## ABBOZZ TA' LIĠI
## msejjaħ

*ATT biex jirregola t-teħid u l-eżami ta' demm uman u komponenti tad-demm u biex jistabbilixxi livelli ta' kwalità u sigurezza għat-tessut u ċelloli umani intiżi għat-trapjanti fil-bniedem.*

IL-PRESIDENT, bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqgħa f dan il-Parlament, u bl-awtorità ta' l-istess, ħareġ b'liġi dan li ġej:-

**1.** (1) It-titolu ta' dan l-Att hu Att ta' l-2006 dwar id-Demm Uman u t-Trapjanti. Titolu u bidu fis-seħħ.

(2) Dan l-Att għandu jibda jseħħ f'dik id-data li l-Ministru responsabbli għas-saħħa jista' b'avviż fil-Gazzetta jistabbilixxi, u jistgħu jiġu hekk stabbiliti dati differenti għal disposizzjonijiet differenti u għal għanijiet differenti ta' l-Att.

TAQSIMA I

PRELIMINARI

**2.** F'dan l-Att, kemm-il darba r-rabta tal-kliem ma tkunx teħtieġ xort'oħra – Tifsir.

"applikazzjoni umana" tfisser l-użu ta' tessut jew ċelloli fuq riċevitur uman, jew ġewwa fih, kif ukoll applikazzjonijiet barra mill-ġisem;

"l-Awtorità dwar il-Liċenzi" tfisser is-Superintendent tas-Saħħa Pubblika kif stabbilit fl-artikolu 3 (1) ta' dan l-Att;

"l-Awtorità dwar il-Mediċina" tfisser l-Awtorità dwar il-Liċenzi stabbilit taħt l-Att dwar il-Mediċini;

Kap. 458.

"bank tad-demm fi sptar" tfisser sezzjoni fi sptar li taħżen u tiddistribwixxi u tista' tagħmel eżamijiet ta' kompatibilità fuq demm u komponenti tad-demm esklużivament għall-użu fil-faċilitajiet li jkunu jinsabu fi sptar, inklużi attivitajiet ta' trasfużjoni li jsiru fl-isptarijiet;

"ċelloli" tfisser ċelloli umani individwali jew kollezzjoni ta' ċelloli umani meta dawn ma jkunux mgħaqqdin flimkien b'xi għamla ta' tessut li jikkonnetti;

"demm" tfisser demm komplut li jittieħed minn donatur u li jiġi proċessat jew għat-trasfużjoni jew għal manufattura ulterjuri;

"Direttiva 2004/23/KE" tfisser id-Direttiva 2004/23/KE tal-Parlament Ewropew u tal-Kunsill tal-31 ta' Marzu, 2004 fuq l-għemil ta' livelli dwar il-kwalità u s-sigurezza għad-donazzjoni, ksib, ittestjar, ipproċessar, preservazzjoni, ħżin u distribuzzjoni ta' tessut u ċelloli uman;

"Direttiva 2004/33/KE" tfisser id-Direttiva 2004/33/KE tat-22 ta' Marzu, 2004 li timplimenta d-Direttiva 2002/98/KE tal-Parlament Ewropew u tal-Kunsill dwar ċerti ħtiġiet tekniċi dwar id-demm u komponenti tad-demm;

"distribuzzjoni" tfisser fil-każ ta' demm u komponenti tad-demm, l-att ta' kunsinna tad-demm u komponenti tad-demm lejn xi postijiet ta' depożitu tad-demm, banek tad-demm fi sptar u lil manufatturi ta' prodotti miksubin mid-demm u mill-plasma oħrajn. Dan ma jinkludix il-ħruġ tad-demm jew komponenti tad-demm għal trasfużjonijiet. Fil-każ ta' tessut u ċelloli umani "distribuzzjoni" tfisser il-ġarr u l-kunsinna ta' tessut jew ċelloli intiżi għall-applikazzjoni umana;

"donatur" tfisser kull materja umana, kemm ħaj kemm mejjet, mnejn jittieħdu ċelloli jew tessut umani;

