



UNIVERSIDADE DE
COIMBRA

Neuza Alexandra Moreira Joaquim

Relatórios de Estágio sob a orientação da Dra. Dina Lopes e da Dra. Tânia Couto e Monografia intitulada “Medicines Wastage in Portugal” sob a orientação da Professora Doutora Victoria Bell, referentes à Unidade Curricular “Estágio”, apresentados à Faculdade de Farmácia da Universidade de Coimbra, para apreciação na prestação de provas públicas de Mestrado Integrado em Ciências Farmacêuticas.

Setembro de 2023

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Eu, Neuza Alexandra Moreira Joaquim, estudante do Mestrado Integrado em Ciências Farmacêuticas, com o n.º 2018288724 declaro assumir toda a responsabilidade pelo conteúdo do Documento Relatórios de Estágio e Monografia intitulada “Medicines Wastage in Portugal” apresentados à Faculdade de Farmácia da Universidade de Coimbra, no âmbito da unidade de Estágio Curricular.

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Coimbra, 1 de setembro de 2023.

Neuza Alexandra Moreira Joaquim
(Neuza Alexandra Moreira Joaquim)

Põe quanto és
No mínimo que fazes

- Ricardo Reis

Agradecimentos

Aos meus pais, pelo amor incondicional, dedicação e incentivo ao longo dos anos. Por sempre terem sido exemplos, um porto seguro e uma casa para regressar.

Ao meu avô, que finalmente tem a oportunidade de ver a primeira neta acabar a faculdade e ao que no decurso do curso partiu.

Ao Pedro, por ter sido o amigo que me incentivou a continuar e à Joana por ter sido a amiga que toda a gente devia ter e que mesmo na distância se faz presente.

Aos padrinhos de Leiria por todos os anos de amizade e apoio.

À Familia Officinallis, um obrigada jamais igualará todo o carinho destes 5 anos. À rafa por ter sido a madrinha mais incrível de sempre e à Mi por se ter tornado como uma irmã. Às minhas 2 afilhadas e demais descendência, um enorme obrigada pela confiança e amizade.

À APEF e projeto Missão País, por terem mudado a minha vida e serem casa para tantos universitários. A todos os amigos que destes mundos levo, um agradecimento será para sempre pouco para o tanto que cresci e aprendi convosco.

Aos meus 3 meninos de Coimbra, o Cris, o Balhau e o Zé, por terem um coração maior que eles próprios e que tanto me ensinaram.

Ao Brostamol, e seus elementos, o nosso 21 vencedor, pois como ele não há nenhum.

Aos CFs+Adotados, um agradecimento por todo o companheirismo e histórias partilhadas.

Um profundo agradecimento a toda a Equipa Maravilha da Farmácia Mosteiro por me ensinarem e fazerem perceber que a profissão farmacêutica é das mais lindas que existe.

Fui muito feliz convosco!

Por fim, um enorme obrigada à professora Doutora Victoria Bell pela orientação e olhar atento, que tornaram tudo isto possível. Foi um privilégio ser sua orientanda.

A ti Coimbra, por tudo!

OBRIGADA!

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Parte I – Relatórios de Estágio

Assuntos Regulamentares do Medicamentos & Farmácia Comunitária



Unidade de Manutenção de Mercado / Direção de Avaliação do Medicamento no INFARMED, IP.

Sob orientação da Dra. Dina Lopes



Farmácia do Mosteiro

Sob orientação da Dra. Tânia Couto

Abreviaturas

AIM – Autorização de Introdução no Mercado

ARM – Assuntos Regulamentares do Medicamento

CTS – *Communication and Tracking System*

DAM – Direção de Avaliação do Medicamento

DC – Reconhecimento Descentralizado

eAF – *eletronic Application Forms*

EMA – Agência Europeia do Medicamento

EMR – Estado Membro de Referência

FFUC – Faculdade de Farmácia da Universidade de Coimbra

FI – Folheto Informativo

FM – Farmácia do Mosteiro

GiMED – Gestão de Informação de Medicamentos

INFARMED, I.P. – Autoridade Nacional do Medicamento e Produtos de Saúde

MA – Módulo de Atendimento

MICF – Mestrado Integrado em Ciências Farmacêuticas

PIM – Preparação Individualizada da Medicação

RCM – Resumo das Características do Medicamento

RM – Reconhecimento Mútuo

SGA – Sistema de Gestão de Alterações

SMUH-Alter – Sistema Medicamento de Uso Humano-Alterações

SPMS – Serviços Partilhados do Ministério da Saúde

SWOT – *Strengths, Weaknesses, Opportunities, and Threats*

TAIM – Titular da Autorização de Introdução no Mercado

UMM – Unidade de Manutenção do Mercado

I. Introdução

De acordo com o artigo 44º da Diretiva 2013/55/EU do Parlamento Europeu, que diz respeito ao reconhecimento das qualificações profissionais do Ensino Farmacêutico, o título de farmacêutico, pressupõe uma formação de pelo menos cinco anos, dos quais a formação teórica e prática a tempo inteiro decorre durante um mínimo de quatro anos, existindo um estágio de seis meses em farmácia aberta ao público ou num hospital durante seis meses.¹

Neste sentido, o estágio curricular assume um papel fundamental na educação e formação dos futuros profissionais farmacêuticos, visto que é no contacto com a prática profissional que se consegue consolidar conhecimentos e desenvolver ou aprimorar novas competências, incorrendo, desta forma, no advogar pela construção de farmacêuticos cada vez mais capacitados.

O Mestrado Integrado em Ciências Farmacêuticas (MICF) da Faculdade de Farmácia da Universidade de Coimbra (FFUC) pauta-se por um plano curricular vasto e completo, preparando os seus estudantes para serem profissionais reconhecidos pela multidisciplinariedade, rigor e excelência. Adicionalmente, a FFUC permite que os alunos finalistas tenham a oportunidade de estagiar em áreas de saídas profissionais que não apenas as de farmácia comunitária e hospitalar, sendo, desta forma, uma mais-valia para o desenvolver e alinhamento de prioridades para os futuros Mestres.

Neste sentido, de forma a conjugar o interesse despertado durante o curso para matérias regulamentares do medicamento e políticas em saúde, realizei o meu estágio curricular no INFARMED I.P. Adicionalmente, efetuei estágio na área da farmácia comunitária, na Farmácia do Mosteiro (FM), tendo ambas as experiências concorrido para o meu enriquecimento enquanto estudante e futura profissional de saúde.

Deste modo, o presente Relatório de Estágio pretende apresentar uma análise SWOT de ambos os estágios, evidenciado os pontos fortes e fracos, bem como denotar as oportunidades e ameaças.

Palavras-Chave: Farmácia Comunitária; Farmácia Mosteiro; Assuntos Regulamentares; INFARMED, I.P.

2. INFARMED, I.P.

O INFARMED, I.P. é a Autoridade Nacional do Medicamento e Produtos de Saúde, com sede em Lisboa, cuja missão se prende na regulação e supervisionamento dos setores dos medicamentos de uso humano e produtos de saúde, incluindo dispositivos médicos, produtos cosméticos e de higiene corporal. Esta Entidade pública independente foi criada em 1993,² e está sob tutela do Ministério da Saúde, atuando de forma autónoma na tomada de decisões. O INFARMED, I.P. tem um papel ativo no que concerne à definição de políticas de saúde, execução das mesmas, bem como promoção da literacia neste campo. Paralelamente, atua ao nível da regulação e autorização de entrada de medicamentos no mercado, farmacovigilância, fiscalização do mercado, promoção da investigação e desenvolvimento de medicamentos e tecnologias em saúde.³

Esta Entidade é constituída pelo Conselho Diretivo, quatro órgãos consultivos e demais unidades orgânicas, subdivididas em áreas de atribuição e áreas de gestão, estando estruturadas e organizadas de acordo com o organograma (Figura I) abaixo apresentado.⁴

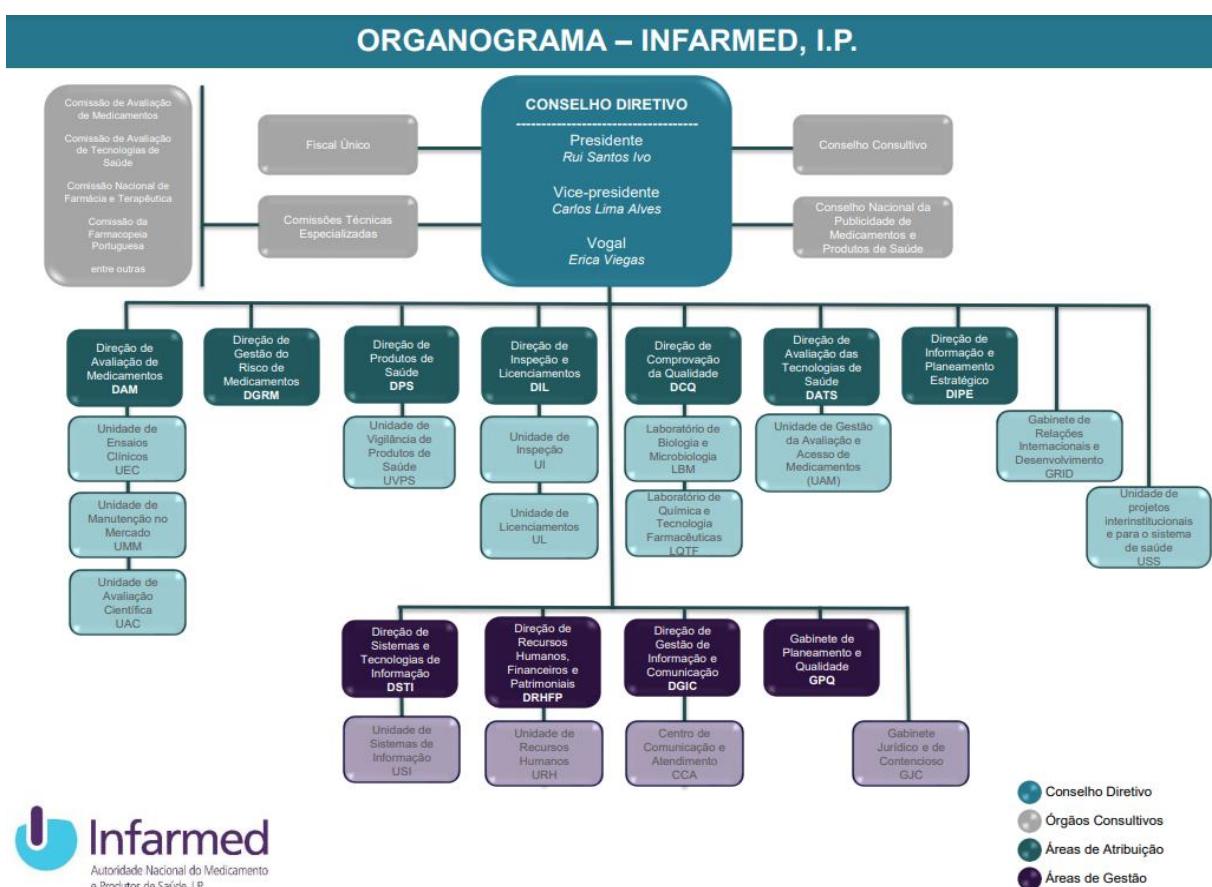


Figura I – Organograma do INFARMED, IP.⁴

O INFARMED participa ativamente nos procedimentos de Reconhecimento Mútuo (RM) e Reconhecimento Descentralizado (DC) como Estado Membro de Referência (EMR), tendo

alcançado em 2018 o top 3 dos Estados-membros que mais contribuem para o sistema de avaliação europeu, levando a que esta Entidade integrasse o grupo europeu de agências com um papel mais ativo na avaliação dos medicamentos.⁵

Adicionalmente, o INFARMED, I.P. promove e apoia a ligação com as Universidades.⁶ Neste sentido, existe, atualmente, um protocolo entre o INFARMED, I.P. e a FFUC com o objetivo de providenciar estágios nas diversas direções da Entidade Reguladora. Estes estágios permitem aos alunos finalistas do MICF, formarem-se e aprofundarem os seus conhecimentos em áreas diferenciadoras que lhes permitirão destacar-se no mercado do trabalho. O farmacêutico na área dos assuntos regulamentares desempenha funções no que concerne a processos de desenvolvimento, registo, acesso ao mercado, informação e apoio aos profissionais de saúde, bem como na monitorização da utilização dos medicamentos e dispositivos médicos. Neste âmbito, com a consciência de que pretendia aprofundar e explorar os conhecimentos adquiridos na unidade curricular de Assuntos Regulamentares do Medicamento (ARM), pretendi que uma das etapas do meu estágio residisse na Direção de Avaliação do Medicamento (DAM) do INFARMED I.P.

No dia 9 de janeiro dei início às atividades enquanto estagiária deste departamento, havendo sido alocada à unidade de Manutenção do Mercado (UMM), onde contei com a orientação da Dra. Dina Lopes, Dra. Cláudia Mendes e Dra. Rita Ventura para a aprendizagem e desempenho de tarefas alocadas à subunidade encarregue das Alterações do Estado-Membro de Referência (EMR).

2.1. Direção de Avaliação do Medicamento – Unidade de Manutenção do Mercado

A DAM é uma das unidades orgânicas do INFARMED, I.P., cujas funções residem na gestão das atividades inerentes aos procedimentos de RM e DC, nomeadamente como EMR e demais procedimentos centralizados e de arbitragem comunitária, bem como manutenção de um contacto profícuo com a Comissão de Avaliação de Medicamentos (CAM) e seu respetivo secretariado.⁷

É da competência da UMM assegurar as atividades inerentes à manutenção de medicamentos já registados ou autorizados no mercado, nomeadamente o desempenhar de tarefas que englobem autorizações de alterações, renovações, revogações ou declaração da caducidade, bem como regtos ou Autorização de Introdução no Mercado (AIM).⁸

2.1.1. Atividades e Funções Desempenhadas

O Estágio Curricular decorreu durante todo o primeiro mês em moldes presenciais, havendo sido dada a possibilidade de passar para regime híbrido em fevereiro. Durante a primeira semana foram-me fornecidas formações, onde tive a oportunidade de aprofundar os meus conhecimentos no que toca à área regulamentar. No total, foram fornecidas sete formações: Sistema de Regulação de Medicamentos; Dossier de AIM; Alterações de AIM; Informação do Medicamento; Envio de textos para publicação no INFOMED; Formação do programa GiMed e Formação do programa CTS.

Adicionalmente, foi ainda fornecida uma lista de leituras de estudo com os regulamentos e documentos mais importantes para o exercício prático na área dos ARM.

Juntamente com os restantes integrantes da equipa da UMM destinada às alterações de Estado-Membro em que Portugal é RMS, fiquei encarregue de atender às alterações submetidas pelos Titulares de Autorização de Introdução no Mercado (TAIM), avaliando-as, validando-as e aprovando as mesmas. No decorrer do exercício destas etapas, por vezes deparei-me com alterações erradamente submetidas no que respeita à categoria ou tipificação, sendo necessário pedir ao TAIM a devida correção. Muito frequentemente, ao analisar cuidadosamente a documentação submetida, como o *electronic Application Form* (eAF), Resumo das Características do Medicamento (RCM) ou Folheto Informativo (FI), constatei que existiam erros nas alterações submetidas ou que a informação não estava suficientemente clara para que o pudesse validá-la de forma segura. Nestes casos, foram efetuados pedidos de elementos, com o objetivo de clarificar determinado ponto e/ou obter correções dos documentos iniciais erroneamente submetidos. Este procedimento, apesar de simples e de garantir que todas as alterações aprovadas têm em vista a segurança, é consideravelmente moroso e nem sempre se obtêm respostas por parte dos titulares dentro dos prazos indicados, levando a um atrasar e acumular de processos.

Quando a alteração é avaliada e cumpre todos os requisitos, estando apta para ser aprovada, e tratando-se de uma alteração IB, inicia-se o calendário do processo. Este só está encerrado após 30 dias. Durante este período, os restantes Estados Membros Envolvidos (EME) têm oportunidade de avaliar e tecer considerações no que concerne à alteração em causa. Ao dia 30 (D30), a alteração é novamente aberta e, após confirmação de que não existem comentários de outros EME, a alteração é finalizada e são enviados textos para publicação no INFOMED ou arquivo, quando aplicável. Caso existam comentários, é efetuado

um *Clock-Stop*, parando-se o processo até que esteja corrigido. Após isto, o calendário reinicia novamente com uma contagem semelhante à inicial para finalização da alteração.

Paralelamente à realização das funções que me eram atribuídas, desenvolvi, para uso interno, *guidelines* de trabalho para a UMM, no que respeita às alterações em que Portugal atua como EMR. Acredito intrinsecamente que os estagiários têm bastante potencial e que a faculdade nos dota de variadas competências que devem ser oferecidas às Entidades prestadoras de estágios para que, também estas, possam ser melhoradas continuamente. As *guidelines* desenvolvidas, são um documento que, no meu entender, serão extremamente úteis para futuros estagiários ou gestores recém-contratados, pois não existia, até à data, nenhum documento atualizado e percutível que compilasse os procedimentos e passos fulcrais para o desempenhar das demais tarefas.

De acordo com o que foi supra-explanado, os gestores de processos, necessitam de deter conhecimentos profundos em matérias de legislação relativa a assuntos do medicamento, especialmente aquela que é proveniente da Agência Europeia do Medicamento (EMA), bem como um vasto entendimento no que concerne ao setor farmacêutico, destacando-se como fundamentais os conhecimentos na área dos Assuntos Regulamentares do Medicamento, Farmacologia, Biofarmácia e Tecnologia farmacêutica. Tive ainda oportunidade de comprovar que, os farmacêuticos que trabalham na área dos ARM conhecem os exigentes padrões de segurança que as autoridades impõem ao campo da Saúde e se regem meticulosamente por estas.

No decorrer do estágio, li variados regulamentos, a fim de confirmar se as alterações das quais era gestora de processo, estavam corretamente submetidas, havendo desenvolvido um espírito crítico aguçado e adquirido um vasto conhecimento no que toca às matérias de Processos Regulamentares do Medicamento.

