclic terpenoids, phenylacetylindoles and benzoylindoles. In addition, five new groups emerged during 2011 and early 2012 — naphthoylpyrroles, naphthoylnaphthalenes, adamantoylindoles (2011), and quinones and cyclopropylindoles (reported in 2012). Furthermore, allosteric modulators, a new type of agonists that belong to chemically diverse families, were identified for the first time. Allosteric modulators bind to receptor sites that are topographically distinct from the agonist-binding site and cause a conformational change in the receptor that alters the activity of the ligand.

While in the previous reporting period control measures mainly consisted of individual listing of already identified synthetic cannabinoids, in 2011 several countries adopted 'generic' or 'generic-like' definitions similar to the ones devised by the UK (2009) and Ireland (2010) ([18]). Most of the generic controls applied currently cover five of the most 'common' families — naphthoylindoles, naphthoylpyrroles, naphthylmethylindenes, phenylacetylindoles and hydroxycyclohexylphenols. Although there are some exceptions, for instance, the Italian legislation is one of the few that covers the family of benzoylindoles (to which RCS-4 or AM-694 belong).

Following the first adverse effects related to synthetic cannabinoids JWH-122 reported in 2010 in Italy and Germany, several studies have described toxicity following the use of 'Spice'-like products. In 2011, a German study reported intoxications following recreational use of herbal products containing synthetic cannabinoids ([19]). The case series consisted of 29 cases hospitalised after inhalation of herbal mixtures containing synthetic cannabinoids. Most of the intoxications were due to JWH-210 (12 cases), JWH-122 (11), JWH-081 (7) and JWH-250 (4). The most frequent symptoms were: tachycardia (76% of the patients), agitation (41%), change of perception/hallucination (38%), hypertension (34%), elevation of plasma glucose (31%), decrease in plasma potassium concentration (28%) and nausea/vomiting (28%).

([18]) Austria, Italy and Lithuania.

([19]) Szabo, B., Auwaerter, V., Kneisel, S. and Hermanns-Clausen, M. (2011), 'Intoxications following recreational use of herbal products containing synthetic cannabinoids', IACM 6th Conference on Cannabinoids in Medicine and 5th European Workshop on Cannabinoid Research, 8-10 September 2011.

The extent to which these products are used is largely unknown. A number of surveys aimed at examining the prevalence of use of 'Spice'-like products have been launched but the coverage and representativeness of the studies carried out are still limited (see section 4.1).

3.2.2 Mephedrone

The *Report on the risk assessment of mephedrone in the framework of the Council Decision on new psychoactive substances* was published in the EMCDDA risk assessment series in May 2011 ([20]). One year after the Decision to control mephedrone ([21]), 26 Member States, Norway and Croatia control the substance under drug legislation ([22]).

Mephedrone is not commonly included in general population surveys, however a few recent studies have assessed the prevalence of its use after the ban (see section 4.1). For example, results from the British Crime Survey 2010/11 ([23]), carried out among a nationally representative population of 16- to 59-year-olds in England and Wales, showed that last year mephedrone use (1.4%) was at a similar level to ecstasy use, i.e. the third most used drug within this age group. In the population aged 16–24 mephedrone was as popular as powder cocaine (4.4%), the second most used drug among young people. Of those who used mephedrone in the last year, the majority had also taken another drug (mainly cannabis, cocaine or ecstasy). Therefore, it is likely that it is existing users of drugs taking mephedrone rather than new users drawn to drug taking. An important caveat to understand the significance of these figures is that the data collection for the survey covered pre-and post-mephedrone ban periods.

In 2010–11, the Hungarian NFP/EWS reported increasing prevalence of the injecting use of mephedrone and other cathinones.

3.3 Public health warnings

The Council Decision stimulates the identification, monitoring and exchange of information on emerging trends in new uses of existing substances and on possible public health-related measures. The warning on adverse health effects of new psychoactive substances through timely and rapid public health alerts is one of the core activities of the EMCDDA EWS. In addition, in 2011, the EWS issued public health warnings to the Reitox network concerning unusual hazards of occurrences related to controlled drugs.

3.4.1 Adverse health effects related to new psychoactive substances

In 2011, the EWS issued public health warnings concerning adverse health effects related to the following substances:

– Para-methoxymethylamphetamine (PMMA)

PMMA was risk assessed in 2001 in the framework of the 1997 Joint Action on new synthetic drugs ([24]) and consequently controlled at European level. It is known to have considerable toxicity and to have been responsible for fatal overdoses in the past. As a follow-up to the warnings sent by the EWS in 2010 on the PMMA-related deaths and seizures in Norway, the Norwegian Institute of Public Health informed that there had been a total of 20 PMMA-related deaths between July 2010 and September 2011. Alerts on fatal cases related to the substance were also received by the Austrian NFP and the UK NFP/EWS (from the Scottish Crime and Drug Enforcement Agency).

([20]) EMCDDA (2011), *Report on the risk assessment of mephedrone in the framework of the Council Decision on new psychoactive substances.* Also available at: http://www.emcdda.europa.eu/html.cfm/index116639EN.html

([21]) Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures. OJ L 322, 8.12.2010, p. 44.

([22]) Except Netherlands (planned for March 2012) and Turkey.

([23]) Smith, K., Flatley, J. (2011), 'Drug misuse declared: findings from the 2010/11 British Crime Survey England and Wales', July 2011, UK Home Office Statistical Bulletin.

([24]) EMCDDA (2003), *Report on the risk assessment of PMMA in the framework of the joint action on new synthetic drugs*. Also available at: http://www.emcdda.europa.eu/html.cfm/index33349EN.html

An important new development related to PMMA was discovery of the substance in 'legal high' products in Scotland and in Spain. The appearance of a controlled substance in 'legal high' products may suggest an interplay between the 'legal high' and illicit markets, and clearly poses a threat to users.

– 4-Methylamphetamine
This phenethylamine closely related to amphetamine was researched in the past as an appetite suppressant and has serotonin, norepinephrine, and dopamine releasing properties. In October 2011, the Belgian EWS (Reitox NFP) reported that three fatalities and three intoxications related to the substance occurred in August/September 2011. In most of the cases, amphetamine was also identified in blood and/or collected samples. Following this alert, the UK NFP/EWS (ROAR Forensics) informed on two previous fatalities (2010 and 2011) involving the same substance.

Following this alert, the EMCDDA requested Europol to appraise the information available on this substance through the 27 Europol National Units (ENUs). Thirteen ENUs answered the request, with Austria, Finland and Luxembourg reporting new information on seizures.