"donazzjoni" tfisser l-għoti ta' tessut jew ċelloli umani intiżi għal applikazzjonijiet umani;

"emoviġilanza" tfisser ġabra ta' proċeduri ta' sorveljanza organizzata li jkollha x'taqsam ma' okkorrenzi gravi avversi jew mhux mistennija jew ma' reazzjonijiet f'donaturi jew riċevituri, u l-prosegwitu epidemjoloġiku ta' donaturi;

"ħżin" tfisser li prodott jinżamm taħt kundizzjonijiet adatti u kontrollati sakemm issir id-distribuzzjoni;

"ipproċessar" tfisser l-operazzjonijiet kollha involuti fil-preparazzjoni, manipulazzjoni, preservazzjoniu ppakkettjar ta' tessut jew ċelloli intiżi għal applikazzjonijiet umani;

"komponent tad-demm" tfisser kostitwenti terapewtiku tad-demm (ċelloli ħomor, ċelloli bojod, *platelets*, plasma) li jistgħu jiġu preparati b'diversi metodi;

"il-Kummissjoni" tfisser il-Kummissjoni Ewropea;

"kwarantina" tfisser l-istat ta' tessut jew ċelloli irkuprati, jew ta' tessut isolat fiżikament jew b'mezzi oħra effettivi, filwaqt li tiġi mistennija deċiżjoni dwar jekk dawn jiġux aċċettati jew rifjutati;

"okkorrenza gravi avversa " tfisser fil-każ tad-demm u komponenti tad-demm, kull ġrajja li mhux suppost tiġri assoċjata mal-kollezzjoni, eżami, ipproċessar, ħżin u distribuzzjoni tad-demm u ta' komponenti tad-demm li tista' twassal għall-mewt jew tkun ta' theddida għall-ħajja, li tinabilita jew tinkapaċita il-kundizzjonijiet għall-pazjenti jew li tirriżulta fi, jew itawwal, iż-żmien li jingħadda fl-isptar jew il-kundizzjoni tal-marda; u fil-każ ta' tessut u ċelloli tfisser kull ġrajja li mhux suppost tiġri assoċjata mal-prokurazzjoni, eżami, ipproċessar, ħżin u distribuzzjoni ta' tessut u ċelloli li jistgħu jwasslu għat-trasmissjoni ta' marda li tittieħed, għall-mewt jew kundizzjonijiet ta' theddida għall-ħajja, inabilità jew inkapaċità għall-pazjenti jew li tista' tirriżultai fi, jew itawwal, iż-żmien li jingħadda fl-isptar jew il-kundizzjoni tal-marda;

"organu" tfisser parti differenzjata u vitali tal-ġisem uman, iffurmat minn tessut differenti, li jmantni l-istruttura, vaskularizzazzjoni u kapaċità li għandu biex jiżviluppa funzjonijiet fiżjoloġiċi b'livell importanti ta' awtonomija;

"posponiment" tfisser is-sospensjoni ta' l-eliġibilità ta' individwu li jagħti d-demm jew komponenti tad-demm, sew jekk dik is-sospensjoni tkun waħda permanenti sew temporanja;

"post ta' depożitu" tinkludi post ta' depożitu tad-demm u post ta' depożitu ta' tessut u ċelloli;

"post ta' depożitu tad-demm" tfisser kull struttura jew korp li jkollu r-responsabbiltà għal kull aspett tat-teħid u l-eżami ta' demm uman jew ta' komponenti tad-demm, ikun x'ikun l-għan intiż tagħhom, u l-ipproċessar, ħżin u distribuzzjoni tagħhom meta dawn ikunu intiżi għat-trasfużjoni, iżda dan ma jinkludix bank tad-demm fi sptar;

"post ta' depożitu ta' tessut u ċelloli" tfisser bank tat-tessut jew sezzjoni ta' sptar jew xi korp ieġor fejn isiru attivitajiet ta' ipproċessar, preservazzjoni, ħżin jew distribuzzjoni ta' tessut u ċelloli umani. Dak il-post jista' jkun ukoll responsabbli għall-prokurazzjoni jew l-eżami ta' tessut u ċelloli;