2.2. Análise SWOT - Estágio em Assuntos Regulamentares do Medicamento

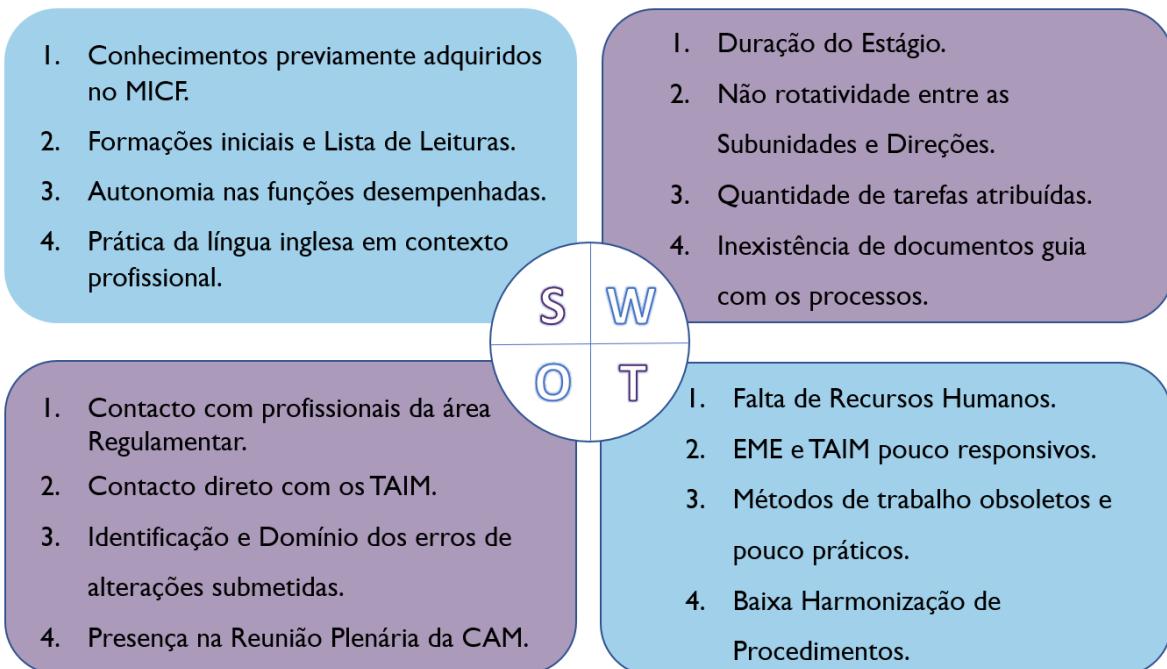


Figura 2 – Esquema da Análise SWOT – Estágio em Assuntos Regulamentar do Medicamento.

Pontos Fortes

1. Conhecimentos previamente adquiridos no MICF

Na FFUC, a cadeira de ARM está no plano de estudos como sendo obrigatória no 4º ano, ao contrário de outras faculdades do país, onde esta é opcional. Considero que os conhecimentos prévios foram uma enorme base, sendo uma mais-valia para a rápida assimilação da aprendizagem e contextualização das tarefas do estágio. Adicionalmente, também a prévia formação dos alunos da FFUC é reconhecida como extremamente pertinente, de acordo com os gestores do INFARMED I.P., que relatam uma clara distinção entre estagiários vindouros de outras faculdades. O percurso prévio que é feito na faculdade demonstra-se crucial e distintivo, pois capacita na medida certa os alunos para o início da profissão farmacêutica na área de ARM.

2. Formações Iniciais e Lista de Leituras

As formações que decorreram na primeira semana demonstraram-se valiosas para a revisão de conceitos e aprofundamento de tópicos mais específicos no que concerne às tarefas que seriam realizadas durante o estágio. Foi essencial ter assistido às formações iniciais referentes à utilização dos programas, nomeadamente, SMUH-Alter/SGA, CTS e GIMED, para

desenvolver uma maior autonomia no manuseamento destes. O facto destas formações terem sido assíncronas e em formato digital, permitiu-me rever e tirar apontamentos, que se demonstraram de extrema importância no exercício de tarefas posteriores. Os documentos de apoio fornecidos na lista de Leituras de Estudo foram igualmente imprescindíveis para orientação inicial e consulta rápida durante os meses de estágio.

3. Autonomia nas funções desempenhadas

O plano de estágio foi desenhado de forma a capacitar os estagiários e a fornecer-lhes os apoios necessários de trabalho, de forma a fomentar a autonomia e sentido de responsabilidade. Características estas fulcrais e transversais aos gestores de processos, que permitiram evitar a sobrecarga dos gestores destacados para esclarecimento de dúvidas, havendo estimulação para a adoção de uma postura proativa na resolução de problemas.

4. Prática da língua inglesa em contexto profissional

No decorrer das tarefas atribuídas, a prática e interpretação do idioma inglês esteve sempre presente, verificando-se uma competência essencial no trabalho. Era necessário analisar e rever documentação em inglês, como também, comunicar com TAIM e demais EME também neste idioma. Este desafio permitiu contactar diariamente com a língua inglesa na prática profissional, sendo uma mais-valia também a nível pessoal.

Pontos Fracos

I. Duração do Estágio

O estágio Curricular na Área de Assuntos Regulamentares teve a duração de 12 semanas. Este ponto é destacado como negativo pois a área regulamentar é complexa e exige um elevado domínio do saber e tempo para aprender a trabalhar com os programas. Apenas 3 meses de estágio não são o suficiente para permitir adquirir conhecimento sobre todas as funções da subunidade a que estive alocada, nem ser plenamente autónoma.

2. Não rotatividade entre as Subunidades e Direções

Dado o tempo limitado do estágio e o enorme espaço temporal até que se atinja a autonomia, não é possível que se efetue rotatividade entre as Subunidades e demais Direções do INFARMED, IP. Considero este ponto negativo pois não permite adquirir uma visão holística de todas as funções desempenhadas por farmacêuticos nesta Entidade, permitindo

apenas convergir e especializar a aprendizagem à subunidade em que inicialmente o estagiário for alocado.

3. Quantidade de tarefas atribuídas

Dado o pouco tempo de estágio, e tendo em consideração que a maioria das alterações pressupõe um calendário de 30 dias, a partir do mês de março, poucas foram as tarefas que me foram atribuídas, pois não estaria presente em abril, para finalizar os processos. Considero este ponto extremamente negativo, pois resultou em pouco aproveitamento da aprendizagem que havia feito nos meses anteriores, não considerando as horas de estágio proveitosas.

4. Inexistência de documentos guia com os processos

Denotei falta de documentos ou guias para orientar e conduzir as diferentes etapas que concernem à gestão de processos. Estes procedimentos, envolvem várias etapas e são distintos de acordo com a tipologia da alteração e fase do processo em que nos encontramos, sendo muitas vezes fácil ocorrerem omissões e falhas devido à falta de um guia.

Oportunidades

I. Contacto com profissionais da área Regulamentar

O contacto direto com os gestores da área regulamentar do INFARMED, IP. demonstrou-se bastante benéfico e proveitoso, no sentido em que estes me alertaram para certos pormenores que só a experiência e a prática conferem. Esta foi uma oportunidade fulcral para trocar ideias e guiar-me no que concerne a futuras escolhas profissionais dentro do mercado de trabalho.

2. Contacto direto com os TAIM

No decorrer das atividades, foi necessário contactar com diversos TAIM a fim de clarificar ou pedir correções relativas a algum ponto das alterações submetidas. Este contacto permitiu aproximar a experiência do estágio com a realidade do setor industrial farmacêutico e aprofundar conhecimentos no que concerne às diversas indústrias e segmento de mercado em que atuam.

3. Identificação e domínio dos erros de alterações submetidas

Vários foram os erros encontrados que precisaram de ser comunicados aos TAIM a fim de serem clarificados ou corrigidos. Após a gestão de um número considerável de processos, começaram a sobressair-se os erros mais frequentes e também a identificação das maiores falhas por TAIM. Estar na Entidade Regulamentar Nacional permite adquirir e aprimorar esta visão holística dos erros mais comuns e de alguns TAIM, sendo uma mais-valia para, eventualmente no futuro, explorar ofertas e mercados de trabalho.

4. Presença na Reunião Plenária da CAM

A presença na Reunião Plenária da CAM permitiu ter uma percepção do funcionamento geral deste órgão, bem como perceber como se analisam, avaliam e aprovam processos que exigem pareceres. Foi possível percecionar como se articulam os diversos avaliadores das diferentes áreas e como é gerada a discussão, tendo como máxima a segurança pública. Paralelamente, foi destacado o facto de os farmacêuticos não terem acesso aos dados clínicos, tendo este ponto condicionado a tomada de decisão de alguns pareceres. Concretamente ouvir a discussão relativamente aos dados clínicos, permitiu inferir sobre a importância deste ponto, não só para a valorização da profissão, como também para o estabelecimento de prioridades do setor.

Ameaças

I. Falta de Recursos Humanos

Desde o início do estágio que foi perceptível que o volume de trabalho ao encargo da DAM-UMM é desproporcional ao número de recursos humanos disponíveis. A avaliação dos processos consome um tempo considerável e nem todas as alterações são passíveis de serem tratadas celeremente, gerando um acumular de processos por tratar. Consequentemente, os elementos da subunidade destacados para esclarecer dúvidas aos estagiários não dispunham de tempo para conseguirem prestar o auxílio necessário. Apesar da boa vontade e dedicação incansável, o acompanhamento não foi o mais fluído, sendo, no entanto, compreensível.

2. EME e TAIM pouco responsivos

Recorrentemente, para o avançar dos trabalhos inerentes à gestão de um processo, é necessária a resposta ou colaboração do TAIM ou dos restantes EME. Inúmeros foram os

casos em que esta resposta tardou ou não chegou, levando a um consecutivo atrasar de procedimentos e impedimento de finalização de procedimentos durante o período de estágio.

3. Métodos de trabalho obsoletos e pouco práticos

Com a prática recorrente de trabalhar com os programas SGA, GIMED e CTS, denotei que muitas das tarefas eram repetidas entre plataformas e que havia um trabalho acrescido por parte dos gestores em realizar etapas de teor mais burocrático. Considero que estas poderiam ser efetuadas automaticamente, caso existisse uma atualização e harmonização dos sistemas informáticos, para o concretizar de um trabalho mais prático e proficiente.

4. Baixa Harmonização de Procedimentos

Foi notório que os métodos de trabalho entre gestores divergem em certos pontos, não existindo uma harmonização clara entre todos. Adicionalmente, as plataformas apresentam alguns erros, que são contornáveis, mas tal informação não é de conhecimento geral, levando a erros consecutivos e a uma desarmonização de métodos de trabalho entre a unidade.

Estes pontos, são em si uma ameaça pois levam a que diferentes estagiários sejam ensinados de formas diferentes e que o próprio trabalho da subunidade seja diferente entre gestores.

3. Farmácia Comunitária

3.1. Farmácia do Mosteiro (FM)

A FM é uma das 4 farmácias pertencentes ao grupo Sanches, do distrito de Leiria. Esta está situada na Batalha, tomando o nome ao monumento Mosteiro da Batalha que se encontra próximo. De todas as farmácias do grupo, esta é a mais recente aquisição e a única que detém um posto de farmácia, situado em Reguengo do Fetal. A localidade de Reguengo do Fetal está consideravelmente mais isolada, tem menores acessos, e alberga uma população maioritariamente idosa, sendo, portanto, uma mais-valia a existência deste posto.

A FM é um estabelecimento de saúde de excelência com um leque diverso de clientes que diariamente visitam as instalações à procura de cuidados de saúde. É de destacar que esta tanto é uma farmácia que detém utentes habituais, como igualmente estrangeiros, que se dirigem à farmácia com o intuito de resolver situações de carácter maioritariamente agudo e pontual.

3.1.1. Atividades e Funções Desempenhadas

O estágio iniciou-se dia 3 de abril, onde fui acolhida e incentivada a conhecer a equipa e instalações da farmácia. Durante as primeiras semanas pude auxiliar nas tarefas logísticas inerentes ao armazém, nomeadamente a confirmação e receção de encomendas, arrumo de produtos farmacêuticos de acordo com o princípio “first-expired, first-out”. Aprendi também nesta fase a efetuar a devolução de encomendas, a auxiliar com o processo de gestão de validades e estive encarregue de montar expositores.

Após autonomização das tarefas de armazém e logística interna, comecei a acompanhar os atendimentos ao balcão, onde fiquei a observar colegas farmacêuticos. Destaco a rápida confiança que depositaram em mim e que culminaram no início da minha prestação sozinha ao balcão. Em todo o momento fui auxiliada por toda a equipa da FM e fui proximamente acompanhada, de forma a sempre fornecer o produto mais adequado e a informação mais esclarecedora.

Para além destas funções, pude observar como era efetuada a programação automatizada das preparações individualizadas da medicação (PIM) pelos farmacêuticos responsáveis. Tive oportunidade de visitar as instalações onde se encontra o robô que efetua todas as PIM do grupo Sanches, tendo sido extremamente enriquecedor e oportuno. Adicionalmente, estive envolvida em outras atividades igualmente importantes, no que concerne ao funcionamento

correto e profícuo da farmácia, como registo dos termo-higrómetros, reposição de stocks, gestão de créditos por regularizar e acompanhamento da gestão da farmácia.

3.2. Análise SWOT - Estágio em Farmácia Comunitária

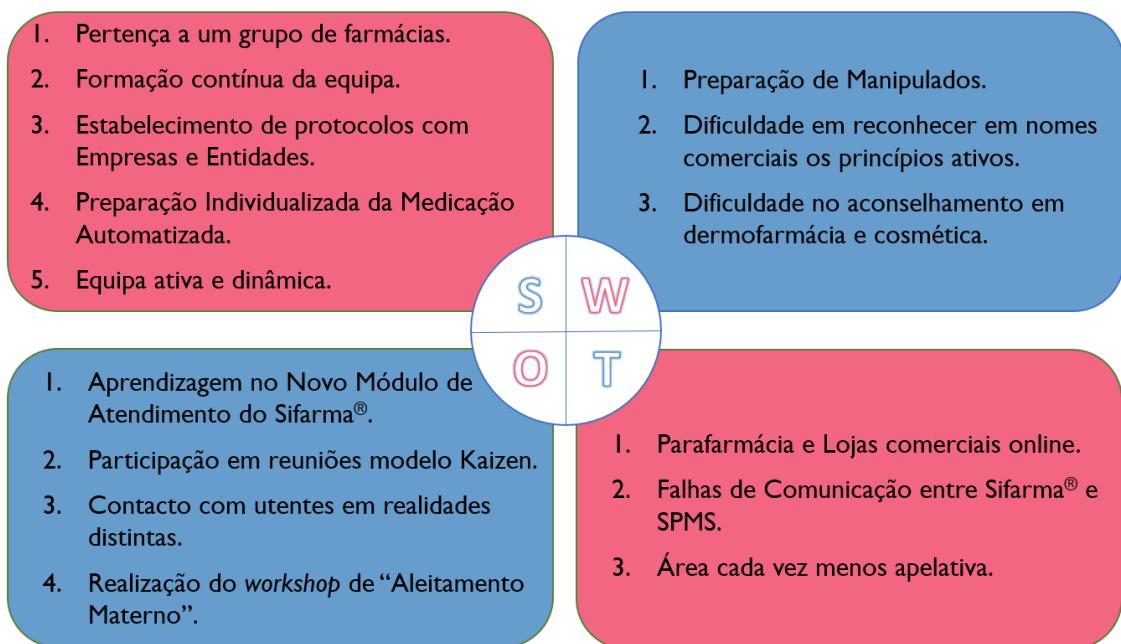


Figura 3 – Esquema da Análise SWOT - Estágio em Farmácia Comunitária.

Pontos Fortes

I- Pertença a um grupo de farmácias

Tal como mencionado anteriormente, a FM é um dos estabelecimentos pertencentes ao Grupo Sanches. Esta inserção num grupo de farmácias permite uma maior rotatividade e fornecimento mais eficaz de produtos farmacêuticos aos utentes.

Destaco este ponto como positivo no meu estágio pois permitiu-me percecionar diversas vantagens na pertença a um grupo de farmácias, bem como de toda a logística interna que é possível efetuar para garantir uma maior cobertura de serviços e produtos aos utentes. Particularmente, esta inserção num grupo foi deveras fulcral no que concerne à resposta perante a realidade da rutura de medicamentos.

2- Formação contínua da equipa

Durante o meu estágio tive a oportunidade de assistir a dez formações fornecidas por delegados de laboratórios e marcas. Estas formações permitiram-me conhecer marcas de produtos existentes nas farmácias, saber o seu posicionamento no mercado, e perceber em

que situações deveriam ser aconselhados. Considero que estas foram especialmente enriquecedoras pois permitiram tirar dúvidas, rever conhecimentos e orientar aquando do atendimento ao balcão. Concretamente, sinto que me fez conhecer melhor várias linhas e marcas, sentindo-me mais confiante quando necessitava de aconselhar os produtos cujas formações tive oportunidade de participar.

3- Estabelecimento de protocolos com Empresas e Entidades

A FM prima por estabelecer protocolos com variadas empresas e entidades locais. Estes protocolos baseiam-se num acordo onde a farmácia efetua descontos a todos os indivíduos pertencentes ao agregado familiar do funcionário da empresa. Por sua vez, a entidade compromete-se a promover a farmácia, explanando as vantagens aos seus funcionários. Considero este um ponto significativamente positivo, uma vez que reconheço nele uma mais-valia para a fidelização de clientes, garantindo a sustentabilidade da FM. Foi importante percecionar como era feita a gestão interna destes protocolos e como era gerida a sustentabilidade da farmácia com os mesmos.

4- Preparação Individualizada da Medicação (PIM) Automatizada

A PIM é em si um serviço de excelência que assegura o uso racional e seguro do medicamento, sendo absolutamente um serviço de valorização e reconhecimento deste profissional enquanto especialista do medicamento. Na FM, este era um serviço robotizado efetuado numa das farmácias do grupo Sanches.

O processo inicia-se com a criação de perfil do utente no *software* e programação das tomas de acordo com a posologia e medicamentos. Com esta automatização do sistema, a margem de erro é menor, comparativamente ao processo manual, uma vez que o embalamento é todo ele feito por um *robô*. Em caso de alterações, estas são imediatamente inseridas no sistema informático. Adicionalmente, este sistema permite que sejam individualizadas tomas a qualquer hora do dia, que geralmente não constam nos dispositivos de PIMS manuais, concretamente tomas em jejum, ao lanche, ao deitar, entre outras.

Destaco este ponto como forte, pois permitiu-me percecionar como esta metodologia automatizada era mais segura e uma mais-valia para o utente. A possibilidade de ocorrência de erros é estritamente baixa e em si permite oferecer a medicação de forma mais organizada e prática.