– 3,4-methylenedioxypyrovalerone (*MDPV)*
Following the reports on adverse effects and fatalities received in 2010 by Finland, in 2011 the Finnish Poison Control Center reported several enquiries concerning this cathinone. The most typical clinical symptoms were agitation, tachycardia, hypertension and dyspnea, and less commonly, a decreased level of consciousness and convulsions. The Belgian and the Greek EWS also informed on psychotic episodes associated with MDPV.

– Pipradol-related substances, diphenylprolinol (D2PM)
Following the alerts issued in 2010 on desoxypipradol (2-DPMP) and 2-(diphenylmethyl)pyrrolidine (desoxy-D2PM), a study on five analytically confirmed cases of acute toxicity related to the recreational use of D2PM was reported in the UK. Patients presented with ongoing prolonged neuropsychiatric symptoms of agitation, anxiety and insomnia. None had evidence of sympathomimetic toxicity on presentation to the emergency department. Following these alerts, the Advisory Council on the Misuse of Drugs published advice to the UK Government in relation to diphenylprolinol (D2PM) and diphenylmethylpyrrolidine and desoxypipradrol recommending that the substances be brought under control.

– Methoxetamine
This arylcyclohexylamine — a derivative of ketamine and phencyclidine — was reported for the first time in November 2010 by the UK NFP. Its mechanism of action involves NMDA receptor blockade and dopamine reuptake inhibition. A study reporting the acute toxicity associated with the recreational use of methoxetamine in a case series of three patients was reported in the UK ([25]). Clinical features were suggestive of a dissociative (catatonic) state similar to that seen with ketamine; in addition, the patients had clinical features of acute sympathomimetic toxicity with significant tachycardia and hypertension. In 2012, upon a request from the UK the EMCDDA launched an information request on this substance.

– Unusual mixture of drugs
Adverse effects related to an unusual mixture of drugs involving 3- or 4-MeO-PCP, 2C-E and possibly N,N-dimethylcathinone were reported in Norway, in August 2011. The National Criminal Investigation Service received reports of several overdoses with hospitalisation, nausea and muscle spasms among users of the powder.

3.4.2 Hazards related to controlled substances

The potent synthetic opioid fentanyl was detected in four cases in Scotland in the period March to April 2011. In all cases, small quantities of white powder containing fentanyl were detected while no opium alkaloids were identified. The substances were being marketed to heroin users as 'China

([25]) Wood, D. M., Davies, S., Puchnarewicz, M., Johnston, A. and Dargan, P. I., (2011), 'Acute toxicity associated with the recreational use of the ketamine derivative methoxetamine', Eur J Clin Pharmacol DOI 10.1007/s00228-011-1199-9.

White' heroin. Fentanyl was detected in two drug-related deaths in Scotland and one in Greece, as well as in two intoxications in Bulgaria.

In March 2011, the French health authorities alerted on six intoxications and a fatality related to the benzodiazepine alprazolam, used as a cutting agent in heroin. In Ireland, two deaths were attributed to counterfeit benzodiazepines sold as Xanax (alprazolam) purchased in the UK.

In October 2011, increased media coverage in Germany of the drug called 'crocodile' prompted a collection of information and an EWS warning. 'Crocodile' is a self-made drug/preparation encountered in Russia, reported to contain among other substances desomorphine, an opiate known for a long time, which is controlled by the 1961 UN Drug Convention on narcotic substances (Schedules I and IV). Following the alert, the French SINTES issued an information note on the case. There are no forensic or toxicological data confirming the availability of 'crocodile' in the EU.

In 2011 the EMCDDA received reports from Greece of a drug circulating in Athens, called 'SISA'. Analyses of seizures confirmed that the active ingredient was methamphetamine. According to user reports, the substance is most frequently smoked, although it can be also injected and it can be used in combination with heroin and/or other medicines. The reported effects are similar to those of methamphetamine. Further investigation is ongoing in 2012 in order to establish a more precise picture and potential fatalities related to this drug.

4. Epidemiology and new approaches

4.1 Emerging prevalence data on new drugs

Prevalence data on new psychoactive substances are scarce and when available have many limitations and associated methodological issues, for example lack of common definitions as well as small and often non-representative population samples.

In Europe, there are few studies on the prevalence of 'legal highs', as a collective term or referring to individual substances. In 2010, a small number of surveys explored the extent, patterns of use and availability of mephedrone in Europe, primarily Internet surveys and studies with self-selected convenience samples. In 2011, representative studies were conducted for the first time on the prevalence of 'legal highs' and new psychoactive substances (see section 3.2.2). The results indicate that prevalence levels are not high but there is potential for rapid rise of use in certain sub-populations.

At European level, the 2011 Eurobarometer survey interviewed over 12 000 young people (aged 15–24) across Europe. Overall, 5% of respondents reported having used 'legal highs'. In most EU countries, not more than 1 in 20 young people reported having used legal substances that imitated the effects of illicit drugs. However, in the UK, Latvia and Poland, self-reported use of 'legal highs' was close to 10% and respondents in Ireland were by far the most likely to say they had used new substances (16%). Of the young people who had experience with new substances, 54% indicated that they had been offered such substances by friends, against 37% who had been offered such substances during a party or in a pub, and 33% who had bought these substances in a specialised shop, e.g. a smart shop. Just 7% of interviewees had bought these substances over the Internet.

In Spain, the national survey on drug use in students aged 14 to 18 years (2010) with a sample of 25 000, introduced a special module on emerging drugs, the prevalence of these substances and the perceived risk and availability. The nine substances studied were: ketamine, 'Spice', piperazines, mephedrone, nexus (2C-B), methamphetamine, magic mushrooms, 'research chemicals' and 'legal highs'. Overall, 3.5% of students reported having consumed one or more of the drugs mentioned above at some time in their life, 2.5% had consumed during the previous year and 1.3% last month. The results showed a low level of prevalence of use of mephedrone among secondary school students aged 14–18 (0.4% lifetime use). The prevalence of consumption in the last month also showed very low levels (0.2%), confirming the sporadic nature and experimental use of these substances among students in this age group. Low percentages of 'Spice' products were also reported: 1.1%, 0.8% and 0.5% for lifetime, last year and last month prevalence, respectively.