"preservazzjoni" tfisser l-użu ta' aġenti kimiċi, tibdil fil-kundizzjonijiet ambjentali jew mezzi oħra matul l-ipproċessar sabiex jiġi prevjenut jew ritardat id-deterjorament bioloġiku jew fiżiku ta' ċelloli jew tessut;

"prodott tad-demm" tfisser kull prodott terapewtiku miksub mid-demm uman jew mill-plasma;

"professjonist kwalifikat tas-saħħa" tinkludi tabib, infermier u kull professjonist tas-saħħa li huma regolati bl-Att dwar il-Professjonijiet tas-Saħħa; Kap. 464.

"prokurazzjoni" tfisser proċess li bih jintgħamlu disponibbli tessut jew ċelloli;

"reazzjoni gravi avversa", fil-każ tad-demm u komponenti tad-demm, tfisser meta d-donatur jew il-pazjent jirrispondu b'mod mhux intiż f'dak li għandu x'jaqsam mat-teħid jew it-trasfużjoni tad-demm u komponenti tad-demm, liema mod hu wieħed fatali, ta' theddida għall-ħajja, inabilitanti, inkapaċitatanti, jew li jirriżulta fi, jew itawwal, iż-żmien li jingħadda fl-isptar jew il-kundizzjoni tal-marda; fil-każ ta' tessut u ċelloli, tfisser meta d-donatur jew ir-riċevitur jirrispondu b'mod mhux intiż, inkluża b'xi marda li tittieħed, f'dak li għandu x'jaqsam mal-prokurazzjoni jew l-applikazzjoni umana ta' tessut u ċelloli, liema mod hu wieħed fatali, ta' theddida għall-ħajja, inabilitanti, inkapaċitatanti, jew li jirriżulta

fi, jew itawwal, iż-żmien li jingħadda fl-isptar jew il-kundizzjoni tal-marda;

"rilaxx ta' komponent tad-demm" tfisser proċess li permezz tiegħu komponent tad-demm ikun jista' jiġi rilaxxat minn stat ta' kwarantina bl-użu ta' sistemi u proċeduri li jkunu jiżguraw li l-prodott finali ikun konformi ma' l-ispeċifikazzjoni tar-rilaxx;

"spezzjoni" tfisser kontroll formali u oġġettiva għall-identifikazzjoni ta' problemi skond livelli adottati biex tiġi evalwata konformità ma' dawn ir-regolamenti;

"tessut" tfisser il-partijiet kostitwenti kollha fil-ġisem tal-bniedem li huma iffurmati miċ-ċelloli;

"trasfużjoni awtologa" tfisser trasfużjoni fejn id-donatur u r-riċevitur ikun l-istess persuna u fejn jintużaw demm depożitat u komponenti tad-demm;

"użu alloġeniku" tfisser ċelloli jew tessut li jittieħdu minn fuq persuna sabiex jiġu applikati fuq persuna oħra;

"użu awtologu" tfisser ċelloli jew tessut li jittieħdu minn fuq persuna sabiex jiġu applikati fuq l-istess persuna.

## TAQSIMA II

## L-AWTORITÀ DWAR IL-LIĊENZI

Funzjonijiet ta' l-Awtorità dwar il-Liċenzi.

**3.** (1) Is-Superintendent tas-Saħħa Pubblika jkun l-Awtorità dwar il-Liċenzi għall-finijiet ta' dan l-Att.

(2) L-Awtorità dwar il-Liċenzi, hawn iżjed 'il quddiem imsemmija l-Awtorità dwar il-Liċenzi, għandu jkollha dawn il-funzjonijiet li ġejjin:

(a) tivverifika li l-postijiet ta' depożitu jkunu konformi mal-ħtiġiet stabbiliti taħt dan l-Att u regolamenti magħmulin taħtu;

(b) tindika lill-post ta' depożitu liema attivitajiet jistgħu jsiru fih;

(ċ) tistabbilixxi x'ikunu l-kundizzjonijiet li japplikaw għall-postijiet ta' depożitu;