5- Equipa ativa e dinâmica

Ter tido a oportunidade de estagiar na FM foi um privilégio. Fui ensinada por colegas que são profissionais de excelência e que se pautam pelo rigor, com foco especial no doente. Esta é uma equipa extremamente ativa e dinâmica, estando sempre a organizar e planear a celebração de efemérides e demais dias comemorativos, como forma de promover a literacia em saúde e adoção de estilos de vida saudáveis. É de destacar, a título de exemplo, a promoção de rastreios e caminhadas solidárias como forma de incentivo à prática de exercício físico. Adicionalmente, a equipa era também proativa no delineamento de workshops grátis à população para aumentar o grau de literacia em saúde e ida às escolas em sessões formativas.

Todas estas atividades fizeram-me ainda mais reconhecer e valorizar o papel que o farmacêutico pode ter na comunidade enquanto agente de literacia e saúde pública.

Pontos Fracos

I- Preparação de Manipulados

Com o avançar dos anos a preparação de manipulados, outrora uma atividade altamente intrínseca às farmácias comunitárias, foi ganhando menos relevância, dada a evolução e industrialização do setor. Na FM, concretamente, não existe o hábito de realizar produtos manipulados, uma vez que o volume de pedidos é muito pequeno, não compensando o investimento em matérias-primas. Apenas se realiza um número limitado de manipulados. Quando surge um pedido por parte de algum utente, caso a FM não o produza, este é encaminhado para uma outra farmácia, que, após a sua preparação, o envia por transportador farmacêutico para a FM.

Desta forma, destaco este ponto como fraco, pois durante os meses de estágio não tive a chance de produzir nenhum produto manipulado, apesar de existir um laboratório com materiais e as condições adequadas a esta tarefa.

2- Dificuldade em reconhecer em nomes comerciais os princípios ativos

Durante o curso, bastantes são as unidades curriculares, especialmente as intrinsecamente ligadas à farmacologia, que ensinam aos alunos os princípios ativos, demais interações, formas farmacêuticas disponíveis e situações em que se utilizam. No entanto, não há estímulo para reconhecer os princípios ativos nas marcas comerciais existentes atualmente no mercado.

Como consequência, com o início de funções no atendimento ao público, torna-se frequentemente difícil efetuar a associação do nome comercial ao composto ativo.

Durante o decorrer do estágio tive oportunidade para ir colmatando esta dificuldade através do auxílio dos colegas e com a prática dos atendimentos. Ainda assim, é de ressalvar que o curso deveria acompanhar mais intimamente aquela que é a realidade profissional, tentando desde mais cedo e ao longo do curso estimular os alunos a reconhecer nomes comerciais.

3- Dificuldade no aconselhamento em dermofarmácia e cosmética

Apesar de considerar que a unidade curricular do 4º ano de Dermofarmácia e Cosmética está extremamente completa em termos de conhecimentos e ferramentas que fornece aos alunos, considero que, na prática, é consideravelmente difícil conseguir efetuar um aconselhamento adequado.

A FM destaca-se por ter várias marcas, linhas e gamas de produtos de dermofarmácia nas suas instalações, sendo, portanto, procurada por utentes que reconhecem nela valor e valorizam o aconselhamento farmacêutico no momento da escolha de algum produto. No entanto, para um aluno finalista, o *gap* entre o conhecimento teórico e o saber como cada gama e linha se posiciona é muito grande.

Oportunidades

I- Aprendizagem no Novo Módulo de Atendimento (MA) do Sistema Sifarma®

Sem dúvida que um ponto externo que saliento como uma grande oportunidade foi o facto de toda a FM ter já implementado o novo MA do Sistema Sifarma® nos demais processos. Desta forma, aprendi a efetuar e a trabalhar com todas as ferramentas deste módulo, que é o mais atual da Glintt.

Apesar de o novo MA de sistema Sifarma® ainda não estar totalmente desenvolvido e otimizado, considero-o uma oportunidade, uma vez que é bastante intuitivo e simples de utilizar, especialmente quando comparado com o Sifarma2000®, que contactei no estágio extracurricular, numa outra farmácia, no verão do 3º ano de curso.

2- Participação em reuniões modelo *Kaizen*

Pela primeira vez, tive contacto com reuniões *Kaizen*, que é um modelo que visa a melhoria contínua. Saliento esta metodologia como uma oportunidade, pois deu-me uma visão prática e simples de como se pode aperfeiçoar procedimentos já implementados, de forma otimizada e profícua.

Estas reuniões permitem fazer um briefing semanal, recapitular objetivos e relembrar a agenda do mês. Ter sido incluída nestas reuniões permitiu-me apurar o espírito crítico e perceber como deve ser o fio condutor para manter a equipa motivada, focada e próspera para alcance dos objetivos comuns.

3- Contacto com utentes em realidades distintas

Dada a inserção da FM na vila da Batalha, e a sua enorme proximidade ao Mosteiro da Batalha, que atrai diariamente turistas, a panóplia de clientes que recorrem a esta é significativamente diversificada.

Considero como altamente positivo ter tido a experiência de contactar com utentes tipicamente designados como “de meios mais pequenos”, cujas necessidades maioritariamente residem na medicação crónica, produtos de veterinária (tanto para animais domésticos como de criação), bem como acompanhamento do utente idoso.

Paralelamente, chegavam à farmácia turistas com necessidades de aconselhamento de carácter mais agudo e pontual, que requeriam outros tipos de atenções.

4- Realização do Workshop de “Aleitamento Materno”

A FM dinamizou a 17 de junho o seu primeiro *Workshop* de Aleitamento Materno fornecido por um elemento da equipa especialista no aconselhamento desta área.

Toda a idealização, preparação e elaboração de materiais foi efetuada pelos variados elementos da equipa, dando-me a possibilidade de perceber como era feita a organização de um evento de maior magnitude com o objetivo de promover a literacia em saúde.

Tive ainda a oportunidade de poder fornecer apoio logístico no decorrer do *workshop*, onde pude aprender os conteúdos transmitidos, que considero fundamentais para tranquilizar futuros pais ou mães com dificuldades durante a amamentação. Estes conhecimentos não são ensinados no curso, e daí destacar como tendo sido uma valiosa oportunidade durante a minha formação enquanto futura farmacêutica.

Ameaças

I- Parafarmácias e Lojas comerciais online

A legalização da venda de produtos farmacêuticos fora dos estabelecimentos de saúde, nomeadamente em superfícies comerciais, parafarmácias e lojas *online*, é em si uma ameaça à sustentabilidade da farmácia. Estas empresas maiores, bem como os negócios *online*, conseguem praticar preços e efetuar promoções com os quais a farmácia não tem margem para competição, uma vez que compram estes produtos em quantidades menores.

Muitas vezes me deparei com pessoas que recorrem à farmácia para receberem um atendimento personalizado e direcionado às suas necessidades, mas que não compram o referido produto, pois numa rápida consulta ao telemóvel conseguem verificar que o preço em plataformas *online* é mais em conta.

2- Falhas de Comunicação entre Sifarma® e Serviços Partilhados do Ministério da Saúde

Num dos dias do estágio, o sistema Sifarma® perdeu a comunicação com os Serviços Partilhados do Ministério da Saúde (SPMS), não havendo suporte para validar as receitas *online*. Este acontecimento verificado a nível nacional, demonstrou-se bastante caótico inclusive para os prescritores, que ficaram sem conseguir emitir receitas eletrónicas.

Estas situações já estão previstas, e as próprias receitas eletrónicas contêm códigos bidimensionais que permitem a dispensa de uma unidade de cada medicamento mesmo com o servidor em baixo. No entanto, os bidimensionais não permitem averiguar se as receitas em questão ainda contêm determinado medicamento. Esta solução não é eficaz, uma vez que apenas resulta caso a pessoa tenha a guia de tratamento em papel (cada vez menos comum) ou a receita atualizada na aplicação do Serviço Nacional de Saúde. Caso contrário, não é possível validar o conteúdo da receita nem dispensa de medicamentos.

Em suma, a dispensa e variadas ferramentas ficam comprometidas. Existem algumas formas para tentar contornar a situação, mas acaba por ser um processo mais moroso, em parte defeituoso e que causa constrangimento.

3- Área cada vez menos apelativa

É certo que a área de saída profissional da Farmácia Comunitária continua a ser a área que mais farmacêuticos emprega dentro do setor, no entanto, esta é cada vez menos apelativa aos

já farmacêuticos e aos futuros Mestres. Uma das principais razões que destaco são os horários rotativos, com necessidade de trabalhar aos fins-de-semana, por vezes em turnos de dez horas e que, a longo prazo, podem ser encarados como desmotivadores.

A crescente procura de farmacêuticos para outras áreas do setor, nomeadamente, indústria farmacêutica e o surgimento de novas áreas emergentes, são, por sua vez, mais aliciantes e com perspetivas de crescimento em carreiras maiores.

Receio, adicionalmente, que a Lei da Revisão dos estatutos das Ordens, que atualmente se encontra em revisão, possa provocar profundas alterações ao ato farmacêutico, o que poderá retirar valor às funções desempenhadas atualmente apenas por farmacêuticos. Como consequência, receio que o próprio MICF comece a ser menos apelativo, e que cada vez mais os recéns mestres embarquem por áreas onde eventualmente se sintam mais valorizados e realizados.

Casos Práticos

Caso 1

Uma senhora de 40 anos chega à Farmácia com uma receita para a filha de 9 anos que acabara de ser observada pelo médico, devido a uma tosse persistente. Após analisar a receita que continha prescrito Monteluscaste 5mg, comprimido orodispersível, um inalador Symbicort® e um Ventilan® notei que o médico havia escrito uma anotação manualmente com as indicações “5 ml desloratadina”. Questionei a senhora quanto ao apontamento, pelo que me disse que o médico não havia prescrito esse medicamento porque a senhora tinha um genérico do AERIUS® em casa, pois já havia tomado no passado. Após esta informação, consultei a ficha da filha, não havendo encontrado nenhum genérico de desloratadina na ficha. Questionei pelo nome da mãe com o intuito de confirmar o seu histórico. Confirmei que havia tomado Desloratadina Azevedos 5mg comprimidos orodispersíveis. Fui consultar a dosagem do Xarope AERIUS®, que se verificou de 0,5 mg/ml,⁹ havendo rapidamente compreendido que a filha deveria apenas tomar uma dose de 2,5 mg e que o medicamento que tinha em casa não era adequado:

$$0,5 \text{ mg/ml} \times 5 \text{ ml} = \underline{\underline{2,5 \text{ mg}}}$$

Imediatamente expliquei a situação à cliente e disse que não poderia dar o medicamento que tinha em casa, pois estava a dar a dosagem superior. A senhora perguntou se poderia partir o comprimido ao meio para dar à filha. Dado que se tratava de uma fórmula farmacêutica orodispersível, não sendo divisível em doses iguais, respondi que não o poderia fazer. A senhora imediatamente compreendeu a justificação e disse que passaria no médico no dia seguinte para conseguir uma receita.

No dia seguinte, ao final do dia, a senhora voltou à farmácia com uma prescrição de AERIUS® Solução oral, tendo agradecido o reparo e atenção.

Considerei este caso extremamente pertinente para este relatório pois coloca em evidência a importância da proximidade ao utente e de colocar as questões certas. Mesmo a utente tendo vindo de um profissional de saúde com uma prescrição médica, é importante que o farmacêutico, enquanto especialista do medicamento, continue a ter espírito crítico, certificando-se que dispensa o medicamento certo, na dose certa, para o utente certo.

Caso 2

Senhora de 27 anos dirige-se à FM para pedir aconselhamento relativamente a um corrimento vaginal anormal e prurido que tem vindo a sentir. Questionei se a senhora já

costumava fazer infecções vaginais recorrentemente e de que cor era o corrimento, ao que me informou que já tinha tido algumas nos últimos tempos e que o corrimento era esbranquiçado e sem odor. Sinais estes de infecção fúngica.

Desta forma, aconselhei a jovem a administrar Gyno-Pevaryl Combipack® dado que este medicamento combina óvulos vaginais com um creme de aplicação externa. Ambos contendo econazol, um antifúngico que atua por lesão das membranas celulares fúngicas. Indiquei que deveria aplicar os óvulos durante 3 dias consecutivos ao deitar, o mais profundamente possível e aplicar o creme na zona vulvar. Alertei para o facto de que era normal de manhã ao acordar sentir maior corrimento e que este seria derivado da aplicação do óvulo¹⁰.

Adicionalmente, questionei se utilizava algum produto para a higiene íntima diária, ao que me respondeu que apenas utilizava gel de duche normal. Posto isto, expliquei que era importante usar um produto diferente para a higiene diária da zona íntima, pois esta era uma área sensível e com um pH diferente da restante pele, sendo que rondava tipicamente os 3,8 e 4,5. A jovem compreendeu a importância deste produto e concordou em levar. Mostrei-lhe as opções disponíveis, havendo indicado Saforelle Gentle® que acalma irritações e sensações de desconforto.¹¹

A jovem agradeceu, pedindo por último uma caixa de preservativos, ao que referi que a utilização concomitante de preservativos com óvulos ou cremes vaginais poderia não ser segura uma vez que o material do preservativo poderia ser danificado. De seguida expliquei que durante o tratamento, o preservativo não seria uma opção viável para proteger contra infecções sexualmente transmissíveis ou evitar uma gravidez não desejada.¹⁰ Havendo recomendado a abstinência sexual durante o tratamento.

Caso 3

Chegou uma senhora à FM a solicitar algo para os enjoos, referindo que estava grávida. A senhora pediu algo que pudesse tomar até ir à consulta médica, que seria brevemente, onde lhe iria falar da situação.

Dada a especificação de gravidez, inquiri sobre se tinha preferência pelo medicamento Nausefe®, um Medicamento Não Sujeito a Receita Médica de venda Exclusiva em Farmácia (MNSRM-EF) ou algum produto para o mesmo efeito, mas à base de plantas, havendo sugerido Antimetil® da Tilman. Expliquei que o medicamento Nausefe® estava especificamente indicado para o tratamento de náuseas e vômitos na gravidez e que era seguro.¹² Posteriormente, explanei que também os suplementos da Tilman® eram seguros para mulheres grávidas e a

amamentar, havendo a opção de comprimidos ou de gomas mastigáveis, ambos contendo gengibre, um antiemético.^{13; 14} A utente acabou por me indicar que preferia levar o AntiMetil, por gostar mais da opção de gomas mastigáveis. Assim sendo, expliquei que deveria tomar 1 goma de manhã e 1 goma ao meio-dia.¹⁴

Caso 4

Um senhor de 77 anos já utente da farmácia, dirige-se ao balcão e mostra-me uma caixa vazia de Advancis Easylax Forte®, um laxante de contacto à base de glicósidos antraquinónicos de Sene, e pede para lhe dar a caixa maior que tivesse.

Fiquei alerta para o pedido e receei que o utente fizesse de forma crónica este produto, tendo questionado se tinha dores abdominais persistentes, náuseas ou vómitos. Perguntei ainda se já era frequente tomar e como o costumava fazer. O utente demonstrou-se irritado com as questões, havendo-me respondido que não tinha dores nem náuseas e que tomava um algumas vezes por semana sempre que era preciso e que funcionava, pois conseguia ir à casa-de-banho. Expliquei que Advancis Easylax Forte® era um produto que fazia com que os intestinos trabalhassem por irritação das suas paredes e que só deviam ser usados em situações de SOS, em que se pretende um efeito rápido.¹⁵

O senhor ficou pensativo e questionou se fazia mal tomar Advancis Easylax Forte®, todas as semanas. Respondi prontamente dizendo que não devia tomar de forma regular e que para situações de dificuldade constante em ir à casa de banho, deveria tomar algo como Laevolac® ou Dulcosoft®. Estes são laxantes osmóticos, cujo mecanismo de atuação se baseia na osmose da água para o intestino, amolecendo as fezes. Expliquei que o efeito destes era mais lento, cerca de 2 a 3 dias, e que era o mais indicado para o senhor tomar diariamente.¹⁵

O senhor acabou por ceder, optando por Laevolac Ameixa® que está indicado para todos os casos de obstipação crónica. Expliquei que deveria dissolver uma tampa do conteúdo num copo com água bem cheio e beber em jejum. Adiantei que o poderia tomar todos os dias, uma vez que o mecanismo de atuação não provoca habituação, não havendo perda de eficácia.¹⁶

Recomendei que referisse a situação ao médico, caso a obstipação continuasse a ser muito persistente. Adicionalmente, também incentivei a que o senhor tentasse ingerir um maior volume de líquidos e que tentasse ingerir mais alimentos ricos em fibras como frutas, legumes e cereais integrais e que tentasse, dentro do possível, fazer algum exercício, como caminhadas.¹⁵

Caso 5

Uma senhora de 40 anos, chega à FM a pedir gotas para os olhos porque tinha muita comichão e sentia desconforto.

Ao observar os olhos, estes não denotavam ter vermelhidão. Questionei se a senhora tinha remela ao acordar ou se acordava com o olho colado, por forma a despistar alguma infecção bacteriana sob a forma de conjuntivite. A senhora respondeu que não, mas que sentia uma espécie de areias e comichão nos olhos.

Questionei se a senhora usava lentes de contacto. Pelo que me respondeu que sim.

Acabou por recomendar Optrex Dupla Ação®, um colírio para olhos com comichão, uma vez que é compatível com o uso de lentes de contacto, aliviando a comichão e lubrificando para um alívio duradouro. Aconselhei-a a aplicar 1 a 2 gotas em cada olho 2 a 3 vezes ao dia e que iria sentir alívio quase instantâneo. Ressalvei que antes de cada aplicação deveria lavar bem as mãos e que depois de aberto, o colírio apenas tinha validade de 3 meses,¹⁷ destacando ainda que após este prazo o poderia entregar na farmácia para o Valormed.

4. Considerações Finais

Finda a etapa do estágio curricular na área dos ARM no INFARMED, I.P. e de Farmácia Comunitária na FM, considero que estes constituíram uma mais-valia no meu percurso acadêmico e foram imprescindíveis para valorização enquanto futura Mestre em Ciências Farmacêuticas.

Ter a oportunidade de estagiar na Entidade Reguladora do Medicamento em Portugal confere uma bagagem imensa no que concerne ao conhecimento dentro da área regulamentar. Pude desenvolver um imenso espírito crítico afincado e ganhar bases de rigor imperativo pelas quais o INFARMED, I.P. se pauta. De longe que esta constituiu uma experiência extremamente enriquecedora e despertou ainda mais o gosto pela área dos assuntos regulamentares.