Mephedrone and 'legal highs' were included for the first time in the drug prevalence survey of households in Ireland and Northern Ireland conducted in 2010/11, i.e. after mephedrone was put under control. The sample comprised 7 669 respondents, aged between 15 and 64. In Northern Ireland, the prevalence rate was around 2%, 1% and 0.1% (lifetime, last year and last month) for both mephedrone and 'legal highs' ([26]). The lifetime prevalence rate for people aged 15–24 was 6% for both mephedrone and 'legal highs'. In the Republic of Ireland, with regard to drug use in the year prior to the survey, new psychoactive substances (4%) were the second most frequently reported illegal drugs after cannabis (6%). People aged between 15–24 years reported the highest last year use of any illegal drug (15%). Those aged 15–24 years also reported the highest use of cannabis (13%), new psychoactive substances ([27]) (10%), amphetamines (1.5%), ecstasy (1.1%) and magic mushrooms (1%).

([26]) In Northern Ireland, the category 'legal highs' includes party pills, herbal highs, party powders, Kratom and Salvia Divinorum.

([27]) In the Republic of Ireland the measurement of new psychoactive substances included herbal smoking mixtures/incense, party pills or herbal highs, bath salts, plant feeders or other powders, Kratom (Krypton), Salvia, Magic Mint, Divine Mint or Sally D and other new psychoactive substances mentioned by the respondent.

A 2008 Polish study among a representative national sample of about 1 250 students aged 18–19 found that just 3.5% had used 'legal highs' at least once in their life, while a follow-up study in 2010 reported an increase to 11.4%. The use of 'legal highs' during the last 12 months was reported by around 2.6% of students in 2008, and increased to 7.2% in 2010. This period saw a rapid development of the smart/head shops sales network in Poland, with the number of shops increasing from around 40 in 2008 to more than 1 500 in 2010. The survey was conducted just after the closure of shops. In terms of awareness and purchasing experience, the 2010 survey found: 90% of the respondents had heard about 'legal highs', 27% had visited a smart/head shop (40% of these made a purchase), while only 1% bought them online. As for types of purchase: 31% bought herbal concoctions, 6% sniffing powders, and 4% paraphernalia.

In contrast, an additional Polish general population study conducted in both 2009 and 2010 among one thousand respondents aged 15–75, revealed a divergent trend on the consumption levels of 'legal highs' — in particular, a drop in use was recorded after closure of the Polish smart shop network. In 2010, 3% of the respondents admitted using 'legal highs' at least once — a reduction from 6% in 2009. Fewer than 2% had used them in the last 12 months, compared with 5% in 2009.

A 2009 study from Frankfurt, Germany, also reported use of 'Spice' among students ([28]). In 2009 (sample of 1 157 respondents), a total of 7% of the 15- to 18-year-olds in Frankfurt reported experience with smoking mixtures. While there was little change in this figure in comparison to 2008 (sample of 1 029 respondents), last month prevalence declined from 3% to 1% with repeated use representing an exception. Students with experience in the consumption of 'Spice' were, for the most part, experienced cannabis consumers.

4.2 EMCDDA 'Trendspotter' methodology

At the end of 2010, an alert and information appraisal on a heroin drought, reported mainly in the UK and Ireland, was sent to the EWS network. While in some countries there seemed to be no evidence of such shortage, others reported varying purity in the heroin available. In October 2011, as a follow-up on this phenomenon, an information request was sent out to the EWS network to appraise the updated information on this.

The first EMCDDA Trendspotter meeting, on *Recent shocks in the European heroin market: explanations and ramifications*, took place in Lisbon on 18–19 October 2011 ([29]). The purpose of the meeting was to increase understanding of the 2010/2011 heroin shortage reported by some European countries, to explore issues of drug replacement, and to undertake a first pilot of EMCDDA 'trendspotter' methodology. Invited participants presented recent trends in heroin availability, use and replacement of heroin by other illicit drugs or medicines, providing insight from different disciplinary perspectives.

The 'trendspotter' methodology involves the collection of data from multiple sources and uses a number of different investigative approaches. The heroin market assessment included a review of the available literature, an electronic survey of experts and three rounds of data collection with the EMCDDA network of Reitox focal points and EWS network. In addition, data were collected in one country using a questionnaire posted in Twitter. The input received covered multiple perspectives on the heroin market including supply-side and law-enforcement expertise, forensic and monitoring data, treatment and care experience, and drug user perspectives. Analysis involved triangulation of the available data with a view to providing as complete and verified a picture as possible.

In summary, some European countries experienced severe heroin shortages or droughts in the 2010 to 2011 period ([30]). A key conclusion from the meeting was that it is important to take a

([28]) Werse, B. (2010), 'Spice, Smoke, Sence & Co. – herbal mixtures containing cannabinoids: use and motivation for use against the backdrop of changing laws', Report from the German Federal Ministry of Health Division 125: Addiction and Drugs.

([29]) Meeting documents available at: http://www.emcdda.europa.eu/events/2011/trendspotter

([30]) EMCDDA (2011), 'Summary report from EMCDDA Trendspotter meeting 18–19 October 2011'. Available at: http://www.emcdda.europa.eu/scientific-studies/2011/trendspotters-report

holistic approach to the European drug market, moving away from a focus on individual substances to consideration of a complex market model with a range of competing products. It appears that both (new) synthetic drugs and medicines may be becoming more important in European illicit drug markets. Supply-side action is probably a factor in recent heroin shortages. Both bounce-back and recovery appear to be occurring and, arguably, Europe may now have a faster moving and more dynamic illicit drug marketplace.

4.3 Sewage epidemiology: wastewater analysis

Sewage epidemiology or wastewater analysis is a rapidly developing scientific discipline with the potential for monitoring population level trends in illicit and new drug consumption. Advances in analytical chemistry have made it possible to identify urinary excretion of illicit or new drugs and their main metabolites in wastewater at very low concentrations. This is comparable to taking a much diluted urine sample from an entire community (rather than from an individual user). With certain assumptions, it is possible to back-calculate from the amount of the metabolite in the wastewater to an estimate of the amount of a drug consumed in a community.

While early research focused on identifying cocaine and its metabolites in wastewater, recent studies have produced estimates on levels of cannabis, amphetamine, methamphetamine, heroin and methadone. The identification of less commonly used drugs, such as ketamine and new psychoactive substances, appears promising. Two expert meetings on wastewater analysis were organised by the EMCDDA in 2011 ([31]).

4.4 Computer-aided prediction of properties (toxicity, psychoactivity)

According to the similarity principle, molecules with similar chemical structures possess similar physicochemical properties and biological activities. The concept of molecular similarity has been exploited in drug discovery and similarity methods have been employed in the prediction of physicochemical properties (solubility, partitioning coefficient), estimation of absorption, distribution, metabolism, excretion and toxicity (ADME/Tox), etc.