(d) toħroġ, iġġedded, temenda, tibdel, tissospendi jew tirrevoka kull liċenza li tista' tenħtieġ b'dan l-Att jew taħtu;

(e) tagħmel spezzjonijiet ta' postijiet ta' depożitu u regolarment torganizza miżuri ta' kontroll f'dawk il-postijiet ta' depożitu li f'ebda każ ma jkunu inqas minn darba kull sentejn;

(f) tagħmel dawk l-ispezzjonijiet addizzjonali f'postijiet ta' depożitu skond ma tqis li jkun meħtieġ bil-għan li tiġi żgurata konformità mal-ħtiġiet ta' dan l-Att u regolamenti magħmulin taħtu;

(g) tispezzjona banek tad-demm fi sptar sabiex tiżgura li dawk il-banek u l-persuni responsabbli għat-tmexxija ta' dawk il-banek ikunu konformi mal-ħtiġiet ta' dan l-Att u regolamenti magħmulin taħtu;

(h) torganizza, fil-każ ta' xi okkorrenza gravi avversa jew ta' xi reazzjoni jew suspett ta' dan, spezzjonijiet u miżuri oħra ta' kontroll;

(i) tistabbilixxi linji direttivi li jirrigwardaw il-kundizzjonijiet ta' l-ispezzjonijiet u tal-miżuri ta' kontroll, u t-taħriġ u l-kwalifiki ta' l-uffiċjali involuti sabiex jintlaħaq livell ta' kompetenza u twettiq konsistenti;

(j) tistabbilixxi u żżomm reġistru li jkun aċċessibbli għall-pubbliku dwar postijiet ta' depożitu ta' tessut u ċelloli li jkunu jispeċifikaw l-attivitajiet li tkun inħarġitilhom liċenza dwarhom;

(k) tagħmel dak kollu li jista' jkun meħtieġ bil-għan li tiġi żgurata konformità mad-disposizzjonijiet kollha ta' dan l-Att jew regolamenti magħmulin taħtu.

(3) L-Awtorità dwar il-Liċenzi tista' b'regoli tiddelega xi jew kull funzjoni msemmija fis-subartikolu (2) ta' dan l-artikolu lill-Awtorità dwar il-Mediċina, jew lil kull awtorità jew istituzzjoni oħra li hija tqis kompetenti.

(4) L-Awtorità dwar il-Liċenzi għandha tiġbor dawk il-ħlasijiet li jistgħu jiġu ordnati għall-għanijiet ta' dan l-Att.

## TAQSIMA III

## POSTIJIET TAD-DEPOŻITU TAD-DEMM U BANEK TAD-DEMM FI SPTAR

Spezzjonijiet u miżuri ta' kontroll .

**4.** (1) L-ispezzjonijiet ta', u l-miżuri ta' kontroll fuq, postijiet ta' depożitu tad-demm u banek tad-demm fi sptarijiet għandhom isiru minn kull persuna li tkun awtorizzata kif imiss bil-miktub mill-Awtorità dwar il-Liċenzi u hija jkollha, meta turi dik l-awtorizzazzjoni, jedd li:

(a) tispezzjona f'kull ħin raġonevoli:

(i) kull fond li jappartjeni lil, jew jitmexxa minn, post ta' depożitu tad-demm jew persuna responsabbli għat-tmexxija ta' bank tad-demm fi sptar, jew fejn il-post ta' depożitu tad-demm jew persuna responsabbli għat-tmexxija ta' bank tad-demm fi sptar twettaq xi attività minn dawk imsemmija f'din it-Taqsima ta' dan l-Att;

(ii) kull fond ta' persuna li twettaq xi attività minn dawk imsemmija f'din it-Taqsima ta' dan l-Att għan-nom ta', u konformement ma' patt kuntrattwali ma', post ta' depożitu tad-demm jew persuna responsabbli għat-tmexxija ta' bank tad-demm fi sptar; u

(iii) fejn il-faċilitajiet għall-valutazzjoni u l-eżami tad-donatur ikunu fil-fond ta' xi persuna oħra li ma jkunx il-post ta' depożitu tad-demm jew bank tad-demm fi sptar, dawk il-faċilitajiet fil-fond ta' dik il-persuna;