No que concerne ao estágio na FM, denotei o quanto imprescindível é uma correta articulação de conhecimentos e interligação entre eles para melhor entender e dar resposta às múltiplas situações que surgem no atendimento ao utente. Tive a oportunidade de estagiar numa farmácia exemplar que me incutiu valores e ensinamentos nos quais me revejo enquanto futura profissional de saúde.

Considero que fui uma estagiária empenhada e que me comprometi a ir mais além nas tarefas que me foram atribuídas. Fico satisfeita pelo sentimento de que o meu trabalho contribuiu para aliviar e melhorar os locais onde estagiei e reconheço que ambas as etapas de estágio me permitiram consolidar, aprofundar e aplicar conhecimentos para o uso seguro, correto e racional do medicamento.

Em suma, considero-me mais apta e capacitada a ingressar no mercado de trabalho, detendo a certeza de que levarei comigo o rigor, altruísmo, autonomia e conhecimentos apreendidos durante os meses de estágio.

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Parte II – Monografia

“Medicines Waste in Portugal”

Sob orientação da Professora Doutora Victoria Bell

Resumo

Considerando o atual panorama de crescente despesa do SNS, bem como a escassez e rutura de medicamentos, e constante contaminação de ecossistemas inteiros por substâncias farmacêuticas, torna-se imperativo perceber o panorama e impacto do desperdício dos medicamentos em Portugal.

Neste sentido, foi realizado um estudo em 3 farmácias da região centro de Portugal, de abril a junho, onde foi categorizado e contabilizado o desperdício de medicamentos. Adicionalmente, foi efetuado um levantamento sobre as razões que estão na base do desperdício, bem como a percepção dos cidadãos em relação ao Valormed. Este é um sistema que pretende assegurar o correto descarte dos medicamentos, resultando da profícua intercolaboração de farmácias, distribuidores grossistas, indústria farmacêutica e outros estabelecimentos de saúde.

Após concluída a fase de recolha de dados, contabilizando 89 respostas e 596 medicamentos entregues, foi possível concluir que a maioria dos respondentes 75,3% (n=67) eram do sexo feminino, 37,5% (n=33) tinham idade superior a 65 anos e 23% (n=21) eram utentes polimedicados. Foi evidenciado que 25% (n=23) dos inquiridos descarta incorretamente formas farmacêuticas líquidas, com 19,1% (n=17) erroneamente a considerarem que somente formas sólidas podem ser entregues no Valormed. As categorias mais desperdiçadas de medicamentos residem no Sistema Cardiovascular (n=88; desperdício=60,8%) e Sistema Nervoso (n=140; desperdício= 52,8%). Ambas as categorias foram destacadas pelo INFARMED, I.P., como sendo os grupos onde se verificou maior rutura de medicamentos em 2021. Por outro lado, estes constituem 2 dos grupos onde o SNS detém mais encargos com os medicamentos. Foi possível evidenciar ainda que o grupo dos antibacterianos apresenta uma taxa de desperdício de 37,6%, sendo uma realidade significativamente alarmante dada a crescente emergência da resistência aos antibióticos.

Por todas as razões supra-explanadas e desenvolvidas em maior detalhe no estudo, torna-se evidente que são necessárias medidas concretamente dirigidas a este problema emergente, devendo para tal desenvolver-se estratégias concertadas para diminuir o desperdício holístico dos medicamentos, a fim de garantir a sustentabilidade do SNS e contínuo fornecimento eficaz de medicamentos.

Palavras-Chave: Desperdício de medicamentos; Resíduos farmacêuticos; Medicamentos desperdiçados; Práticas de descarte; Impacto Ambiental; Impacto Económico.

Abstract

Given the rising costs of the Portuguese National Health System (NHS), medicine shortages, and the persistent contamination of ecosystems due to inadequately disposed pharmaceutical substances, it becomes essential to determine the current status and repercussions of medication waste in Portugal. A significant volume of unused medicines is regularly returned to community pharmacies to discard in Valormed. Operational in Portugal, this disposal system ensures the secure and appropriate disposal of medications by ongoing collaboration between community pharmacies, medicine distributors, the pharmaceutical industry, and other healthcare institutions.

To address medicine waste, an extensive study was undertaken, from April to June of 2023, in three community pharmacies located in the central region of Portugal. The primary objective was to comprehensively categorize and quantify the discarded medications delivered to Valormed. Additionally, a survey was administered to understand the reasons underlying this wastage and to assess citizen's perceptions regarding Valormed. After the completion of the data collection phase, which involved a total of 89 responses and 596 discarded medicines, several significant results were obtained. The majority of the respondents, 75.3% (n=67), were female, 37.1% (n=33) were 65 years or older and 23% (n=21) were polymedicated. Regarding their knowledge of Valormed, 19.1% (n=17) of the respondents were not sure if disposal was restricted of solid dosage forms and 25% (n=23) disposed of liquid dosage forms incorrectly. When questioned about the reason for discarding their medicines, 57.3% (n=51) mentioned expiry date and 16.9% (n=15) therapeutic substitution.

The categories with the highest percentage of waste belonged to medicines prescribed for the Cardiovascular System (60.8%) and the Nervous System (52.8%). In 2022, these categories were listed among those with greatest burden on the Portuguese NHS. In addition, antibiotics also presented a high wastage rate, 37.6%. This situation is especially alarming in light of the growing problem of bacterial resistance.

Medicines wastage and the improper disposal of unused medicines is a major problem in modern society. It is imperative to acknowledge the significance of implementing proactive and effective measures to address these issues. A particular emphasis should be placed on antibiotics due to the escalating concern of antibiotic resistance.

Keywords: Pharmaceutical Waste; Medicine Wastage; Pharmaceutical Residues; Unused Medicines; Disposal practises; Unwanted Medicines; Environment Impact; Economic Impact.

Abbreviations

API – Pharmaceutical Ingredients

ATC – Anatomical Therapeutic Chemical

EMA – European Medicines Agency

EU – European Union

FIP – International Pharmaceutical Federation

GP – General Practitioners

HMA – Heads of Medicines Agencies

INFARMED, I.P. – Portuguese National Authority of Medicines and Health Products, I.P

NHS – National Health System

OCDE – Organisational for Economic Co-operation and Development

OTC – Over-the-counter

PF – Financial Allowance

SIGREM – Integrated System of Packaging Waste and Medication

UK – United Kingdom

USA – United States of America

WHO – World Health Organization

WHOCC – World Health Organisation Collaborating Centre for Drugs Statistics
Methodology

WWTP – Wastewater Treatment Plants

I. Introduction

According to the World Health Organization (WHO), “Pharmaceutical Waste” can be defined as “Pharmaceuticals that are expired or no longer needed; items contaminated by or containing pharmaceuticals”.¹ Medication waste is a growing, prevalent, and global issue with negative impacts in economic, environmental, and human health fields. In recent years, pharmaceutical prescription has increased due to demographic, epidemiological and lifestyle changes, such as the growing need for drugs to treat ageing-related and chronic diseases, the rise of chronic health conditions as well as the increased availability of accessible medicine/treatments in addition to changes in clinical practise.² These changes led to an increased number of unused medicines and, consequently, wastage.

The Product Stewardship Council announced in 2019 that one-third of the four billion prescription products in the United States of America (USA) had become waste.³

Medicine wastage may occur during and after therapy or due to the patient’s death, as well as through variable routes, such as household waste disposal or toilet/sink flushes. This issue is expected to worsen in the future since it is projected that worldwide the consumption of pharmaceuticals will increase.⁴

The significance of pharmaceutical waste significance becomes an even more relevant topic when it is analysed from an economical perspective, especially when considering that medicine unavailability is a European and global problem. Reducing medicine waste, when preventable, is then crucial not only to ensure efficient supply to those who are in need and guarantee that well-preserved pharmaceuticals are not stockpiled or improperly disposed of. Additionally, wasted medicines represent direct economic losses with no beneficial outcomes for patients. Considering that healthcare expenses are rising each year in Europe, and Portugal is no exception,⁵ it becomes imperative to diminish health expenditures in all possible ways.

There are some promising policies and strategies that are emerging to address this problem. However, the legal and financial liability remains hypothetical, or it is not yet legally allowed.⁶

Unfortunately, not much information is available regarding this topic, concretely, which therapeutic classes and which pharmaceuticals forms are being wasted. Nonetheless, it is crucial to explore these lacunae to determine and understand the real economic impact of medicines waste, as well as to plan a strategy that could be used in the future to reduce medicine wastage.

With this in mind, a study in Portuguese Pharmacies was carried out to collect data regarding medicine wastage. The aim of the study was to identify the principal causes of medicine wastage and evaluate whether discharge practices are appropriate. The main goal was to identify and quantify the major therapeutic classes wasted, in order to provide consistent recommendations for implementing policies regarding unnecessary medication waste. Moreover, one additional goal of this study was to evaluate and highlight the role of the community pharmacist intervention in medicine waste mitigation as well as to evaluate the citizens perception of Valormed.

This topic is extremely relevant since it addresses an emerging issue that needs to be diminished in order to achieve a sustainable Europe by 2030, guided by the Sustainable Development Goals (SDG). Concretely, medicine waste is related to SDG n°3 – “Good Health and Well-being”; SDG n°6 – “Clean Water and Sanitation” and SDG n°12 – “Responsible Consumption and Production”.⁷

2. Valormed

Valormed is a Portuguese non-profit society belonging to the integrated system of packaging waste and medications (SIGREM) that was created in 1999 by the pharmaceutical sector (industry, distributors, and pharmacies) under the framework of extended producer responsibility.⁸

Valormed, the entity responsible for the collection system for medicines in Portugal, provides community pharmacies and establishments authorised to sell medicines not subject to medical prescription with appropriate containers to collect medicine waste.⁸

All the materials that were originally part of a medicine can be delivered to Valormed. This includes the blisters, spoons, lids, cups, vials, bottles, applicators, information leaflets, among others. Due to the danger that some items may represent for those who participate in the process of handling containers and sorting of waste collected, it is totally forbidden to dispose of sharp materials, such as syringes or needles, surgical instruments, electrical or electronic equipment, thermometers, and radiographs.⁹

The disposal process (Figure 1) begins when unused and/or expired medicines that people have in their homes are disposed of in Valormed containers. When the container is full, it is sealed, and the medicine distributors collect and take it to a sorting centre. At this centre, the waste is sorted into recyclable materials (paper, cardboard, plastic, glass, among others). Simultaneously, the remaining waste, such as medicines, is safely incinerated with energy recovery. There is, however, no segregation or classification of the medicines found at any point during this process.⁸

Pharmaceutical industries pay a financial contribution, an ecotax called Financial Allowance (PF), to Valormed, for the transfer of their responsibility in the management of packaging waste drugs. This ecotax is therefore the main funder of the SIGREM system.⁸ This mechanism is stated in Portuguese legislation, applying the principle of Extended Producer Responsibility, which states that the responsibility for a product and its environmental cost during its life cycle, belongs to the producer.¹⁰ Presently the value of PF is 0.00512€ per package introduced in the market.¹¹

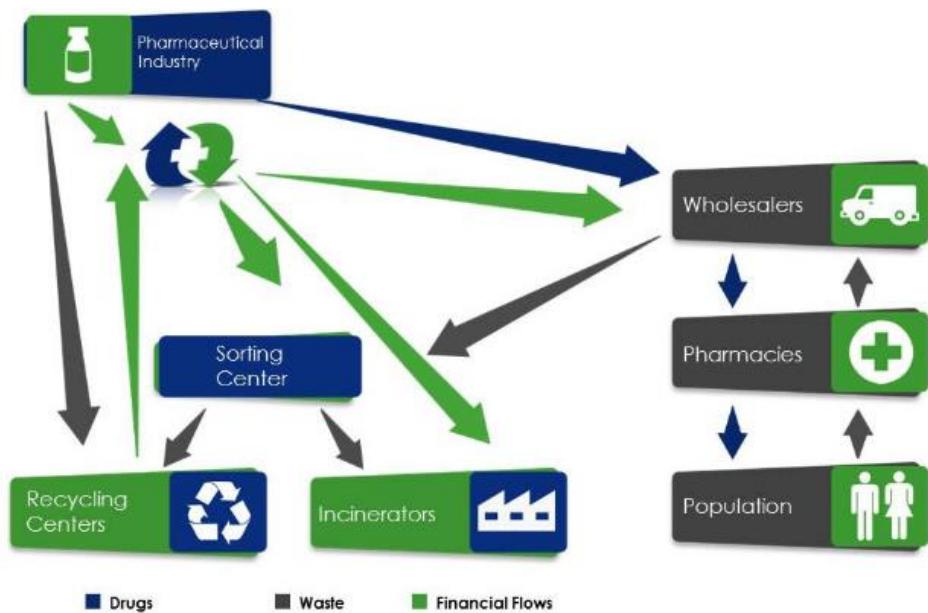


Figure I - Valormed Process.⁸

Valormed's mission is to continue to ensure the correct management of packaging and medicine waste, as well as engage and raise awareness on good practices for a healthier environment, through the implementation of initiatives that, with a multiplier effect in the community, can enhance environmental consciousness and inspire behavioural change.

3. Medicine Waste

Medicine waste is a global phenomenon and a current problem that needs to be addressed. Each year, the total amount of medicines prescribed escalates, increasing medicine wastage. In fact, the United Nations (UN) estimated that the annual growth rate of the pharmaceutical industry is 6.5%,¹² proving that this is a highly important expanding sector. There are several reasons that lead and contribute to the worsening of medicine wastage. Some of the aggravating causes will be addressed below.

3.1. Factors that contribute to Medicine Waste

3.1.1. Ageing and polypharmacy

Population ageing is a global phenomenon. Life expectancy at birth has increased rapidly in recent years, becoming one of the biggest achievements of the last century and a landmark of progress.¹³ For instance, the global average life expectancy at birth, in 2000 was 66.8 years compared to 73.16 years in 2023.^{14; 15} This increase in life expectancy is due to the combination of multiple factors, namely, reduction in infant mortality, better life conditions, improved and healthier lifestyles, better education, as well as advances in medicine and healthcare services.¹⁶ This phenomenon is expected to continue in the future.¹⁷ European population will continue to age in the coming decades, with the portion of the population aged 65 and over increasing from 20.5% in 2019 to 29.1% by 2070.¹⁷ In Portugal, life expectancy is predicted to keep its upward trend, significantly increasing from 82 to 88 years, between 2019 and 2070.¹⁸

Furthermore, population ageing and increase in longevity are significant societal concerns. As the population ages, the prevalence of chronic illnesses tends to increase, resulting in multiple comorbidities and chronic conditions, that often require the use of multi-drug regimens.¹⁹ Despite the absence of a concrete universal definition, polypharmacy refers to the concurrent use of multiple medicines. In line with WHO, it can be defined as the use of five or more medications on a daily basis, regardless of whether they are over-the-counter (OTC), prescription and/or traditional and complementary medicines used by a patient.²⁰

As a result, the number of polymedicated patients is increasing among older adults.²¹ This phenomenon has been linked not only to drug-related problems such as interactions and toxicity, but also to the potential risk of “prescribing cascades”. Complex therapeutic regimens may also be a result of polymedication, which may lead to non-adherence behaviours. The latter issue, poor adherence, is a particular critical concern in population healthiness and health economics, since it severely affects the effectiveness of treatments.²²

To conclude, the use of pharmaceuticals is projected to increase due to population ageing and longer lifespan. All the above-mentioned facts contribute to a higher consumption of medicines and its consequential waste.

3.1.2. Health Literacy

Health Literacy refers to an individual's ability to obtain and comprehend health related knowledge and information in order to maintain and enhance health in a way that is appropriate for both their personal needs and the broader healthcare system.²³

It has been proven that there is a direct correlation between adequate health literacy and higher medication adherence in older patients with multimorbidities.²⁴ This fact is highlighted when considering that patients with comorbidities, who present difficulties in understanding information about health and medication regimens, are the ones most likely to report a high treatment burden, resulting in non-adherence and medication waste.²⁵

On the other hand, studies indicate that the majority of the population does not know or follow the rules for the proper disposal of expired pharmaceuticals.^{26; 27} Notably, a study in Portugal reported that the majority of population do not know how to use the collecting medicine system, Valormed.²⁸ Results showed that 39% of the respondents stated that lack of information on how to proceed was the main reason for not using this disposal system. Additionally, almost 50% stated that they did not know enough about the impact of pharmaceuticals on the environment.²⁸ Lastly, according to the findings, discussing the negative health and environmental impacts with individuals, greatly improves the chances of correct disposal of household pharmaceutical waste.²⁹

Health literacy and knowledge of the impact of medicine waste can have a strong positive influence on individual behaviour. It has been proved that, when proper instructions about disposal are provided, people are more likely to return pharmaceutical waste to the correct collection points.²⁷

3.1.3. Increase in Medicines Consumption - A Cultural Perspective

In recent years, the number of pharmaceuticals consumed annually in the EU has increased substantially.³⁰ Mass media, advertising, and increased access to the Internet are factors that have contributed to the growth in the consumption of medicines, recasting them as consumer goods.³¹ Furthermore, there is a considerable increase in the use of OTC medicines, due to the fact that these products are easily available and affordable and industries can legally advertise them, contrasting with prescription needed medicines.

Taking all this into account, it is necessary to understand that the use of pharmaceuticals is not always linked to medical need or therapeutic necessity.

It is also fundamental to perceive that culture may impact prescription practices. For example, in England, a study on antidepressant prescription found that general practitioners (GPs) under the age of 55 years, who had qualified in the UK, were more likely to submit to a culture of prescribing than older prescribers, or who had qualified elsewhere.³² Additionally, the patient socioeconomic situation may also impact on prescription. For instance, a recent study in the UK demonstrated that people from lower socioeconomic groups were more likely to be given antidepressant medications than people from higher income groups and were the most likely to offer resistance to attend psychological “talking therapies” when compared to people from wealthier backgrounds.³³

Additionally, societal beliefs and attitudes towards mental health and other illnesses have a direct impact on patient compliance. Not many health systems are satisfactorily resourced to properly implement a more personalised and culturally sensitive approach.³¹ It is crucial to comprehend that pharmaceuticals can be linked to personal identity and social relations.³⁴ When these perceptions and circumstances are explored and addressed, treatments are more likely to be followed as recommended, resulting in positive health outcomes and less wastage.