Computational modelling for the assessment of toxicity entails prediction of the binding and efficacy of molecules at biological receptors; thus some of the key properties to be examined are solvation effects and heterogeneity of binding sites. Chemogenomics comprises a systematic relationship between targets and ligands that are used as target modulators in living systems. *In silico* target prediction tools can suggest likely biological targets of small molecules via data mining in target-annotated chemical databases.

The psychoactive potential of Ostarine (first notified in 2011, see Annex 1), an androgen receptor targeting agent used for oral testosterone replacement therapy, male contraception, treating and imaging prostate cancer was assessed by a computational study using *in silico* methods ([32]). The analysis was two-fold: firstly, it entailed a prediction of the protein targets likely to be modulated by the compound and, secondly, the likelihood of the substance to permeate the CNS was assessed. The results of the study indicated that no targets known to be involved in psychoactive effects seem to be modulated by Ostarine and that the substance is unlikely to permeate the CNS although possibilities of active transport could not be ruled out. Therefore, based on currently available data, Ostarine appears to be unlikely to cause psychomodulatory effects in human.

([31]) http://www.emcdda.europa.eu/wastewater-analysis

([32]) Mohd-Fauzi, F., Bender, A. (2012), *Computational analysis of the possibility of Ostarine eliciting psychoactive effects*, University of Cambridge.

5. Production and distribution of new psychoactive substances

5.1 Europol

Over the last years, most of the new psychoactive substances notified by Member States to the EMCDDA via the EWS were produced (synthesised) and acquired (imported) from outside Europe. China and, to a lesser extent, India were identified as the source countries. With the production of new psychoactive substances taking place predominantly outside of Europe, a new niche for lucrative business has emerged, as reported by Belgium, Ireland and the Netherlands. Facilities which involve the importation, mixing and packaging of these substances in Europe have developed. The products are subsequently sold mainly as 'legal highs' via the Internet, smart and head shops. The initial production of such products/substances is very cheap and can provide easy profits to Organised Crime Groups (OCGs) and individual entrepreneurs.

Europol has received reports indicating that European Organised Crime Groups are engaged in both the tableting and marketing of these substances as ecstasy (MDMA) often disguised by use of logos usually associated with this type of drug. This has been related to the decrease in the availability of MDMA precursors, reported in 2010/11.

At the end of 2010 and the beginning of 2011, Europol's project Synergy was assigned an active role in the coordination of investigations concerning new psychoactive substances, such as the trafficking of mephedrone. The substance, manufactured in China, often entered European countries in which it was controlled, via a third country where it was not. Furthermore, Europol has become increasingly involved in transnational cases concerning mixing/packaging facilities and the trafficking of new psychoactive substances. Consequently, there has been an increase in reported seizures of new psychoactive substances submitted to the Synergy project's related expert systems ([33]) — with minor seizures reported in Estonia, Hungary, Latvia and Germany and more significant seizures involving consignments of hundreds of kilograms entering the European Union via the Netherlands.

In contrast to the main sources of these new psychoactive substances, Poland reported the dismantling of a production site in late 2011 which resulted in the seizure of 5 kg of mephedrone and charges related to the illicit production and trafficking of a further 50 kg. Other production places (points of importation, mixing and packaging) include facilities seized in Ireland, Belgium and the Netherlands. At the facility found in the Netherlands, 150 kg of white powders and approximately 20 000 packages containing several synthetic cannabinoids were seized.

Information on seizures of small quantities has been received from Hungary, Germany and Estonia concerning mainly cathinones and synthetic cannabinoids, and from Denmark, concerning mCPP. More substantial seizures concerning mainly unspecified new psychoactive substances were reported in Latvia (about 5 kg), the Netherlands (150 kg), Czech Republic (more than 20 kg of mephedrone originating from India) and Spain (seizure from a head shop totalling 96 kg).

5.2 The UK Serious Organised Crime Agency (SOCA)

In the UK, the Serious Organised Crime Agency (SOCA) found that some seized new psychoactive substances, sold as 'plant food' or 'research chemicals', contained controlled drugs. This is particularly the case for cathinones and piperazines. A recent report of forensic analysis of seized samples indicated that 19% of samples tested contained a controlled substance ([34]) — 20%, 18% and 22% contained cathinones, synthetic cannabinoids and piperazines, respectively.

([33]) All project Synergy subject-related expert systems are incorporated into a database system comprising the Europol Ecstasy Logo System, Europol Illicit Laboratory Comparison System, Europol Synthetic Drug System and Europol Synthetic Drugs Other Substances sub-systems.

([34]) Serious Organised Crime Agency (2011), 'Drugs: risks associated with new psychoactive substances', Intelligence report.

The extent to which organised criminals are involved in the trade of new drugs is unclear. Currently, the market seems to be driven by opportunist entrepreneurs taking advantage of the Internet for marketing and selling their products, and consumers who believe they are purchasing substances which are legal and safe but which may in fact contain hazardous substances.

In 2010/11 SOCA took action against websites which continued to advertise mephedrone and naphyrone for sale following their classification as Class B drugs in April and July 2010 respectively. In 2010/11 over 120 websites were closed down as a result of SOCA action, disrupting the supply of these drugs ([35]).

([35]) Serious Organised Crime Agency (2011), *Serious Organised Crime Agency Annual Report and Accounts 2010/11*. Available at: http://www.soca.gov.uk/about-soca/library/doc_download/301-annual-report-2010-11.pdf

6. The way forward

New drugs ('legal highs') have become a global phenomenon which is developing at an unprecedented pace. The speed at which new drugs appear on the market — reflected not only in the sheer number of substances, but also in their diversity and in how they are produced, distributed and marketed — challenges established procedures for monitoring, responding to and controlling the use of new psychoactive substances. This in turn has generated a much higher level of political, general public (media, society at large) and scientific interest and concern about the 'legal highs' phenomenon.

At political level, combating synthetic drugs and new psychoactive substances has been identified by the Committee on Internal Security (COSI) of the European Union as one of the EU priorities in combating organised crime and incorporated into a set of strategic goals and action plans for 2012–13. This calls for a re-evaluation of both the information sources we use and the ways in which we disseminate information to inform policy, practice and the general public. The important work of the EMCDDA and Europol in this area informed the assessment of the Council Decision 2005/387/JHA undertaken by the European Commission in the framework of the EU drugs action plan for 2009–12. The assessment concluded that the instrument is useful to tackle new substances at the EU level, in particular the Early-warning system. It also highlighted three major shortcomings related to the control phase: 'it is not able to tackle the large increase in the number of new psychoactive substances on the market, because it addresses substances one by one, through a lengthy process; it is reactive, as substances submitted to control measures are quickly replaced with new ones with similar effects, often through small modifications of their chemical composition; it lacks options for control measures'.