(b) teħtieġ li jinġieb, u tispezzjona kull oġġett jew sustanza fil-fond;

(ċ) teħtieġ li jinġieb, u tispezzjona u tagħmel kopji ta', jew tieħu siltiet minn, kull ktieb, dokument, *data* jew reġistrazzjoni, jinżammu f'liema forma jinżammu fil-fond, jew kull *data* jew reġistrazzjoni fil-*computer* u li jistgħu jkunu aċċessibbli fuqu;

(d) tieħu pussess ta' kampjuni għall-eżami u analisi u kull oġġett, sustanza, ktieb, dokument, data jew reġistrazzjoni oħra, jinżammu f'liema forma jinżammu fil-fond, jew kull *data* jew reġistrazzjoni fil-*computer* u li jistgħu jkunu aċċessibbli fuqu;

(e) issaqsi mistoqsijiet lil kull persuna li hija ssib fil-fond u li jkollha tassew għaliex taħseb li din tkun tista' tagħtih informazzjoni rilevanti;

(f) teħtieġ lil kull persuna tipprovdilha dik l-assistenza li hija tista' tqis li tkun meħtieġa dwar kull ħaġa li taqa' fil-kontroll ta' dik il-persuna, jew li għar-rigward tagħha dik il-persuna jkollha xi responsabbiltajiet;

(g) teħtieġ, skond ma tqis li jkun neċessarju, lil kull persuna tipprovdilha dawk il-faċilitajiet li hija tista' tkun raġonevolment teħtieġ lil dik il-persuna tipprovdilha;

(h) twettaq kull attività li hija tista' tqis li tkun adatta għall-eżekuzzjoni kif imiss tad-dmirijiet u r-responsabbiltajiet tagħha kif provdut b'dan l-Att u regolamenti magħmulin taħtu.

Liċenzi għal postijiet ta' depożitu tad-demm.

**5.** (1) Ebda persuna ma tista' twettaq xi attività minn dawk elenkati fis-subartikolu (2) jekk mhux skond liċenza maħruġa taħt l-artikolu 3 ta' dan l-Att.

(2) L-attivitajiet imsemmija fis-subartikolu (1) ta' dan l-artikolu huma:

(a) it-teħid ta' komponenti ta' demm uman, ikun x'ikun l-iskop intiż għal dan; u

(b) l-eżami ta' komponenti ta' demm uman, ikun x'ikun l-iskop intiż dan; u

(ċ) il-preparazzjoni, ħżin u distribuzzjoni tagħhom meta dawn ikunu intiżi għat-trasfużjoni, kemm-il darba xi attività bħal dik ma ssirx f'post ta' depożitu tad-demm li jkollu liċenza għal dak l-iskop mill-Awtorità dwar il-Liċenzi.

(3) Ma tkun meħtieġa ebda liċenza –

(a) għall-ħżin u d-distribuzzjoni ta', u t-twettiq ta' eżamijiet ta' kompatibilità fuq, demm u komponenti tad-demm li jkunu esklużivament għall-użu ġewwa faċilitajiet li jkunu jinsabu fi sptar, inklużi attivitajiet ta' trasfużjoni meta dawk l-attivitajiet isiru minn bank tad-demm fi sptar; jew

(b) għal xi persuna li tkun qegħda twettaq xi attività minn dawk imsemmija fis-subartikolu (2) meta dik il-persuna twettaq dik l-attività għan-nom ta', u konformement ma', patt kuntrattwali –

(i) ma' post ta' depożitu tad-demm li jkollu liċenza taħt din it-Taqsima biex iwettaq l-attività involuta; jew

(ii) ma' persuna responsabbli għat-tmexxija ta' bank tad-demm fi sptar.

(4) L-applikazzjoni għall-għoti ta' liċenza għandha ssir lill-Awtorità dwar il-Liċenzi u magħha għandu jsir il-ħlas dovut.

(5) Fl-applikazzjoni għandu jkun hemm dik l-informazzjoni li tista' tiġi ordnata u din għandha tiġi ppreżentata fl-għamla u bil-mod hekk kif jista' permezz ta' regoli jiġi stabbilit mill-Awtorità dwar il-Liċenzi.