To sum up, culture has a direct impact on both prescribers and patients, influencing the amount of medicine prescribed as well as its proper consumption and, in last instance, its wastage.³¹

3.2. Causes of Medicine Waste

The causes of medication waste can be divided into preventable, non-preventable and non-adherence behaviors.³⁵

It is necessary to understand that initial treatments may be unexpectedly modified, meaning the previous medicines are no longer required. This is a non-preventable cause of medicine waste since it is not possible to predict if a certain drug will always be effective and suitable for every patient. Another non-preventable reason for medication waste is the death of the patient, which results in unused medicines becoming wasted.

Patients may also exhibit non-adherence tendencies. These can be split up into intentional and unintentional behaviours.³⁶ Some examples of intentional non-compliance attitudes are personal beliefs, and the occurrence of adverse reactions, leading to medicine self-abandonment. On the other hand, forgetfulness, and poor record in taking medication are

considered as unintentional behaviours.³⁶ The patient might also experience a faster recovery than foreseen. Moreover, pharmaceuticals for ‘just-in-case’ situations might be stocked and reach their expiration date before being completely utilized. These attitudes generate drug waste, which could be prevented. Non-prescription drugs and OTC pharmaceuticals are seen as pharmaceuticals commonly stockpiled at home for any future situation.² This latter reason is particularly perceptible in a Polish study, whose findings indicated that nearly 60% of the participants buy OTC pharmaceuticals before they need them.²⁶

Additionally, over prescription and the lack of control of the sales of prescription medications in community pharmacies were also recognized as causative factors for medication wastage,³⁷ as well as deprescription. Beside this, considering that patients can frequently obtain duplicate supplies of the same medication because of multiple follow-up appointments from different clinics, it is clear that it will generate wastage.^{38; 39}

To conclude, an article from a systematic review of the literature on “medication wastage”, showed that the most common cited factors for drug waste are medication changed, patients’ death, resolution of patient’s condition, outdated medicine, excessive stock at home and self-discontinuation (Figure 2).³⁷

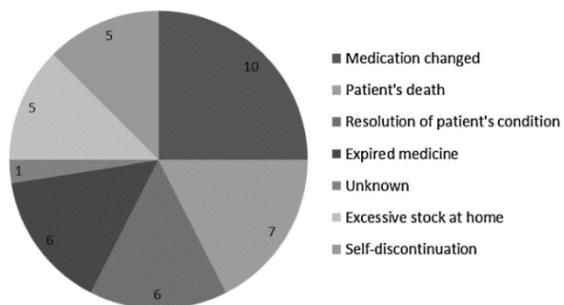


Figure 2 – Frequency of studies reporting reasons for medication wastage.³⁷

Preventable behaviours that may lead to medicine wastage are lack of knowledge, difficulty in understanding the reason for taking the prescribed medicine, beliefs that alternative interventions are more effective, insufficient quality of professional support and lack of suitable guidance on appropriate medication disposal methods.⁴⁰

3.3. Medicine Waste Impact

3.3.1. Environmental Impact

The environmental impact of medicines results of both their usage and disposal. Pharmaceutical household waste from unused or expired medication contributes to

heightened pollution levels, with significant repercussions. It is noteworthy to mention that incorrect disposal, such as throwing medicine wastage into bins, sink or sewers from toilet, is estimated to be the second major pathway by which medicines enter the environment.²⁸

The leakage of medicines into freshwater and terrestrial ecosystems results in their bioaccumulation and intensifies adverse consequences on both plant and wildlife health. This phenomenon is highly evident in a recent global review, which stated that of the 713 pharmaceutical substances tested for in the environment, 631 were found to be above their detectable thresholds.⁴¹ This is particularly concerning because the presence of Pharmaceutical Ingredients (APIs) in ecosystems modifies the behaviour and physiological function of living creatures.⁴²

Antibiotic overuse and wastage are major drivers of bacteria resistance. According to estimates, over 35 000 people die each year in Europe due to antibiotic-resistant bacteria related causes⁴³. This reality is extremely concerning, especially when considering that while some of these drugs are easily degraded, such as penicillin, others are markedly more resistant, such as fluoroquinolones and tetracyclines. The latter have high chemical stability and are not easily degraded by temperature or hydrolysis, persisting for extended periods of time, spreading larger distances and accumulating in higher concentrations.⁴⁴

Antibiotics are also known for reducing growth in environmental bacteria, algae and aquatic plants, which interferes with the correct function of entire ecosystems, dysregulating them.² In order to avoid these consequences, urgent strategies need to be taken to mitigate the introduction of antibiotics into the environment and to combat antimicrobial resistance.

However, antibiotics are not the only pharmaceutical substances to worry about. Analgesics such as diclofenac can induce organ damage in fish as well as genotoxicity, neurotoxicity and oxidative stress at molluscs. Metformin, a widely utilised drug for treating diabetes, can lead to potential endocrine-disrupting effects in fish. Moreover, behaviour changes, growth as well as reproduction toxicity are common effects on invertebrates caused by antihistamines, such as hydroxyzine, fexofenadine, diphenhydramine.²

To avoid the direct contamination of ecosystems by APIs, collection programmes for household medicine wastage must be implemented as a precautionary measure. Unfortunately, they do not exist in every country, nor do they comprehensively address the problem.

Since the publication of Directive 2004/27/EC that European Union (EU) Member States (MS) have to implement systems for the collection and recovery of medicine packaging waste.⁴⁵

When such take-back systems are implemented and effectively operational, the medicine detrimental impact on human and environmental health, as well as contamination levels are reduced, creating positive repercussions for public safety.⁴⁶ However, it remains important to reduce the total amount of medicine waste, even if it is properly disposed of, since the Directive does not provide proper guidelines on implementation of such programmes.⁴⁷

Toxic pollutants may be released from incinerators unless a chemical deactivation system is implemented. Considering that there are significant differences between Member States programmes and the inexistence of proper guidelines and requirements for this process.⁴⁶ This may result in a potential environmental risk. In addition, there is little detailed information about efficiency of collection schemes, and it is not clear that all EU countries, in particular, Bulgaria, Cyprus and Malta, have implemented their obligations.⁴⁸

As previously referred, APIs often contaminate waterways and sources of drinking water, posing a serious threat. This fact is worsened by water reclamation facilities not being designed to break down medicines and, in Europe, there are no legislative requirements compelling Member States to use methods or systems to remove micropollutants, such as pharmaceuticals, from wastewater. According to Council Directive 91/271/EEC of 21 May 1991, which aims to safeguard the environment from the adverse effects of urban wastewater discharges, EU Member States must only ensure that the treated wastewater released into water meets the requirements for biochemical and chemical oxygen demand and total suspended solids. Moreover, in the case of emissions, it is only compulsory to control some specific nitrogen and phosphorus contents.⁴⁹ Meaning that there are not enough requirements regarding the detection of drugs in waste waters discharge.

Additionally, it is important to note that conventional wastewater treatment plants (WWTPs) use mechanical, biological and chemical processes to mitigate pharmaceuticals in water. These procedures rely on two primary processes: sorption and biodegradation (oxidation, hydrolysis, demethylation and cleavage of glucuronide conjugates).^{50; 51} However, the main aim of these methods is to remove easy to moderate biodegradable carbon, nitrogen and phosphorus compounds. Pharmaceutical compounds, however, may be complex and have different sorption ratios, not being entirely removed from wastewaters - compounds with low sorption coefficients tend to remain in the aqueous phase. For instance, WWTPs can remove 100% of paracetamol (high coefficient) whereas only 30% of diclofenac is removed by this process, proving WWTPs low efficiency.^{51; 52} During the degradation process,

pharmaceuticals can also interact with each other, resulting in higher toxicity compounds than the original ones.⁵³

Taking all this into consideration, believing that take back systems and water reclamation facilities treatments are enough to protect the environment from contamination by APIs is unrealistic. It is important to ensure that medicines are discharged properly, as well as, decreasing the total amount of drug wastage to mitigate environmental impacts.

3.3.2. Health Impact

Besides environmental consequences, humans can be exposed to contaminated water and ingest pharmaceutical residues in meat, fish, dairy products, and plant crops. Exposure to some endocrine disrupting chemicals or other medicines, can trigger human diseases related to reproductive and endocrine systems, causing significant health concerns. As examples of this, it can lead to the development of breast/prostate cancer, infertility, diabetes, early puberty and other diseases related to cardiopulmonary, such as asthma or heart disease, and nervous systems (Alzheimer's disease, Parkinson's disease). It is noteworthy to mention that vulnerable populations, such as pregnant women, children and people with allergies are more susceptible to risk.^{2;3}

Secondly, approximately 75% of Europeans rely on groundwater for their principal water supply, which is concerning since it is estimated that 65% of drinking water is sourced by this supply.⁵⁴ The number of pharmaceuticals detected in groundwater and drinking water has been increasing and is now an urgent problem that needs to be addressed. For example, in Barcelona, 72 pharmaceuticals were detected in groundwater samples and antibiotics were the most prevalent ones.⁵⁵ In China, nine out of seventeen antibiotics were detected in 80% of all groundwater samples.⁵⁶ These results, are extremely alarming since it proves that humans are daily exposed to pharmaceutics on water resources, resulting in serious public health concerns.

In addition, it is common for people to stockpile medicine for "just-in-case situations". Having unused medicines stockpiled in houses can lead to drug abuse. Furthermore, the unsafe disposal or improper storage of medicine can lead to accidental ingestion by children and/or animals, leading to poisoning.

3.3.3. Economic Impact

In most EU Member States, health care costs are covered by both private and public sources. The latter is financed by contributions from the active working age population.⁵⁷ The

Portuguese NHS is a universal tax funded system and coexists with other health systems, covering all residents. Over the past years, health care expenditure has been rising across the developed world. The costs associated with medicines are rising faster than overall health costs.⁵⁸

In Portugal, part of the cost of a medicine is covered through reimbursement, in which the NHS pays part of the price of the medicine, depending on its pharmacotherapeutic classification. In certain cases, related to certain diseases or particular medicines, the creation of a Special Co-payment Scheme may be justified.

In recent years, the Portuguese NHS expenditure on medicines has escalated,⁵⁹ as it is possible to observe in the graphic below (Figure 3).

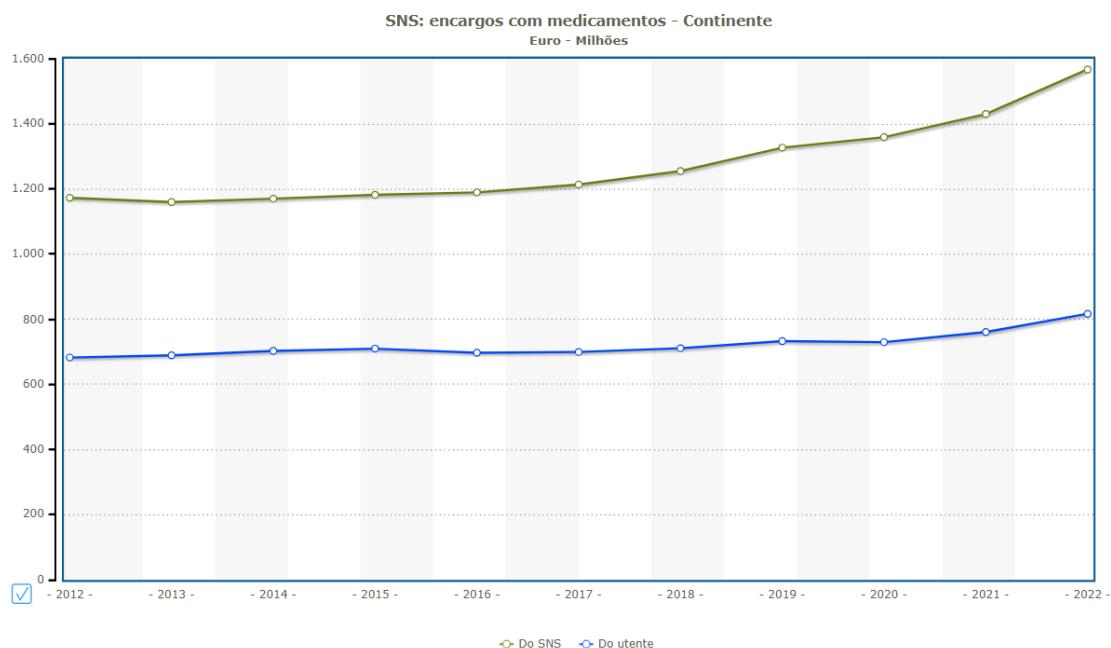


Figure 3 - Portuguese NHS expenditure on medication over the years.⁵⁹

Subsequently, the associated costs of medication waste are also considerably high. For instance, a study conducted in Barcelona, where the total cost of the returned medicines was assessed, demonstrated that 75% of the total wasted cost had been paid by the public health system, which highlights the importance of analyzing the return of unwanted medicines, to reduce unnecessary health expenditures.⁶⁰

Medicine Wastage gains an even greater relevance as medicine shortages are a continuous problem in Europe. In Portugal, the primary reasons cited for the shortages/discontinuations, reported in 2021, were manufacturing issues and increased demand,⁶¹ leading to numerous breakdowns in medicine supply.

It is important to recognize that unused pharmaceuticals represent wasted healthcare resources and economic losses and lead to a decline in the quality of healthcare services, directly impacting on the sustainability of health systems, and access to medicine by patients. For these reasons, it is absolutely crucial to formally address this emerging problem and propose immediate actions.⁶²

4. Materials and Methods

The present study was conducted between April and June 2023 in three community pharmacies located in Central Portugal. Pharmacists were not instructed to encourage their customers to return their medicines, but they were asked to collect the drugs voluntarily returned. When a medicine was returned, the pharmacist interviewed the person returning it to complete a part of a questionnaire that was developed specifically for the study. The citizen was previously asked about the participation in the study and asked for informed consent. This first part of the questionnaire included questions to determine demographic characteristics (sex, age, level of education and number of medicines taken daily). To understand the perception of people regarding Valormed, questions about liquid medicine discharge, reasons for the medicine return, and how they knew about Valormed were made. Each patient was then given a study code. The remaining section of the questionnaire was subsequently filled out by a pharmacist or a master's Pharmaceutical Sciences student, who was doing their curricular internship in the community pharmacy. This part of the questionnaire gathered data about the returned drugs, such as the amount remaining in the package (number of pills), package size and type of medicine. The pharmacist or student analysed each returned medicine safely and wrote down all pertinent considerations. Semi-solid and liquid medicines were excluded from the wastage analysis because of the difficulty in calculating the amount remaining. Medicines for veterinary use were also excluded from the analysis, since only drugs for humans were considered. Both questionnaires can be found in Appendix I and 2.

Valormed was contacted in advance to guarantee that the medicine packages could be opened, and the waste accounted for.

Medicines were categorised in line with the Anatomical Therapeutic Chemical (ATC) classification by the World Health Organisation Collaborating Centre for Drugs Statistics Methodology (WHOCC), which is the standard for international drug utilisation research and is used by the European regulatory medicine authorities.⁶³

The categories (first, second, and third ATC levels) were chosen to include and specify the drugs that are most frequently returned to pharmacies, and the categories that cannot be accepted by Valormed were removed.⁹ More detailed information about the medicine classification used can be found in Appendix 3.

During the analyses of medicine waste, several measures were implemented to ensure a meticulous collection of data. When a medicine was constituted by more than one API, it was classified according to the ATC category of the one that was in predominant quantity. In cases where only blister packs were delivered, a search was made in the pharmacy's computer system to understand the package size.

Descriptive statistical analysis was performed with Jamovi (2.3.24) and the Excel programme.

5. Results

Of the 103 people who returned medicine, only 89 customers agreed to participate in this study anonymously, resulting in a total of 596 drugs returned. The number of packages per patient ranged between a maximum of 33 and a minimum of 1, and the average number of packages per person was 6.7. The categorization of the respondents can be found in Table I.

Table I – Demographic Characteristics of the population.

	Level	Number	Total	Proportion	p
Gender	Feminine	67	89	0.753	< .001
	Masculine	22	89	0.247	< .001
Age	[19-24]	4	89	0.045	< .001
	[25-34]	8	89	0.090	< .001
	[35-44]	11	89	0.124	< .001
	[45-54]	17	89	0.191	< .001
	[55-64]	16	89	0.180	< .001
	more than 65	33	89	0.371	0.019
Education	Higher Education	27	89	0.303	< .001
	Never gone to school	1	89	0.011	< .001
	Year 12	20	89	0.225	< .001
	Year 4	16	89	0.180	< .001
	Year 6	8	89	0.090	< .001
	Year 9	17	89	0.191	< .001
Nº of Medicine taken daily	0	18	89	0.202	< .001
	More than 10	6	89	0.067	< .001
	More than 5	15	89	0.169	< .001
	[1-2]	28	89	0.315	< .001
	[3-4]	22	89	0.247	< .001

The majority of the participants in our study were female (n=67; 75.3%). Population age was analyzed to be from under 18 to over 65 years old, and the predominant range of age was above 65 years old (n=33; 37.1%). 23% (n=21) of the participants were polymedicated (more than 5 medicines taken per day), and from these, 6.7% (n=6) are hyperpolimedicated (more than 10 drugs used per day). In terms of education level, the analyzed population ranged from having no education at all to having achieved higher education. The majority of the population had a higher education degree (n=27; 30.3%).

When inquired about their perception of Valormed and how they knew about Valormed, 55 (61.8%) declared that the pharmacist was the main source of information. 10 (11%)

respondents could not specify how they knew about the possibility of returning medicines for accurate disposal. The answer “Valormed School Campaign” was introduced in this study, since, three citizens gave this unexpected answer. In March 2023, pharmacists from one of the pharmacies organized a school campaign, where the Valormed System and the correct discharge of medicines were explained. From the 195 children involved in these Valormed School Campaigns, at least 3 had a positive outcome: transmission of information from children to their families, and consequent delivery of medicines to pharmacies. The range of answers to this topic is expressed in the bellow graphic:

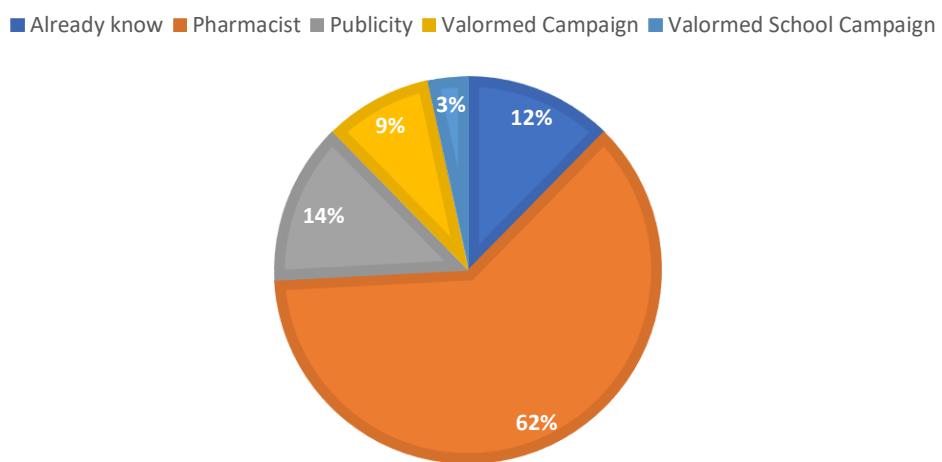


Figure 4 – Evaluation of Valormed’s Knowledge.