Currently, the Commission is carrying out an Impact assessment on a new instrument to replace the Council Decision 2005/387/JHA and, as announced in the Communication from the Commission 'Towards a stronger European response to drugs' ([36]), will propose stronger EU legislation on new psychoactive substances taking into account the rapid developments in this field and scientific evidence on the risks posed by these substances. The new proposal will:

- 'Enhance the monitoring and risk assessment of substances, by extending support for forensic analysis, toxicological, pharmacological and epidemiological studies.
- Provide swifter and more sustainable answers to the emergence of these substances, possibly by exploring ways to address groups of substances, notwithstanding the need to determine scientifically the harmfulness to health of the individual substance.
- Enable a faster response to the emergence of substances, including, possibly, through temporary bans on substances that pose immediate risks.
- Better align laws in the field of drug control, product and food safety, consumer protection and medicines to cover the wide variety of substances that emerge.'

These developments have increased the profile of the EWS and the workload of the networks at national and European levels while resources often remain unchanged. As a response to the need to remain vigilant and react rapidly to the new substances and products identified, the EWS network has increased its operational capacity and has expanded to include not only new forensic science and toxicological laboratories but also a range of health and law-enforcement professionals, as well as many independent researchers. The current system, however, remains reactive rather than proactive. So whilst significant reporting capabilities now exist which facilitate the speedy exchange and triangulation of information from existing sources, the current system lacks the ability to anticipate emerging threats, by actively purchasing, synthesising and studying new compounds. Investment to improve capacity for investigative forensic analysis and research at the European level, linked to and coordinated by the EWS, is therefore essential.

([36]) European Commission (2011), Communication from the Commission to the European Parliament and the Council, 'Towards a stronger European response to drugs', Brussels, 25.10.11, COM(2011) 689/2.

Annexes

Annex 1: New psychoactive substances reported to the EMCDDA and Europol for the first time in 2011 under the terms of Council Decision 2005/387/JHA

Annex 2: Working definitions on new drugs as used by the EMCDDA

Annex 3: Main groups of new psychoactive substances monitored by the EWS

Annex 1. New psychoactive substances reported to the EMCDDA and Europol for the first time in 2011 under the terms of Council Decision 2005/387/JHA

1. **CRA-13** (naphthalen-1-yl-(4-pentyloxynaphthalen-1-yl)methanone) – 11 January 2011 – Germany

2. **4-MeO-PCP** (4-methoxyphencyclidine) – 11 January 2011 – Finland

3. **Methylthienylpropamine** (N-methyl-1-(thiophen-2-yl)propan-2-amine) – 13 January 2011 – Finland

4. **AM-2201** (1-(5-fluoropentyl)-3-(1-naphthoyl)indole)– 18 January 2011 – Latvia

5. **N,N-dimethylamphetamine** (N,N-dimethyl-1-phenylpropan-2-amine) – 2 February 2011 – Bulgaria

6. **JWH-251** (2-(2-methylphenyl)-1-(1-pentyl-1H-indol-3-yl)methanone) – 22 February 2011 – Germany

7. **JWH-018 adamantoyl derivative** (1-adamantoyl(1-pentyl-1H-indol-3-yl)methanone) – 22 February 2011 – Germany

8. **JWH-182** (1-pentyl-3-(4-ethyl-1-naphthoyl)indole) – 1 March 2011 – Denmark

9. **5-IAI** (5-iodo-2-aminoindane) – 1 March 2011 – United Kingdom

10. **JWH-250 derivative** (1-(2-methylene-N-methylpiperidyl)-3-(2-methoxyphenylacetyl) indole) – 17 March 2011 – Poland

11. **DMMA** (3,4-dimethoxymethamphetamine) – 4 April 2011 – France

12. **α-PVP** (α-pyrrolidinopentiophenone) – 4 April 2011 – France

13. **RCS-4 ortho isomer** ((2-methoxyphenyl)(1-pentyl-1H-indol-3-yl)methanone) – 20 April 2011 – Sweden

14. **JWH-007** (1-pentyl-2-methyl-3-(1-naphthoyl)indole) – 25 May 2011 – Germany

15. **AM-1220** (1-[(1-methylpiperidin-2-yl)methyl]-1H-indol-3-yl}(naphthyl)-methanone) – 25 May 2011 – Germany

16. **AM-1220 azepane isomer** (1-(1-methylazepan-3-yl)-1*H*-indol-3-yl](naphthyl)methanone) – 25 May 2011 – Germany

17. **5-HTP** (5-hydroxytryptophan) – 25 May 2011 – Germany

18. **WIN 48,098** / **pravadoline** ((4-methoxyphenyl)-[2-methyl-1-(2-morpholin-4-ylethyl)indol-3-yl]methanone – 26 May 2011 – Germany and Poland

19. **2C-C-NBOMe** (2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine) – 10 June 2011 – Finland

20. **Ostarine** (3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methyl-propanamide) – 20 June 2011 – Sweden

21. **JWH-122 fluoropentyl derivative** (1-(5-fluoropentyl)-3-(4-methyl-naphthoyl)indole) – 20 June 2011 – Netherlands and Germany

22. **6-APB** (6-(2-aminopropyl)benzofuran) – 30 June 2011 – Hungary

23. **4-APB** (4-(2-aminopropyl)benzofuran) – 30 June 2011 – Hungary

24. **RCS-4(C4)** (4-methoxyphenyl-(1-butyl-1H-indol-3-yl)methanone) – 30 June 2011 – Hungary

25. **Phenazepam** (7-bromo-5-(2-chlorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one) – 14 July 2011 – Germany

26. **JWH-387** (1-pentyl-3-(4-bromo-1-naphthoyl)indole) – 20 July 2011 – Germany

27. **JWH-412** (1-pentyl-3-(4- fluoro-1-naphthoyl)indole) – 20 July 2011 – Germany

28. **JWH-307** ((5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone) – 5 August 2011 – Finland

29. **AM-2233** (1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole) – 5 August 2011 – Finland

30. **Org27569** (5-Chloro-3-ethyl-1H-indole-2-carboxylic acid [2-(4-piperidin-1-yl-phenyl)-ethyl]-amide)) – 5 August 2011 – Finland

31. **Org 27759** (3-Ethyl-5-fluoro-1H-indole-2-carboxylic acid [2-94-dimethylamino-phenyl)-ethyl]-amide) – 5 August 2011 – Finland