(6) Meta l-Awtorità dwar il-Liċenzi tirċievi applikazzjoni, din tista' –

(a) tikkonċedi jew tiċħad applikazzjoni;

(b) tikkonċedi dik il-liċenza għar-rigward ta' xi postijiet jew attivitajiet partikulari biss;

(ċ) tikkonċedi dik il-liċenza kif soġġetta għal xi kundizzjonijiet;

(d) tiċħad li tipproċessa l-applikazzjoni jekk dik l-applikazzjoni ma tkunx ġiet ippreżentata skond dan l-Att u regolamenti magħmulin taħtu;

(e) titlob lill-applikant jgħaddilha informazzjoni addizzjonali skond ma hija tista' teħtieġ.

(7) Meta l-Awtorità dwar il-Liċenzi toħroġ liċenza wara li ssirilha applikazzjoni, hija għandha tagħti avviż bil-miktub lill-post ta' depożitu tad-demm li permezz tiegħu tispeċifika -

(a) dawk l-attivitajiet li l-post ta' depożitu tad-demm jista' jiġġestixxi taħt dan l-Att u regolamenti magħmulin taħtu f'kull post li għar-rigward tiegħu tingħata liċenza; u

(b) il-kundizzjonijiet li japplikaw għall-ġestjoni ta' dawk l-attivitajiet.

(8) L-Awtorità dwar il-Liċenzi tista' f'kull waqt tneħħi jew tibdel xi kundizzjoni tal-liċenza, jew tista' timponi kundizzjonijiet addizzjonali.

(9) Meta l-Awtorità dwar il-Liċenzi tneħħi jew tibdel xi kundizzjoni jew timponi xi kundizzjoni addizzjonali, l-Awtorità dwar

il-Liċenzi għandha tinforma bil-miktub lill-post ta' depożitu tad-demm involut u tagħti r-raġunijiet għal dik id-deċiżjoni tagħha.

(10) Post ta' depożitu tad-demm ma jista' jagħmel ebda bidla sostanzjali fl-attivitajiet li jiġġestixxi mingħajr ma jkollu l-approvazzjoni bil-miktub ta' l-Awtorità dwar il-Liċenzi mogħtija bil-quddiem.

(11) Kull applikazzjoni għall-approvazzjoni biex issir bidla sostanzjali fl-attivitajiet tagħha għandha ssir lill-Awtorità dwar il-Liċenzi bil-miktub, u magħha għandu jsir il-ħlas dovut.

(12) Għall-għanijiet ta' dan l-artikolu, hija bidla sostanzjali fl-attivitajiet li jsiru f'post ta' depożitu tad-demm, meta din tkun bidla -

(a) fil-fond minn fejn il-post ta' depożitu tad-demm ikun jopera jew fl-attivitajiet li għandhom jiġu ġestiti f'kull fond;

(b) li tirriżulta f'kontravenzjoni ta' dan l-Att jew regolamenti magħmulin taħtu jew ta' xi kundizzjoni speċifikata mill-Awtorità dwar il-Liċenzi; jew

(ċ) fis-sistema tal-kwalità li x'aktarx ikollha impatt sostanzjali fuq l-imġieba, jew li tista' tikkomprommetti s-sigurezza, ta' xi waħda mill-attivitajiet li dwarha post ta' depożitu tad-demm ikun ingħata liċenza li jiġġestixxi.

Revoka jew sospensjoni ta' liċenza.