Of the 596 packages returned, 61 (10.2%) could not be coded according to the ATC system classification used in this study. Some ATC levels were excluded in this approach.

When evaluating the perception people have about whether only solid pharmaceutical forms can be delivered to Valormed, the results showed that 19.1% (n=17) of the respondents do not know if Valormed is restricted to solid medicines or not, and 13.5% (n=12) believe incorrectly that it is. However, 67% (n=60) of the respondents demonstrated correct knowledge regarding the pharmaceutical forms that can be delivered to Valormed, and in more than half of the cases, 65.2% (n=58), the patients affirmed that they also return liquid medicines to Valormed. More detailed information about the evaluation of liquid medicine discharge, can be consulted in Table 2.

Table 2 – Liquid Medicine Disposal Answers.

	Level	Number	Total	Proportion	p
Liquid Medicine Disposal	Complete use	4	89	0.045	< .001
	Do not use	4	89	0.045	< .001
	Normal Recycling	1	89	0.011	< .001
	Sink	9	89	0.101	< .001
	Toilet	7	89	0.079	< .001
	Trash	6	89	0.067	< .001
	Valormed	58	89	0.652	0.006

Considering only the answers that show improper disposal (n=23, 25%), presented in Figure 8, it is possible to conclude that of these, 36% (n=9) disposed their unused medicines via sink, 32% (n=7) in the toilet, 27% (n=6) of liquid medicines were disposed in the trash, and 5% (n=1) discarded to normal recycling bins.

By examining the reasons presented (Figure 5), it is possible to conclude that “expiration date” was the main motive (n=51; 57.3%) referred to. In 16.9% (n=15) it was reported that the drug treatment was discontinued due to medication switch. In 6.7% (n=6) of the respondents, their condition had improved and/or there was no further need for the medicine. From all respondents, 9% (n=8) stated that the reason for returning pharmaceutical products was due to having concluded their treatments. Four of the patients (4.5%) did not mention the reasons that led to the medicine’s return.

Of the 596 medicines, 77.9% (n=464) were solid forms, 13.3% (n=79) liquid forms and 8.90% (n=53) semi-solid forms – Figure 6.

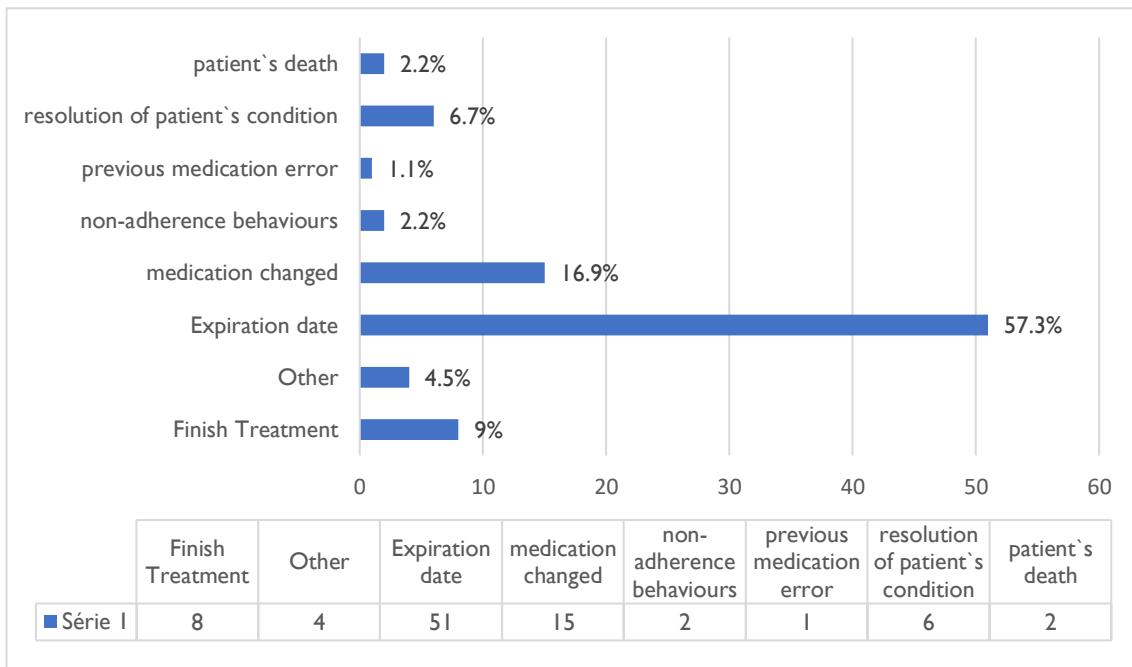


Figure 5 – Reasons for returning unused Medicines.

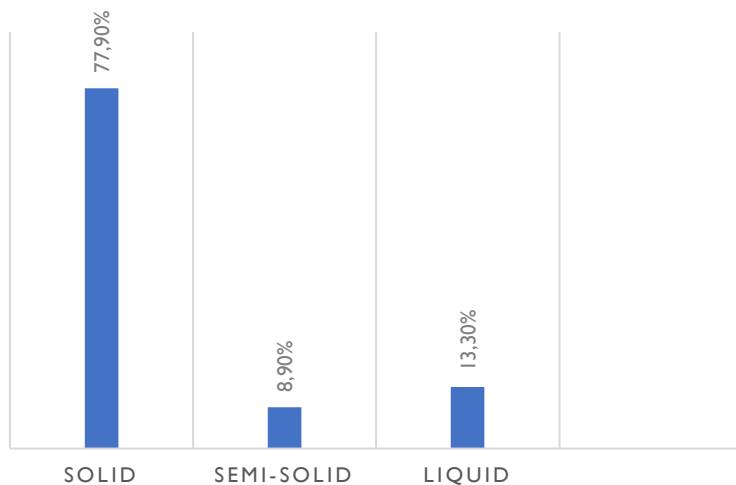


Figure 6 – Distribution of medicines per pharmaceutical forms.

When evaluating the wastage per first level of the ATC category (Table 3), it is possible to conclude that the categories which were delivered the most (group C – cardiovascular system and group N – Nervous System) were also the ones that presented the highest final wastage (60.8% and 52.5% respectively). Groups A, group C, group M, group N and group R (Figure 7), also had high percentages of wastage.

Even though Group L presented a considerable percentage of wastage (94.8%), it was not considered representative since the only 5 packages belonging to this group were all returned by one person, whose reason for the discharge was the patient's death.

Table 3 – Distribution of Solid Medicines returns and subsequent wastage according to the first level of ATC classification system.

Level	Frequency	% Delivered	Frequency of solid forms	% Global Wastage including packages with no waste	Frequency of solid forms, excluding packages with no waste	% wastage excluding packages with no waste
A	55	9.2%	49	50.4%	37	68.5%
B	20	3.4%	20	23.4%	10	50.7%
C	88	14.8%	88	60.8%	67	78%
G	18	3.0%	11	32%	7	49.6%
H	9	1.5%	8	36.2%	4	72.5%
J	32	5.4%	26	36.8%	18	52.9%
L	7	1.2%	5	94.8%	5	94.8%
M	77	12.9%	67	61%	62	65.9%
N	140	23.5%	134	52.8%	110	64.9%
R	56	9.4%	36	50%	28	64.3%
S	33	5.5%	2	0%	0	0%
Others	61	10.2%	18	73.5%	16	82.7%
Total	596		464		364	

Legend: A - alimentary tract and metabolism; B - blood and blood forming organs; C - cardiovascular system; G - genito urinary system and sex hormones; H - systemic hormonal preparations, excluding sex hormones; J - general antiinfectives for systemic use; L - antineoplastic and immunomodulating agents; M - musculoskeletal system; N - nervous system; R - respiratory system; S - sensory organs.

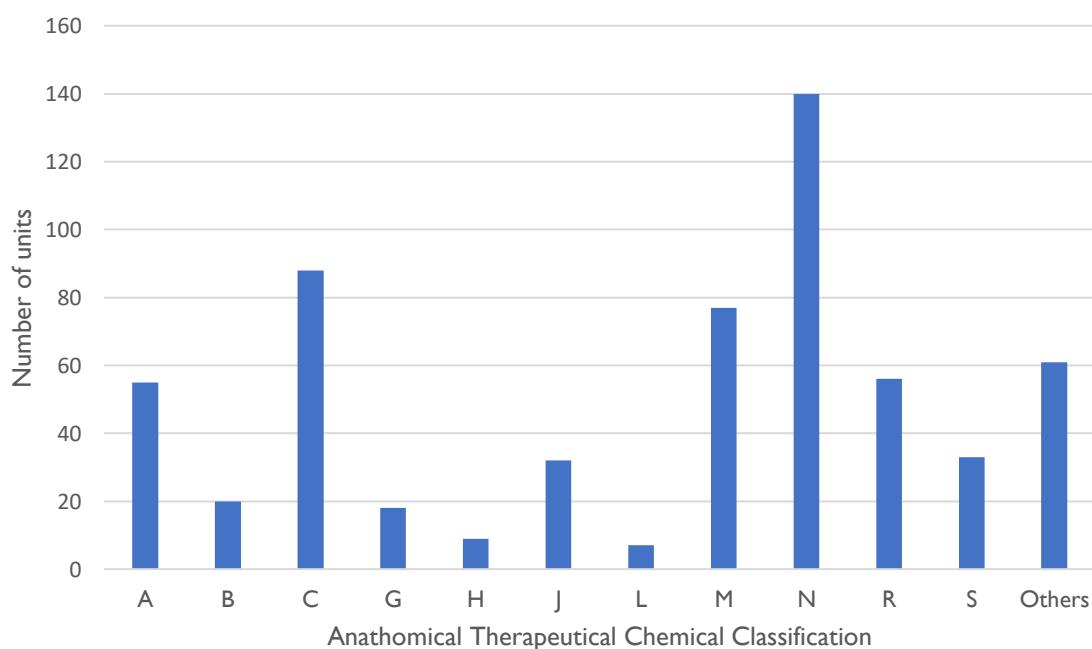


Figure 7 – Distribution of the waste items into different therapeutic classes of drugs

Legend: A - alimentary tract and metabolism; B - blood and blood forming organs; C - cardiovascular system; G - genito urinary system and sex hormones; H - systemic hormonal preparations, excluding sex hormones; J - general antiinfectives for systemic use; L - antineoplastic and immunomodulating agents; M - musculoskeletal system; N - nervous system; R - respiratory system; S - sensory organs.

Considering the second and third levels of ATC classification (Table 4), the most delivered categories were also those with the highest associated waste: Agents acting on the renin-angiotensin system (C); Analgesics (N); Antacids (A); Antidepressants (N); Antihistamines for systemic use (R); Anti-inflammatory and antirheumatic products (M); Anxiolytics (N); Beta-blocking agents (C); Lipid-modifying agents (C) and Drugs used in Diabetes (A).

Despite not having a significant rate of delivery, Calcium channel blockers had a very considerable wastage rate (75.6%), becoming the most wasted category (93.1%).

Antibacterials had a delivery rate of 4.5% (n=27). Of these, when considering only the packages where some wastage was found (n=14), it is found that the waste rate was 56.3% (n=14). Only 7 of the 21 solid antibiotic packages did not present any waste at all.

The categories with less wastage were simultaneously the ones less returned: Anti-Dementia drugs (n=1; waste=0%); Anti-parathyroid agents (n=1; waste=0%); Cardiac glycosides (n=1; waste=0%); Cardiac stimulants (n=1; waste=0%); Ophthalmologics (n=2; waste=0%); Anti-Parkinson agents (n=2; waste=0%); Pituitary and hypothalamic hormones and analogues (n=3; waste=0%) and Drugs for obstructive airway diseases (n=6; waste =0%).

Table 4 – Distribution of Solid Medicines returns and subsequent wastage according to second and third levels of ATC classification system.

	I	II	III	IV	V	VI
Agents acting on the renin-angiotensin system	27	4.5%	27	46.4%	22	70.0%
Analgesics	50	8.4%	45	72.7%	42	77.9%
Anesthetics	1	0.2%	0	0%	0	0%
Antacids	14	2.3%	14	57.7%	13	62.1%
Antianemic preparations	13	2.2%	13	12.6%	3	54.4%
Antiarrhythmics	2	0.3%	2	91.7%	2	91.6%
Antibacterials	27	4.5%	21	37.6%	14	56.3%
Anti-dementia drugs	1	0.2%	1	0%	0	0%
Antidepressants	44	7.4%	44	50%	37	59.9%
Antidiarrheals, intestinal antiinflammatory/antifungal agents	7	1.2%	4	72.5%	4	72.5%
Antiemetics and antinauseants	5	0.8%	5	65.4%	5	65.4%
Antiepileptics	3	0.5%	3	41.9%	3	41.9%
Antihemorrhagics	2	0.3%	2	57.5%	2	57.5%
Antihistamines for systemic use	30	5.0%	25	55.8%	23	60.7%
Antihypertensives	0	0%	0	0%	0	0%
Antiinflammatory and antirheumatic products	69	11.6%	63	61.8%	58	66.1%
Antimycotics, Antimycobacterials; Antivirals for systemic use	5	0.8%	5	51.6%	4	64.5%
Anti-parathyroid agents	1	0.2%	1	0%	0	0%
Anti-parkinson drugs	2	0.3%	2	0%	0	0%

Antipsychotics	6	1%	6	15.6%	3	31.1%
Antithrombotic agents	5	0.8%	5	45.8%	5	45.8%
Anxiolytics	30	5.0%	30	45.5%	23	59.4%
Beta blocking agents	10	1.7%	10	57%	9	63.4%
Bile and liver therapy	0	0%	0	0%	0	0%
Calcium channel blockers	16	2.7%	16	75.6%	13	93.1%
Cardiac glycosides	1	0.2%	1	0%	0	0%
Cardiac stimulants excl. Cardiac glycosides	1	0.2%	1	0%	0	0%
Corticosteroids for systemic use	4	0.7%	4	72.5%	4	72.5%
Cough and cold preparations	7	1.2%	5	81%	5	81%
Diuretics	10	1.7%	10	41.3%	6	69.7%
Drugs for constipation	5	0.8%	5	59%	4	73.8%
Drugs for obstructive airway diseases	10	1.7%	6	0%	0	0%
Drugs for peptic ulcer and gastroesophageal reflux disease (gord)	0	0%	0	0%	0	0%
Drugs for treatment of bone diseases	0	0%	0	0%	0	0%
Drugs used in diabetes	24	4%	21	35.7%	11	75%
Hypnotics and sedatives	3	0.5%	3	29.8%	2	44.6%
Immunostimulants	0	0%	0	0%	0	0%
Immunosuppressants	7	1.2%	5	94.8%	5	94.8%
Lipid modifying agents	19	3.2%	19	62.8%	13	91.8%
Muscle relaxants	4	0.7%	4	63.8%	4	63.8%
Nasal preparations	9	1.5%	0	0%	0	0%
Ophthalmologicals	24	4.0%	2	0%	0	0%
Otologicals	9	1.5%	0	0%	0	0%
Pancreatic hormones	0	0%	0	0%	0	0%
Parathyroid hormones and analogues	0	0%	0	0%	0	0%
Peripheral vasodilators	0	0%	0	0%	0	0%
Pituitary and hypothalamic hormones and analogues	4	0.7%	3	0%	0	0%
Sex hormones and modulators of the genital system	18	3%	11	31.5%	7	49.6%
Thyroid therapy	0	0%	0	0%	0	0%
Topical products for joint and muscular pain	4	0.7%	0	0%	0	0%
Vasodilators used in cardiac diseases	2	0.3%	2	62.5%	2	62.5%
other	61	10.2%	18	73.5%	16	82.7%
TOTAL	596	100%	464		364	

Legend: I - Frequency of all medicine returned; II - Percentage of all medicine returned; III - Frequency of solid forms only; IV - Percentage of solid forms global wastage including packages with no waste; V - Frequency of solid forms, excluding packages with no waste; VI - Percentage of solid forms wastage excluding packages with no waste

Considering all of the 494 returned packages containing solely solid medicines, only 99 (21.3%) did not present any wasted drugs, resulting in an average waste of medicine of 64.8%.

6. Discussion

This study pertains solely to waste returned to the pharmacy by patients and does not consider the volume of unreported medication wastage that is disposed of down the sink or into the household garbage. The results also do not take into consideration the wastage that occurs in other health facilities, such as hospitals, healthcare centres, and elderly households, or that is simply kept stockpiled unreported at home.

6.1. Amount of Drugs Collected

In the present study the overall quantity of drugs collected was relatively small. Only three pharmacies voluntarily participated, without any remuneration or incentive. The fulfilment of the questionnaires proved to be difficult, due to the large amount of work in community pharmacies. Concretely, it was not consistently feasible to complete the first part of the questionnaire, especially in instances where patients were sensitive to some relative's death, were running out of time, or did not agree to participate.

Secondly, the results concerning the solid pharmaceutical forms being the most returned were expected, since it has already been reported, in previous studies, that solid forms were more likely to be returned compared to semi-solid and liquid forms.^{62; 64} For instance, in New Zealand, tablets and capsules alone made up 89% of all evaluated pharmaceutical waste items.⁶⁴

6.2. Who Returned the Unused Medicines

The study findings revealed that gender exerted an influence on the practice of returning unwanted or unused medications for proper disposal. Female respondents demonstrated a higher likelihood compared to male respondents (75.3% and 24.7% respectively). This fact was further corroborated in a Saudi Arabian population;²⁷ nevertheless, it contrasts with a study in Poland,²⁶ where gender was proven to not impact the return of medicines, meaning that some cultural factors may be involved. However, it is key to note that not all of the returned drugs necessarily belonged to the person returning them.