32. **Org 29647** (5-Chloro-3-ethyl-1H-indole-2-carboxylic acid (1-benzyl-pyrrolidin-3-yl)-amide, 2-enedioic acid salt) – 5 August 2011 – Finland

33. **N-ethylbuphedrone** (2-(ethylamino)-1-phenylbutan-1-one) – 12 August 2011 – Denmark

34. **Brephedrone** (1-(4-bromophenyl)-2-methylaminopropan-1-one) – 5 September 2011 – Finland

35. **Iso-pentedrone** (1-methylamino-1-phenyl-pentan-2-one) – 30 September 2011 – Austria

36. **4-Ethylmethcathinone** ((RS)-2-methylamino-1-(4-ethylphenyl)propane-1-one) – 7 October 2011 – Sweden

37. **4-Benzylpiperidine** ((phenylmethyl)piperidine) – 24 October 2011 – Bulgaria

38. **bk-MDDMA** (1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one) – 28 October 2011 – Finland

39. **4-methylbuphedrone** (2-(methylamino)-1-(4-methylphenyl)butan-1-one) – 1 November 2011 – Netherlands

40. **Methoxyphenamine** (1-(2-methoxyphenyl)-N-methylpropan-2-amine) – 30 November 2011 – United Kingdom

41. **Ethylphenidate** (ethyl 2-phenyl-2-(piperidin-2-yl)acetate – 30 November 2011 – United Kingdom

42. **Camfetamine** (N-methyl-3-phenylbicyclo[2.2.1]heptan-2-amine – 30 November 2011 – United Kingdom

43. **JWH-022** (naphthalen-1-yl(2-(pent-4-enyl)-1H-indol-3-yl)methanone – 30 November 2011 – United Kingdom

44. **Etizolam** (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2- f][1,2,4]triazolo[4,3-a][1,4]diazepine) – 2 December 2011 – United Kingdom

45. **AM-2232** (5-[3-(1-naphthoyl)-1H-indol-1-yl]pentanenitrile) – 6 December 2011 – Germany

46. **3-amino-1-phenyl-butane** – 12 December 2011 – Belgium and Poland

47. **α-PBP** (1-phenyl-2-pyrrolidino-butanone) – 20 December 2011 – Finland

48. **AM-694 chloro derivative** (1-(5-chloropentyl)-3-(2-iodobenzoyl)indole) – 21 December 2011 – Germany

49. **1-phenyl-1-propanamine** – 21 December 2011 – Bulgaria

Annex 2. Working definitions on new drugs as used by the EMCDDA

The Joint Action 97/396/JHA and the Council Decision 2005/387/JHA provide legally binding definitions of the substances they cover; however, there are a number of other terms in common usage in this area which may cause confusion. For example, historically, new psychoactive substances have often been referred to as 'designer drugs' although today the term 'legal highs' is used more often. Much overlap exists between these terms but for practical purposes it is worth delineating the concepts.

The term 'new' in all definitions is not intended to refer exclusively to newly invented/synthesised substances, but rather should be understood as 'newly available' or 'newly misused' substances.

New synthetic drug (1997 Joint Action 97/396/JHA)

The 1997 Joint Action 97/396/JHA ([37]) concerned **new synthetic drugs** '*which are not currently listed in any of the Schedules to the 1971 United Nations Convention on Psychotropic Substances* ([38])*, and which pose a comparable serious threat to public health as the substances listed in Schedules I or II thereto and which have a limited therapeutic value*' (Article 2).

The Joint Action '*relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances ([39]) and Council Directive 92/109/EEC of 14 December 1992 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances ([40]) provide for a Community regime*' (Article 2).

New psychoactive substance (Council Decision 2005/387/JHA)

Council Decision 2005/387/JHA broadened the scope of, and replaced, the 1997 Joint Action. Like the Joint Action, it takes the United Nations drug control Conventions as a point of reference, both to define the scope of the Decision (Article 2) and for the definition of a new psychoactive substance (Article 3).

Council Decision 2005/387/JHA ([41]) defines a **new psychoactive substance** as '*a new narcotic drug or a new psychotropic drug in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs* ([42])*, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV'* (new narcotic drug) or '*under the 1971 United Nations Convention on Psychotropic Substances* ([38])*, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV*' (new psychotropic drug). A preparation is defined as '*a mixture containing a new psychoactive substance*' (Article 3).

([37]) Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs. *Official Journal L 167*, 25/06/1997 p. 0001–0003.

([38]) *Convention on Psychotropic Substances, 1971*, United Nations.

([39]) OJ No L 357, 20. 12. 1990, p. 1. Regulation as last amended by Commission Regulation (EEC) No 3769/92 (OJ No L 383, 29. 12. 1992, p. 17).

([40]) OJ No L 370, 19. 12. 1992, p. 76. Directive as amended by Directive 93/46/EEC (OJ No L 159, 1. 7. 1993, p. 134).

([41]) Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances. *Official Journal L 127*, 20/05/2005 P. 0032–0037.

([42]) *Single Convention on Narcotic Drugs, 1961*, as amended by the 1972 *Protocol amending the Single Convention on Narcotic Drugs, 1961*, United Nations.

This formulation has a number of implications, for example substances already listed under the UN Conventions are by definition excluded from the scope of the Council Decision. An important difference to the 1997 Joint Action is the inclusion of narcotic drugs (1961 UN Convention) and psychotropic substances which pose a comparable threat as substances listed in Schedules III or IV of the 1971 UN Convention.

'This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances ([43]), and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors ([44]) provide for a Community regime' (Article 2).

'The new psychoactive substances covered by this Decision may include medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products ([45]) and in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use ([46])' (point 5 of the recital to the Council Decision). However, '*substances of established and acknowledged medical value are therefore excluded from control measures based on this Decision*' (point 8 of the recital to the Council Decision) as are psychoactive substances used to manufacture a medicinal product (Article 7.3).

Designer drugs and 'legal highs'

It is not new to design a drug using the structure of a parent compound with known properties. The term 'designer drugs', however, emerged in the 1980s and became particularly popular with the emergence of the 'ecstasy' compounds (MDMA, MDA, MDE, etc) on the illicit drug market.

Designer drugs were typically manufactured from chemical precursors in a clandestine laboratory. They can be best defined as unregulated (new) psychoactive substances intentionally designed to mimic the effects of controlled drugs by slightly altering their chemical structure in order to circumvent existing controls.