According to the results, not only was the age distribution mostly above 65 years old (n=89; 37.1%), but also a significant portion of our study sample was polymedicated. This data

aligns with information already in the literature, which indicates that the age group with higher rates of polypharmacy is the elderly.^{65; 66} A recent study in Portugal, demonstrated that the rate of polymedication among individuals aged above 65 in Portugal was 36.9%.¹⁹

In terms of literacy, most respondents are shown to have advanced levels of education (n=27; 30.3%) of the participants completed higher education and 22.5% (n=20) finished year 12. However, these values might not be representative of a relation between level of education and rate of wastage, but instead, only a reflection of the overall level of education of the Portuguese population. Results found in the 2021 Portugal National Census, show that 44.5% of the population has completed secondary education or higher.⁶⁷ It is also noteworthy to mention that, during mandatory education, health literacy and good medication disposal practices, as well as the importance of medication adherence, are not addressed in the curricula. Despite university being a higher level of education, depending on the course, such topics are also not covered.

Besides this, taking into consideration that approximately 76% (n=68) of respondents are non-polymedicated, and that the average number of medicines delivered is 7, it is possible to conclude that people are returning more medicines than those taken daily. This suggests that individuals may tend to store medications at home or return medicine belonging to others. This is reinforced by the fact that the range of medicines returned varies from 1 to 33. This may suggest that citizens are stockpiling medicines at home, which is a tremendously concerning situation. As elucidated in point 3.3.2 – “Health Impact”, having medicines available at home increases the risk of inappropriate medicine being taken, possibly leading to accidental poisoning by children and increasing the chances of self-inappropriate medication. To illustrate, in the USA, unintentional poisonings from medicines (both prescription and OTC) caused more younger children’s hospitalizations than car accidents, with easy access to pharmaceutical products being more common at grandparents’ homes.⁶⁸

6.3. Population`s Medicine Discharge Perception

One of the aims of this study was to evaluate how respondents dispose of their unwanted medicines and if it was believed that only solid forms could be placed in Valormed. According to the collected data, 32.6%, a significant portion of the respondent population, does not know or merely returns solid medicines to Valormed. At least one quarter of the respondents also do not know how to accurately dispose of unused liquid pharmaceuticals. This reality has been reported in a case study in Poland, which had similar findings.²⁶ This is particularly important

since it reflects that more information and sensibilization campaigns should be provided to the population in order to promote the correct disposal of liquid and semi-solid forms.

From the evaluation of how people discharge liquid medicines, it is possible to conclude that the majority deliver them correctly to Valormed. However, it is not possible to extrapolate that most of the Portuguese population returns liquid drugs to pharmacies, since all the respondents already knew about Valormed. A considerable portion of Portuguese citizens may not be properly informed or even know about the existence of a collection medicine system, throwing liquids in the sink, toilet and/or trash (Figure 8). Considering inappropriate liquid disposal (figure 8), the collected data shows that flushing them into the toilet (32%), throwing them into the sink (36%) or trash (27%) are the most common forms of disposal, which is extremely alarming, since they will most probably enter into the environment, affect ecosystems since, as explained previously, WWTP are not designed to extract these substances.

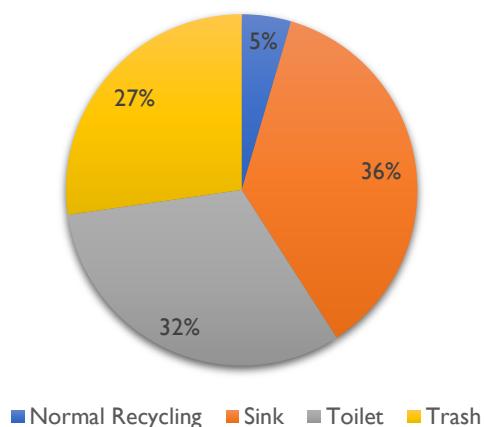


Figure 8 – Distribution of incorrect liquid medicine discharge.

In the Netherlands, similar findings show that 17.5% of the citizens were unaware that liquid medicines should not be flushed.² The fact that the incorrect disposal of liquids reaches values of 25%, in the present study, is extremely critical because it leads to serious environmental impacts.

It is necessary to understand that the results from the portion of patients who correctly return liquid medicine to Valormed (65.2%) are in line with the rate of people affirming that the pharmacist had an impact on their choice to return medicine (62%), which may indicate that the pharmacist is the key player in providing the correct information on accurate waste disposal. According to the results, pharmacists are an important source of information to increase the proper disposal of unwanted medicines. The pharmacist emerges in this analysis

as the primary advocate of Valormed (62%), emphasizing its pivotal role as promoter of public health literacy.

These health professionals, according to the results, also fulfil a crucial position in the education of younger populations in schools. The fact that three returns were due to the positive impact of a Valormed School Campaign led by pharmacists enables us to deduce that schools must be considered as focal points to improve Valormed's adherence and that these professionals do have an important role in this area.

Addressing the young population at schools is one of the strategies that improves awareness among populations. According to the Portuguese National Strategic Waste Management Plan 2014-2020, one of the central points to increase awareness, compliance, and promotion of recycling was the promotion of environmental education across various educational levels. This policy document advocates for the promotion of literacy-related activities to correct residues discharge in schools.⁶⁹

The duty of pharmacists to promote health education and health literacy is well documented, not only in the Portuguese Pharmacists Code of Ethics,⁷⁰ but also in the Portugal Health Basic Laws.⁷¹

6.4. Reasons for Returned Drugs

In multiple scenarios, medicine wastage is unavoidable, such as when a patient dies, when there are previous medical prescription errors, or when medication is changed, to achieve better outcomes or avoid an adverse event.

The present findings suggest, however, that expiration date is the predominant factor leading to the majority of the returned drugs. Similar findings have been reported in Sweden, where the expiration date was the first reason given, followed by the death of the patient, the patient not needing the medicine anymore, and the occurrence of changes in medication regimen.⁷² However, it should also be taken into account that several of the returned packages contained multiple medicines and that 'Expiration date' could have been given as the main reason. In other words, due to the delivery of multiples medicine packages, people answered by generalization "expiration date", even though some of them may not reached expiration date yet.

Another possible contributing factor that may explain this scenario is that people might tend to store medicines at home for long periods of time, reaching their expiration date. This possibility is sustained by a Pakistan study, where 87% of the respondents had unused

medicines at their homes and reusing the medications was the purpose of medicine storage (50%). This highlights the susceptibility of medicines to expiring easily, as they are accumulated without being used to treat any immediate illness.⁷³ Expiration date being the main reason for medicine disposal, it is possible to reduce this preventable cause of pharmaceutical waste through health literacy and educational programmes.

Secondly, focusing on the third and fourth most significant factors given for returning medicines – the end of treatment (9%) and the resolution of the patient's condition (6.7%) – it can be inferred that package sizes are not suitable to cover all of the different treatments and respective posologies. Both reasons are, in part, avoidable.

Non-adherence behaviors were reported only by two individuals. However, these results do not reflect the possibility of non-adherence behaviors leading to the discontinuation of a treatment, and consequently medicines being stored at home until their expiration date, which would result in that being presented as the cause.

6.5. Therapeutic Classes and Medicine Wastage

After a detailed analysis, considering only solid forms, and the first level of the ATC classification system, the most delivered categories are group C – cardiovascular system (14.8%) and group N – Nervous System (23.5%). These results are in concordance with a previous study in Spain, where group C and N were also the predominant ones to be delivered (1.7% and 18.2%, respectively). However, in this Spanish study, the most delivered category was medicines from group A, and our results do not reflect a considerable return rate of

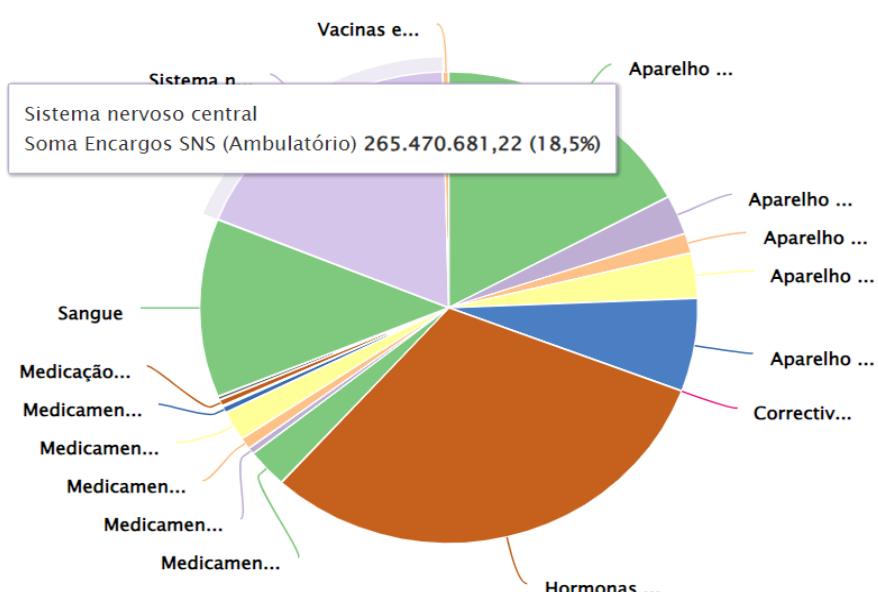


Figure 9 – Portuguese NHS expenditure per pharmacotherapeutic group in 2022.⁷⁴

group A medicines⁶⁰. On the other hand, a recent study from New Zealand revealed that the most common medicines were those acting on the nervous system, making up 34.1% of all waste items, followed by cardiovascular (18.3%) and alimentary tract (20.3%).⁶⁴

ATC Group N includes, among others: anesthetics, analgesics and treatments used in psychiatry such as antidepressants and anxiolytics. ATC Group C covers medications used to address hypertension, high cholesterol levels and problems with cardiac rhythm and heart function. One potential reason contributing to the significant waste percentage (60.8% and 52.5% respectively), is the fact that medicines from the nervous systems require some dosage adjustments, that, involuntary, may lead to wastage and cardiovascular medicines commonly need to be amended due to frequent changes in doses.³⁵

This is extremely important, considering that these represent two of the groups with the greatest burden for NHS expenditure in 2022, according to INFARMED, I.P. (Figure 9) – Nervous System – 265.470.681,22€ (18.5%); Cardiovascular System – 246.714.340,87€ (17.2%). There is no current data yet available for 2023.⁷⁴

Additionally, as reported by INFARMED, I.P., the pharmacotherapeutic groups most affected by shortages, in 2021, were those intended for cardiovascular and nervous system.⁶¹ Moreover, these two groups were pointed out as the two most frequent categories of medicines subject to shortages in 14 OECD countries (including Portugal), during 2017 and 2019 – 21% of the shortages were of medicines related to the nervous system and 19% to cardiovascular system.⁷⁵

Figure 9 also enhances the considerable portion of expenditure on hormones and medicines used to treat endocrine diseases – 444.183.564,53€ (31%).⁷⁴ This group includes drugs used in diabetes, sex hormones and modulators of the genital system, which are highly consumed medicines. Drugs used in diabetes present a global rate of wastage of 35.7%. Excluding packages with no waste inside, the medicine waste rate rose to 75%. This is extremely alarming since it means that a considerable amount of money is being directly wasted. Considering all the above-mentioned reasons, immediate actions must be taken.

However, this is not a global transversal reality, such as the highest prevalent illnesses per country. For example, in Ethiopia anti-infective medicines were the most predominant therapeutic classes of drug waste.⁶² This is potentially due to the fact that these medicines treat illnesses and particular medical conditions that are highly prevalent in this geographical area, contrasting with Portuguese reality. Moreover, in the above-mentioned country, anti-

infectives have been available without a medical prescription, which may have promoted greater rates of anti-infective consumes and, consequently, wastage.^{35; 76}

Analgesics, Anti-inflammatory and antirheumatic products exhibit high rates of return. They are often the most recurrent leftover medicines at home, presumably due to usually being the first-line treatment of common health conditions, such as fever and headaches. Moreover, these are available in multiple OTC products and do not require a medical prescription.

In our study, antibiotics were also part of the leftover medicines (4.5%). As mentioned earlier, this class is pointed out in many African studies as one of the groups most frequently returned to pharmacies.^{62; 77} For instance, in a study that took place in Ghana, 17.9% of the medicines were antibacterials.⁷⁸

The average waste of antibacterials, in the present study, was 37.6%, however, when considering only the packages with leftovers, the average rises to 56.3%, which is an alarming finding since this may imply that treatment is often not adhered to, contributing to antibiotic resistance. From the results, it is possible to conclude that two out of three packages of antibiotics returned, contained drug waste inside.

One of the reasons that may justify antibacterials high waste rates is that antibiotics, along with cardiovascular drugs, are pointed out as one of the most frequently self-discontinued medications.⁷⁹ This may be due to the fact that people tend to not complete their treatments because they feel better, stockpiling antibiotics at home for other occasions. According to the WHO, one in three people use antibiotics without a medical prescription (leftover antibiotics from a previous prescription or obtained them without a prescription over the counter from a pharmacy).⁸⁰

Despite increased policy action and awareness, antibiotics resistance continues to increase. The last 20 years have seen the emergence of microorganisms resistant to all available antimicrobial classes, and it is predicted that by 2050, antimicrobial resistance will cause an estimated 10 million fatalities worldwide, surpassing cancer as the second largest killer.⁸¹ Having a current waste rate of 37.6% proves that urgent measures should be taken to raise awareness and adherence to treatments.

Our study showed that, the overall waste rate was 64.8%, and it is possible to affirm that four in every five returned packages containing only solid medicines presented waste. This is a concerning reality given the fact that health expenditures have reached astronomical levels. In April of 2023, in the centre of Portugal around EUR 25.5 million were spent on medicines.⁸²

6.6. Limitations of the study

One of the main constraints of the study was the reduced number of responses. In view of the results, it is important to continue and improve this study, enrolling more pharmacies to obtain more representative data.

Furthermore, it was unfeasible to quantify the wastage of liquid and semi-solid medicine forms, resulting in inconclusive information about this topic. For instance, if this study is repeated in the future, it ought to be considered to employ a weight differential approach, if suitable materials are available.

Moreover, one of the primary obstacles was identifying relevant literature reflecting the European reality on this subject, since a considerable number of articles are originally from Africa. In addition, the variance in therapeutic categorization systems used across different countries, official platforms, and studies evaluating medication waste hinder result interpretation.

7. Future Perspectives and Measures to reduce Medicine Waste

Reducing the amount of pharmaceutical waste and ensuring its responsible disposal are crucial steps in mitigating the medicine wastage. It is equally important to act on drug waste prevention as it is to mitigate the consequences of incorrect medication disposal. Both are multistage processes that include, *inter alia*, the rational prescription of pharmaceuticals, proper regulation by the competent authorities, and encouragement of proper disposal. Currently, there is no global strategy for limiting the production and disposal of medicine wastage. The following measures focus on possible strategies to reduce, control, and prevent medicine waste and action plans to mitigate and avoid wastage negative impacts.

7.1. Prevent Disease and Focus on Rational Medical Prescriptions

The priority to prevent pharmaceutical waste lies in reducing medicine consumption by improving disease prevention. For instance, developing better health and hygiene conditions, as well as teaching contagious prevention measures. Personalised and precision medicines, when possible, are also recommended as potential approaches since they can result in fewer and more effective treatments², leading to less generated waste.

Secondly, better prescribing practices and access to clinical data by GP and other health professionals can significantly reduce drug waste, since they allow a better understanding of the diagnosis and may avoid some prescription mistakes.

Additionally, prescriptions and dispenses can be managed from a “Green Pharmacy” perspective. Green Pharmacy recognizes the potential for new drugs to be designed to be less harmful to the environment. Such technologies include co-crystallization for improving bioavailability, salt formation, cyclodextrin encapsulation, or obtaining amorphous forms for improved solubility. Depending on the molecule, other strategies can be applied, such as using microorganisms for biodegradation.⁸³ Additionally, some green pharmacies strategies focus on green chemistry metrics, such as atom economy, atom efficiency and process mass index.⁸⁴ This information could be available to doctors and pharmacists during prescription and dispensing phases. As a result, if no better therapeutic were more beneficial, the greener medicine could be provided, instead of the regular one.⁸³

Another strategy could focus on encouraging a continuous improvement in communication between health professionals and patients in order to achieve higher rates of adherence among patients. Commonly, patients rationally stop treatments due to irrational beliefs.

Lastly, considering the current panorama of medicine shortages in Europe, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) call for prudent use and to avoid stockpiling medicines, especially antibiotics, that should continue to be used prudently to maintain their efficacy and avoid antimicrobial resistance.⁸⁵ Medical professionals have a key role to play, and antibiotics, as well as all medicines, should only be prescribed when necessary.

7.2. Improve Health Literacy - Educational Campaigns

Immediate actions must be taken to educate consumers on the rational use of medicines and the correct disposal of unused or expired medication. The achievement of this main goal and the success of these actions depend mainly on society's awareness, since proper consumer behaviour is mainly influenced by consciousness of the environmental, economic and health effects of improper disposal of unused/expired medication.²⁶

Patients must become aware that their conduct has serious consequences. Actions regarding pre-school and other education levels, as well as society educational campaigns focusing on both environment and health literacy should be taken at various levels: local,

regional, and national, with referral to various social groups. There is already evidence that addressing smaller targets can be more effective in changing people's attitudes towards medicine and household stockpiling.⁸⁶ For example, a Turkish company campaign revealed that more than 50% of their employees changed how they dealt with expired and unused pharmaceuticals. Additionally, employees were also less likely to dispose of drugs inappropriately, practise self-medicate, and stockpile expired drugs. Another positive outcome from this Turkish campaign was in regard to an increased tendency to influence positively others to change their behaviours regarding medicine wastage.⁸⁶

Another example of a successful target audience programme to raise awareness about antibiotics is the e-Bug Programme. The e-Bug Programme is an educational resource that focuses on teaching young people and school children about the importance of hygiene, proper handwashing, and understanding infections caused by bacteria and viruses. It is designed to align with school curricula, and it offers training sessions and workshops.

Higher education institutions should also be a focus. A previous study, that evaluated the knowledge and practices concerning unused and expired medicine among pharmacy and nursing students, indicated that 78.9% of pharmacy students and 80.5% of nursing students discard incorrectly medicine.⁸⁷ These findings suggest that creating awareness, regarding proper medicine disposal procedures, in academic institutions, among health students is of critical importance.

Actions concerning Valormed, and the rational use of medicine should be taken at multiple levels in order to achieve a more informed population and diminish drug waste. However, it must be noted that shaping social awareness and consciousness is a long-term and continuing process.

7.3. Follow-up Programmes

Follow-up programmes could be implemented in pharmacies to strengthen treatment monitorization and follow-up of medicine intake, with a special focus on drugs whose wastage rate is higher: Nervous and Cardiovascular system. This can be done, for instance, by monitoring health indicators and predictors in weekly appointments in pharmacies or by following up patients remotely.

In Portugal, a new company, EZFY, has emerged recently and compensates pharmacies for providing services to optimise patient treatment with newly launched medicines. For patients, this programme is extremely beneficial since they have free access to some pharmacy services

that are patient-centred, such as, counselling and monitoring to help manage their conditions effectively, as well as measuring blood pressure and performing glycaemia tests, without cost. This company provides the patients data concerning the use of a particular medicine to industry companies and ensures that there is a personalised and close follow-up of the user, enhancing compliance. This scheme could be more widely implemented across the country, with personalised services in pharmacies being promoted through remuneration or other incentives. This would be highly beneficial to obtain better medical outcomes, as well as to reduce medicine wastage resultant from non-adherence behaviour.

Implementing programmes specifically for antibiotics, whose impacts are more concerning due to the rise in antibacterial resistance, would be beneficial to help patients manage their medications more efficiently and ensure adherence. A solution for this could be to create a national telephone line to monitor users' treatment, or the pharmacy could have this service itself. Moreover, national health phone applications, such as the Portuguese NHS app, that already provide access to medical prescriptions, could be programmed to send automatic alerts on when medication should be taken and/or send a final message, after finishing treatment, for the remaining medication (if any) to be disposed of at Valormed. This way, we are concomitantly acting to increase adherence and avoid inappropriate wastage.

Other innovative ideas can and must be explored. The aim should always be to enhance medicine adherence, promote the rational use of medicine and raise awareness among the population.

7.4. Optimise Volumes of Medicine Dispensed Packages

7.4.1. Re-size of Packages and Starter Packs

As referred to in point 6.4 – “Reasons for Returned Medicines”, in order to reduce avoidable drug waste, the reduction of package size could be beneficial. Currently, in Portugal, the size of the packaging of medicines, that may be reimbursed by the State, should be appropriate according to the duration of therapy; need for clinical surveillance, and pharmaceutical form, as defined by Order N° 1471/2004 of 21 December 2004. Concretely, the solid forms intended for short or medium treatment of predominantly acute diseases, may be in packages of up to 20 units, except antibiotics, whose packs can be up to 16 units. Sedatives, hypnotics, and tranquillisers intended for medium-term treatment; anticoagulants and fibrinolytics, for treatment subject to strict clinical supervision, can be purchased in packs of up to 30 units. For long-term treatment of chronic diseases, two types of packs are available: therapeutic test packs of up to 20 units and maintenance treatment packs of up to 60 units.⁸⁸

However, in certain circumstances, for instance in case of acute pain or occasional situations, even the pack of 20 units contains too many medicines to treat the initial condition. The possibility of reducing pharmaceutical waste by optimising the package size of pharmaceuticals has been debated, so that medicines can be dispensed in smaller quantities that better match the needs of the patient. This could be a hypothesis to be explored in the future by the pharmaceutical industry and the competent national authorities.⁸⁹

In addition, another measure would be the creation of starter packs, to allow patients to try the medicine when a new treatment is started and change it in the case of ineffective treatment or side effects. In this way, if the dose is not appropriate or an adverse effect occurs, the medication can be stopped, without resulting in a high associated waste.²⁸

7.4.2. Unit Dose Dispensing Drug System

In various situations, as previously stated, the packages for some treatments, do not cover the entire posology of the treatment, meaning that medicine will be left over inevitably.

In many European countries, such as Ireland and Poland unit dose dispensing medicine systems are used in pharmacies. These systems allow to dispense of the exact medicine number needed to complete the treatments, avoiding unnecessary leftovers.

In Portugal this practice is not yet applied, although the law that establishes the experimental regime of individualised dispensation of medication has been approved since 2009.⁹⁰ In 2010, since no pharmacies joined the experimental regime,⁹¹ the law underwent revision, allowing for another experimental period to evaluate outcomes. During this period, only individualised quantities of antibiotics, antihistamines, non-steroidal anti-inflammatory drugs, paracetamol, and antifungals were included in this system,⁹² which could lead to 150 million euros of savings.⁹³ Unfortunately, despite these efforts, this system has not been implemented to date, since no pharmacies have participated.

In a 2021 study that took place in the Azores, aimed to evaluate the benefits of a unit dose system for oral antibiotics dispensing and extrapolate the results at the Portuguese nationwide level, the findings proved that this system could provide a significant socioeconomic benefit for healthcare systems. The Portuguese nationwide extrapolation indicated that a total of 276.833 pharmaceutical interventions could be registered, corresponding 1.544.317 pharmaceutical units saved equivalent to €434.085.85.⁹⁴

From a holistic perspective, this scenario should not be compromised only because no community pharmacies adhered. The pharmaceutical industry and community pharmacies

should come up with solutions and achieve the main goal of implementing a unit dose drug system.

7.5. Implementation of a Re-dispensing-system

Currently, medicine donation in pharmacies is forbidden by law.^{95; 96} This means that, it is not permitted that a medicine that has left the pharmacy may return to it to be re-dispensed to another patient. Nevertheless, this ideology is suggested due to the potential cost savings of applying this inverse logistics, highlighting it as the key to a switch in the medicine wastage paradigm.^{35; 97} It is advised that strict criteria should be applied. For instance, incorporating newer packaging technologies to alert pharmacists if medicines were kept in inappropriate conditions, and compel information if any attempt to open the package occurred.

When evaluating patient's willingness to adhere to this systems, it was demonstrated that patients would use unused medication returned to the pharmacy by another patient, if quality was guaranteed.⁹⁸ Likewise, an online study proved that the majority of the general public would favourably accept reused medicines for personal use.⁹⁹ Similarly, another study, demonstrated that this system could be cost-beneficial if applied to expensive medications in particularly.⁹⁷

Nonetheless, given that no efficient methodology has yet been developed to guarantee the complete safety and integrity of the medicine, as well as to ensure that all storage conditions such as temperature and humidity are met, this system remains hypothetical.

7.6. Focus on Laws and Regulatory Framework

It is crucial that policymakers and competent authorities develop interventional measures for reducing pharmaceutical waste and rapidly execute proper pharmaceutical waste management practices.

Since the take-back systems are considerably different among EU Member States, as referred to in point 3.3.1 – “Environmental Impact” and taking into account that there are no proper guidelines on their implementation, the EU MS could advocate for the harmonisation of pharmaceutical take-back systems and promote an ideal and universal collection scheme.

In a regulatory perspective, it would also be beneficial to control excessive purchasing pharmacies, especially in countries where medicine is available for free or at very low cost for some population groups. Additionally, it could be interesting to compensate people for medicine returns, as a form of incentive for citizens to return unused medicines.

8. Pharmacist Intervention in Minimising Medicine Waste

Pharmacists are highly qualified health professionals that act at multiple levels and contribute to achieve positive health outcomes. Community Pharmacists are in a privileged position to play an important role in avoiding and reducing medicine waste.⁸⁴

It is clear, when reviewing the causes and types of pharmaceutical waste, that prescribers, dispensers, and patients all participate, directly and indirectly, in waste creation. Community Pharmacists should actively promote the rational use of medicines, educating consumers on their correct and proper consumption, while guaranteeing that the correct medicine is taken by the right patient, at the right time, in the right dosage and form.

Pharmacists are key players in educating patients regarding self-medication, clarifying any doubts that may exist and in guiding customers to seek a physician before taking any medication on their own.¹⁰⁰ Enhancing adherence to medicines has the potential to reduce medication wastage, as well as improving individual and collective health.²² Furthermore, pharmacists should educate patients on how to organise their home medicine cabinet to avoid household accidents and excessive accumulation of unused medicines.¹⁰¹

It is also essential that certain services, such as medication revision and reconciliation, are increasingly promoted. Medication revision allows the identification and resolution of issues related to therapy adherence, dosing, unintentional duplications, adverse reactions, drug interactions, and incorrect dosage, among others. In 2021, with the aim of supporting pharmacists in providing safer care and the implementation of medicine use reviews, the FIP launched a toolkit for pharmacists regarding medicines reconciliation, which can be used to guide pharmacists through these services.¹⁰² As a result, by providing the patient with assistance in the management of their therapeutic regimens, pharmacists can significantly mitigate medication errors and increase compliance with prescribed therapies, which results, therefore, in medicine waste reduction.¹⁰³

Furthermore, immediate actions should be taken to educate consumers on the appropriate disposal of unused and/or expired pharmaceuticals. In order to correctly educate citizens, pharmacists must primarily be well-informed themselves. Familiarity with take-back systems, which products can be returned and the consequences of improper discharge, is imperative to enhance the patient's willingness to use an appropriate method of disposal.¹⁰⁴ Pharmacists should additionally be alert to the importance of not disposing of medicines in household waste bins or in sinks/bathrooms, in order to avoid polluting surface and groundwater.¹⁰¹

During counselling on new treatments, pharmacists can also instruct patients on how to properly dispose of unused medications.

On the other hand, community pharmacists can actively be involved in both community and school awareness campaigns and advocate for high standards in pharmaceutical waste disposal.

Lastly, the pharmaceutical profession should actively engage in policy making strategies to minimise medicine wastage, which makes it critically important that pharmacists be involve with national policymakers and in the strategic planning for health care.

9. Conclusion

Pharmaceutical waste has become an undeniable reality within Portuguese society, posing as a considerable environmental, health, and economic risk. Despite the existence of a collection programme that ensures the correct disposal of returned packages, pharmaceutical waste is still a pressing issue. In response to this concern, a preliminary study was performed in three pharmacies in Portugal. The aim was to categorize and assess medicine waste and evaluate the perception citizens had of the collection programme Valormed.

Our study concluded that the overall pharmaceutical waste rate was 64.8%, and that the highest percentage of waste belonged to medicines prescribed for the cardiovascular and nervous systems. In addition, antibiotics also presented a high wastage rate, which is especially alarming in light of global concerns regarding bacterial resistance.

When analysing citizens' perception of Valormed, we were able to conclude that it is urgent to increase awareness regarding correct disposal practises. According to the results, pharmacists are regarded as an important source of information and may contribute to increase the proper disposal of unwanted medicines.

While this is a preliminary study on medicine wastage in Portugal, it provides valuable insights that highlight the urgency of addressing this emerging issue. Further research is necessary, and it is crucial to engage in proactive and effective measures. These measures should not only focus on waste reduction, but also on preventing improper disposal. Potential actions could include awareness campaigns in schools, advocating for the resizing of medicine packaging and implementing a unit dose system in community pharmacies.

Ultimately, it is equally crucial for policymakers and healthcare professionals to take broader actions aimed at raising awareness and instigating a cultural change regarding medicine disposal.

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– UTENTE –

No âmbito da conclusão do Mestrado Integrado em Ciências Farmacêuticas na Faculdade de Farmácia da Universidade de Coimbra, com vista à elaboração de uma monografia cujo mote é *Medicine Wastage in Portugal*, surge a necessidade de elaborar um estudo em pequena escala, junto de Farmácias Comunitárias aderentes à Valormed. O estudo tem como objetivo principal caracterizar e quantificar o desperdício de medicamentos em Portugal, identificar as suas causas e provar o valor do Farmacêutico enquanto agente promotor da redução do Desperdício de Medicamentos.

Não serão recolhidos dados pessoais nem registados dados de natureza racial ou étnica, sobre crenças religiosas ou orientação sexual.

1. Sexo:

- Feminino
 - Masculino
 - Outro:
-

2. Idade:

- Até 18 anos
- 19 a 24 anos
- 25 a 34 anos
- 35 a 44 anos
- 45 a 54 anos
- 55 a 64 anos
- 65 ou mais.

3. Grau de Escolaridade:

- Ensino básico 1º ciclo (atual 4º ano/antiga instrução primária/4ª classe)
- Ensino básico 2º ciclo (atual 6º ano/antigo ciclo preparatório)
- Ensino básico 3º ciclo (atual 9º ano / antigo 5º liceal)
- Ensino secundário (atual 12º ano/ antigo 7º liceal /ano propedêutico)
- Ensino Superior

4. Nº medicamentos usualmente tomados por dia:

- 0
- 1-2
- 3-4
- +5
- +10

5. Como soube que podia entregar os medicamentos no Valormed?

- Através do Farmacêutico
 - Campanhas do Valormed
 - Publicidade
 - Outra:
-

6. Acha que na Valormed só se podem entregar medicamentos sólidos?

- Sim
- Não
- Não sei

7. Como descarta os medicamentos líquidos? (ex: despeja na sanita, lava-louça...)

8. Razão para a entrega dos medicamentos:

- Validade expirada
 - Nova prescrição médica para substituir a antiga terapia
 - Resolução da situação inicial que levou à toma do medicamento
 - Não adesão intencional (ex: efeito adverso/crenças)
 - Erro de prescrição anterior
 - Falecimento do paciente
 - Outra: _____
-

Assinatura do Utente:

– FARMACÊUTICO / ESTAGIÁRIO –

1. N° Total de embalagens entregues: _____

2. Forma Farmacêutica dos produtos entregues:

- ____ Sólido (comprimidos, cápsulas, drágeas, pastilhas e supositórios)
- ____ Semi-sólido (pomadas, géis e cremes)
- ____ Líquido (xaropes, gotas, soluções nasais, oftálmicas)

3. Medicamentos Entregues:

Classe Farmacoterapêutica	Nº Caixas Entregues	Nº total tomas desperdiçadas
Agentes antiparatiroideios (calcitonina)		
Analgésicos		
Anestésicos		
Ansiolíticos		
Antiácidos		
Antianémicos (ex: ferro, vitamina B12 e ácido fólico)		
Antiarrítmicos		
Antiasmáticos e broncodilatadores		
Antibacterianos (Antibióticos)		
Antidepressivos		
Antidiabéticos		
Antidiarreicos		
Antidislipidémicos		
Antiepilepticos e anticonvulsivantes		
Anti-Hemorrágicos		
Antihipertensores		
Anti-Histamínicos de uso sistémico		
Antiinflamatórios e antirreumáticos		
Antimicoticos, Antimicobacterianos e Antivirais de uso sistémico		
Antiparkinsonicos		
Antipsicóticos		
Antitrombóticos		
Antitússicos e expectorantes		
Anti-vômito e anti-nauseas		

Beta-Bloqueadores		
Bloqueadores dos canais de Cálcio		
Corticosteróides de uso sistémico		
Diuréticos		
Estimulantes Cardíacos		
Fármacos para as demências		
Fármacos para obstipação		
Glicosídeos Cardiotónicos		
Hipnóticos e sedativos		
Hormonas e análogos da paratiróide		
Hormonas da tiroide e antitiroideus		
Hormonas e análogos do eixo hipotálamo-pituitária		
Hormonas Pancreáticas		
Hormonas sexuais e moduladores do sistema reprodutor		
IECAs/ARAs		
Imunoestimulantes		
Imunossupressores		
Preparações nasais		
Produtos oftálmicos		
Produtos para aplicação no ouvido		
Produtos tópicos para as articulações e dores musculares		
Relaxantes musculares		
Terapia da bélis e fígado		
Vasodilatadores Periféricos		
Vasodilatadores utilizados em patologias cardíacas		

Appendix 3 – ATC classification for the study

ATC First Level		ATC Second Level	ATC Third Level	ATC Code
A	Alimentary tract and metabolism	Drugs for acid related disorders	Antiacids	A02A
			Drugs for peptic ulcer and gastro-esophageal reflux disease (gord)	A02B
		Antiemetics and antinauseants		A04
		Bile and liver therapy		A05
		Drugs for constipation		A06
		Antidiarrheals, intestinal antiinflammatory/antiinfective agents		A07
		Drugs used in diabetes		A010
B	Blood and blood forming organs	Antithrombotic agents		B01
		Antihemorrhagics		B02
		Antianemic preparations (iron preparations; vitamin b12 and folic acid)		B03
C	Cardiovascular system	Cardiac Therapy	Cardiac glycosides	C01A
			Antiarrhythmics, class i and iii	C01B
			Cardiac stimulants excl. Cardiac glycosides	C01C
			Vasodilators used in cardiac diseases	C01D
		Antihypertensives		C02
		Diuretics		C03
		Peripheral vasodilators		C04
		Beta blocking agents		C07
		Calcium channel blockers		C08
		Agents acting on the renin-angiotensin system		C09
		Lipid modifying agents		C10
G	Sex hormones and modulators of the genital system			G03
H	Hystemic hormonal preparations, excl. Sex hormones and insulins	Pituitary and hypothalamic hormones and analogues		H01
		Corticosteroids for systemic use		H02
		Thyroid therapy		H03
		Pancreatic hormones		H04
		Calcium homeostasis	Parathyroid hormones and analogues	H05A
			Anti-parathyroid agents	H05B
J	Antiinfectives for systemic use	Antibacterials		J01
		Antimycotics, Antimycobacterials; Antivirals for systemic use		J02, J04, J05

L	Antineoplastic and immunomodulating agents	Immunostimulants	I03	
		Immunosuppressants	I04	
M	Musculo-skeletal system	Antiinflammatory and antirheumatic products	M01	
		Topical products for joint and muscular pain	M02	
		Muscle relaxants	M03	
		Drugs for treatment of bone diseases (ex: bisphosphonates)	M05	
N	Nervous system	Anesthetics	N01	
		Analgesics	N02	
		Antiepileptics	N03	
		Anti-parkinson drugs	N04	
		Psycholeptics	Antipsychotics	N05A
			Anxiolytics	N05B
			Hypnotics and sedatives	N05C
		N06 Psychoanaleptics	Antidepressants	N06A
			Anti-dementia drugs	N06D
R	Respiratory system	Nasal preparations	R01	
		Drugs for obstructive airway diseases	R03	
		Cough and cold preparations (cough suppressants and expectorants)	R05	
		Antihistamines for systemic use	R06	
S	Sensory organs	Ophthalmologicals	S01	
		Otologicals	S02	