'Legal highs' is an umbrella term for unregulated (new) psychoactive substances or products claiming to contain them that are specifically intended to mimic the effects of controlled drugs.

The term encompasses a wide range of synthetic and/or plant-derived substances and products, which may be presented as 'legal highs' (emphasising 'legality'), 'research chemicals' (implying legitimate research use), 'party pills' (alternative to 'party drugs'), 'herbal highs' (stressing the plant origin), etc., which are usually sold via the Internet or in smart/head shops and in some cases intentionally mislabelled with purported ingredients differing from the actual composition.

The 'legal highs' are usually manufactured in chemical laboratories outside of Europe and legally imported, either as chemicals or as already packaged products. The 'legal highs' market is distinguished by the speed at which suppliers circumvent drug controls by offering new alternatives to restricted products and advertising them with aggressive and sophisticated marketing strategies (room odorisers, herbal incenses, bath salts, plant fertilisers, collectors items, etc.).

([43]) OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).

([44]) OJ L 47, 18.2.2004, p. 1.

([45]) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

([46]) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

The term ‘legal highs’ is used in inverted commas because describing these substances/products as ‘legal’ can be incorrect or misleading to customers as many of them can be covered, for example, by medicines or food safety laws. In addition, ‘legal highs’ products may contain substances controlled under drugs legislation.

Finally, the term ‘legal highs’ is often used to refer to the phenomenon, rather than to a specific substance, similarly to the ‘Spice’ phenomenon, which is used to describe the marketing and sale of herbal products containing synthetic cannabinoid receptor agonists.

Annex 3. Main groups of new psychoactive substances monitored by the EWS

It is scientifically sound practice to classify the new psychoactive substances based on their chemical structure (i.e. in chemical families) (see table below). An exception is the group of synthetic cannabinoids, which can be placed in a category based on their mode of action rather than on their chemistry which varies considerably. Described below are the main families of psychoactive substances reported via the EWS so far (see also the EMCDDA drug profiles) ([47]).

- Phenethylamines encompass a wide range of substances that may exhibit stimulant, entactogenic or hallucinogenic effects. Examples include the synthetic substances amphetamine, methamphetamine and MDMA (3,4-methylenedioxymethamphetamine) and mescaline, which occurs naturally.

- Tryptamines include a number of substances that have predominantly hallucinogenic effects. The main representatives are the naturally occurring compounds dimethyltryptamine (DMT), psilocin and psilocybin (found in hallucinogenic mushrooms) as well as the semi-synthetic lysergic acid diethylamide (LSD).

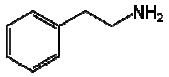
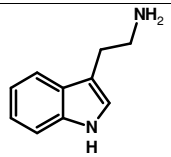
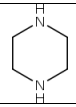
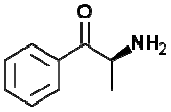
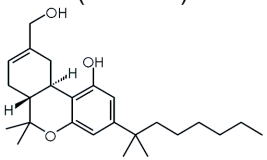
- Piperazines are represented by mCPP (1-(3-chlorophenyl) piperazine) and BZP (1-benzylpiperazine), both of which are central nervous system stimulants.

- Cathinones have stimulant effects. The main cathinone derivatives are the semi-synthetic methcathinone and the synthetic compounds mephedrone, methylone and MDPV (3,4-methylenedioxypyrovalerone).

- Synthetic cannabinoids are functionally similar to delta- 9-tetrahydrocannabinol (THC), the active principle of cannabis. Like THC, they can have hallucinogenic, sedative and depressant effects. They have been detected in herbal smoking mixtures such as ‘Spice’.

- Other substances reported to the Early-warning system include various plant-derived and synthetic psychoactive substances (e.g. indanes, benzodifuranyls, narcotic analgesics, synthetic cocaine derivatives, ketamine and phencyclidine derivatives), which do not strictly belong to any of the previous families. Also included here are a small number of medicinal products and derivatives.

([47]) EMCDDA drug profiles, available at: http://www.emcdda.europa.eu/publications/drug-profiles

Family	Parent compound	Chemical structure of the parent compound	Effects	Representatives	No of substances notified (2005–11)
Phenethylamines	phenethylamine (N)		stimulant and/or hallucinogenic	amphetamine, methamphetamine, MDMA, mescaline (N)	26
Tryptamines	tryptamine (N)		hallucinogenic	psilocin and psilocybin (N), dimethyltryptamine/DMT, lysergide/LSD (S)	12
Piperazines	piperazine		stimulant and/or hallucinogenic	*m*CPP, BZP, TFMPP	8
Cathinones	cathinone (N)		stimulant	cathinone (N), mephedrone, methylone, methcathinone (S)	34
Synthetic cannabinoids	N/A – the category includes a number of chemically unrelated but functionally similar families of cannabinoid receptor agonists that mimic the effects of Δ^9 – THC	(HU-210) 	hallucinogenic, sedative, depressant	JWH-018, CP 47,497, HU-210	44
Miscellaneous substances	N/A – the category includes new psychoactive plants as well as synthetic psychoactive substances, derivatives of well-established drugs not belonging to any of the families listed above, designer medicines, narcotic analgesics, etc.	N/A	stimulant, hallucinogenic, narcotic analgesic / opiate, depressant, etc.	N/A	40

(N) naturally occurring, (S) semi-synthetic, (N/A) non applicable

Appendix

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0387:EN:HTML

(...)

Legislações nacionais no que respeita a novas substâncias psicoativas

Nos últimos anos, a Europa testemunhou a ampla disponibilização, a um ritmo sem precedentes, de uma grande diversidade de novas substâncias psicoativas. A velocidade a que essas novas substâncias surgem, conjugada com a falta de informação sobre os riscos associados ao seu consumo, põe em causa o procedimento consagrado de ir acrescentando substâncias à lista das que são abarcadas pela legislação em matéria de droga. Muito embora a maioria dos países europeus continue a seguir este procedimento, vários são os que reagiram através da introdução de alterações inovadoras na sua legislação ou nas suas políticas de aplicação da mesma.

As alterações mais fundamentais envolveram a aprovação de novas disposições legislativas em matéria penal que criminalizam a distribuição não autorizada de substâncias psicoativas, como aconteceu na Irlanda, na Áustria e na Roménia. Observam-se algumas semelhanças, mas também diferenças fundamentais, entre estes três exemplos. No que diz respeito às próprias substâncias, todos os três países definem como substância psicoativa as que estimulam ou deprimem o sistema nervoso central e estão associadas à dependência, a alucinações ou a perturbações da função motora ou do comportamento. Na Irlanda, é preciso que estas perturbações sejam «significativas»; na Áustria, as substâncias só podem figurar numa lista se forem suscetíveis de gerar toxicodependência em determinados setores da sociedade constituindo uma possível ameaça para a saúde dos consumidores. Na legislação romena deixou de existir um requisito especificado associado à nocividade, ao contrário do que acontecia numa decisão governamental emitida anteriormente, no mesmo ano. Na Áustria, cumpre ao Ministro da Saúde mencionar o nome das substâncias ou dos grupos de substâncias num regulamento, ao passo que na Irlanda e na Roménia não é necessário mencionar o nome das substâncias – qualquer substância que possua as propriedades definidas na legislação é implicitamente abrangida. Na Áustria a oferta de droga constitui um crime se o fornecedor tiver o intuito de beneficiar com a mesma e pretender que o produto seja utilizado devido aos seus efeitos psicoativos; na Irlanda, apenas é necessário ter conhecimento da probabilidade de consumo humano; na Roménia, nenhum destes requisitos se aplica. As penas máximas para a oferta de droga são dois anos de prisão na Áustria, cinco na Irlanda e oito na Roménia, com um agravamento significativo na Áustria e na Roménia essa oferta conduzir a lesões graves ou à morte.

Mantendo embora a sua legislação já existente em matéria de droga, diversos países introduziram aperfeiçoamentos a fim de reforçar ou acelerar os procedimentos utilizados para incluir novas substâncias na lista das drogas. Foram formalmente criados painéis científicos de avaliação do risco na Hungria (2010) e na Finlândia (2011) que fornecem a fundamentação científica para a tomada de decisões relativas ao controlo de novas substâncias. Em 2011, o Reino Unido adotou um novo procedimento («*temporary class drug orders*») que permitirá que determinadas substâncias identificadas sejam rapidamente sujeitas a controlo ao abrigo da legislação em matéria de droga no máximo durante um ano; durante este período de tempo poder-se-á investigar a necessidade de controlo permanente. Uma proposta semelhante relativa a uma lista de controlo temporário foi aprovada pelo parlamento eslovaco, mas foi suspensa antes das eleições de 2012. Outra medida de aperfeiçoamento aplicada por alguns países foi o alargamento do âmbito de aplicação da legislação existente em matéria de droga através da listagem de substâncias como grupos definidos, e não individualmente, à semelhança do que acontecia anteriormente. Em 2009 e 2011, os canabinóides sintéticos foram definidos como grupos de substâncias controladas, respetivamente, pelo Luxemburgo e por Itália; posteriormente, Itália acrescentou uma definição de grupo para as catinonas. Em 2011, Chipre acrescentou à sua legislação em matéria de droga definições de grupos de canabinóides sintéticos, catinonas e fenetilaminas, estando simultaneamente França e a Alemanha a estudar a exequibilidade desta abordagem.

As alterações legislativas podem ser um processo moroso, e alguns países utilizam outras leis já existentes para acelerar a sua resposta a novas substâncias. Foram utilizadas leis relativas aos medicamentos para controlar substâncias não terapêuticas em pelo menos oito países. Foram aplicados, em Itália, na Polónia, em Portugal e no Reino Unido, diferentes tipos de leis relativas à segurança dos consumidores visando produtos psicoativos em geral (do que resultou o encerramento de lojas) ou substâncias individualmente consideradas. Por exemplo, a mefedrona era vendida como «substância fertilizante» ou «sais de banho» apesar de não servir para esses fins. Estas medidas podem constituir intervenções rápidas antes da aprovação de um controlo com base na legislação em matéria de droga, porém, também têm proporcionado aos países tempo para a conceção de respostas inovadoras.

Outra opção para controlar substâncias potencialmente nocivas é adaptar legislação já existente. Em 2010, a Polónia excluiu da definição de «droga substituta» (uma substância a utilizar em vez de uma droga para os mesmos fins que esta) os requisitos da nocividade e da aplicação das leis gerais relativas à segurança dos produtos. Paralelamente, foi atualizada a legislação relativa à proteção da saúde de modo a ter força executória em caso de suspeita de que uma droga substituta constitui uma ameaça para a saúde humana. Na Hungria, em 2012, foi aditada à Lei relativa aos Medicamentos uma lista temporária para inscrever drogas não terapêuticas que afetam o sistema nervoso central, têm capacidade para alterar o estado mental, o comportamento ou a perceção, e por isso podem constituir uma ameaça tão grave para a saúde pública como as substâncias incluídas nas listas de drogas. Nos termos da versão alterada da secção relativa às drogas do Código Penal, a oferta ou a distribuição de tais substâncias é punível com uma pena que pode chegar aos três anos de prisão. Na Suécia, em 2011, foram conferidos novos poderes aos organismos de aplicação da lei para atuarem no sentido de proteger a segurança pública e apreenderem e destruírem substâncias especificadas presumivelmente utilizadas para fins de intoxicação e suscetíveis de causar lesões ou morte. Nos termos das novas leis na Áustria e no Reino Unido, a polícia pode, em determinadas circunstâncias, confiscar qualquer quantidade de uma substância mesmo que não tenha sido cometido delito algum.

Observa-se um número crescente de respostas que têm como alvo a publicidade e a venda livre de novas substâncias psicoativas. Publicitar os efeitos psicoativos de uma substância que está à venda é punível com uma pena que, na Irlanda, pode chegar aos cinco anos de prisão e que na Roménia vai de um a três anos. Na República Checa, promover a dependência relativamente a uma substância psicoativa pode ser punido com uma pena que chega aos oito anos de prisão. Na Roménia, publicitar que a venda dos produtos é legal é punível com 3 a 10 anos de prisão. Na Polónia, a oferta de «drogas substitutas» pode ser punida com uma pesada multa, contudo, a sua publicidade pode ser punida com um ano de prisão. Na Roménia, será aplicada uma pesada multa se um sítio Web transgressor não for eliminado no prazo de 12 horas após à solicitação ministerial nesse sentido.

O rápido aparecimento de drogas novas e desconhecidas conduziu a numerosas respostas diferentes, que se mantêm em evolução: desde 2009, pelo menos sete países implementaram uma resposta inovadora, tendo, posteriormente, adotado outra. A dimensão das sanções penais e o grau de psicoatividade ou de perigo potencial que as desencadeia variam muito nos diversos países da Europa. São, todavia, visíveis duas tendências: o recurso à ameaça de prisão para dissuadir os fornecedores e a exclusão de sanções penais para quem esteja na posse de uma substância para consumo próprio.

(...)

novembro/2012