**6.** (1) L-Awtorità dwar il-Liċenzi tista' tissospendi jew tirrevoka l-liċenza ta' post ta' depożitu tad-demm għal xi waħda jew aktar minn dawn ir-raġunijiet li ġejjin -

(a) meta l-post ta' depożitu tad-demm ikun naqas, f'xi fatt materjali, milli jkun konformi mal-ħtiġiet ta' dan l-Att jew regolamenti magħmulin taħtu;

(b) meta l-kollezzjoni, eżami, ipproċessar, ħżin jew distribuzzjoni tad-demm jew komponenti tad-demm li jsiru mill-post ta' depożitu tad-demm ma jkunux jistgħu jitwettqu b'mod sigur;

(ċ) meta ma jkunux jistgħu jiġu fornuti demm jew komponenti tad-demm lill-banek tad-demm fi sptar f'tali stat li dawn ikunu jistgħu jiġu amministrati b'mod sigur għat-trasfużjoni; jew

(d) meta l-informazzjoni mogħtija mill-post ta' depożitu tad-demm kienet qarrieqa jew mhux kompluta f'xi fatt materjali.

(2) Qabel ma tiġi sospiża jew revokata l-liċenza ta' post ta' depożitu tad-demm, l-Awtorità dwar il-Liċenzi għandha tinnotifika lill-post ta' depożitu tad-demm b'avviż li jkun jiddikjara li hija bu ħsiebha tissospendi jew tirrevoka l-liċenza tagħha b'seħħ mid-data speċifikata fl-avviż, fejn jingħataw raġunijiet għal deċiżjoni bħal dik:

Iżda s-sospensjoni jew ir-revoka għandhom jibdew iseħħu minnufih malli l-Awtorità dwar il-Liċenzi tqis li xi waħda jew l-oħra tkun meħtieġa minħabba fis-sigurtà.

(3) F'dawk il-każijiet fejn -

(a) il-post ta' depożitu tad-demm ikun naqas, f'xi fatt materjali, milli jkun konformi mal-ħtiġiet ta' dan l-Att jew regolamenti magħmulin taħtu; jew

(b) l-informazzjoni mogħtija mill-post ta' depożitu tad-demm kienet qarrieqa jew mhux kompluta f'xi fatt materjali,

u l-Awtorità dwar il-Liċenzi tqis li n-nuqqas involut ma jkunx wieħed gravi biżżejjed li fl-ewwel lok ikun jeħtieġ sospensjoni jew revoka tal-liċenza tal-post ta' depożitu tad-demm, l-Awtorità dwar il-Liċenzi tista' tinnotifika avviż fuq il-persuna responsabbli tal-post ta' depożitu tad-demm li bih:

(i) tidentifika l-ħtiġiet li l-post ta' depożitu tad-demm ma jkunx qiegħed josserva jew, fil-każ ta' informazzjoni qarrieqa u mhux kompluta, dik l-informazzjoni ulterjuri li tkun meħtieġa;

(ii) tidentifika l-azzjoni li l-post ta' depożitu tad-demm ikun meħtieġ li jieħu; u

(iii) tagħti ż-żmien li fih il-post ta' depożitu tad-demm għandu jieħu dik l-azzjoni identifikata fis-subparagrafu preċedenti.

(4) Jekk il-post ta' depożitu tad-demm jonqos milli jkun konformi mal-ħtiġiet stabbiliti fl-avviż fiż-żmien speċifikat, l-Awtorità dwar il-Liċenzi tista', b'avviż li jiġi notifikat lill-post ta' depożitu tad-demm, tissospendi jew tirrevoka l-liċenza tal-post ta' depożitu tad-demm.

(5) Kull sospensjoni għandha tkun għal dak il-perjodu li l-Awtorità dwar il-Liċenzi tqis li jkun meħtieġ meta tqis xi jkunu r-raġunijiet tas-sospensjoni.

(6) Is-sospensjoni jew ir-revoka ta' liċenza jistgħu jkunu għal kollox, jew limitati għal xi attività partikulari jew għal xi attività waħda jew aktar attivitajiet ġestiti f'xi post jew fond partikulari, jew għal xi komponent tad-demm partikulari.

Avviż li jiġi notifikat lil banek tad-demm fi sptar.

**7.** (1) Jekk l-Awtorità dwar il-Liċenzi tkun tal-fehma li -

(a) l-persuna responsabbli għat-tmexxija ta' bank tad-demm fi sptar tkun naqset, f'xi fatt materjali, tkun konformi mal-ħtiġiet ta' din it-Taqsima; jew

(b) l-eżami, il-ħżin jew id-distribuzzjoni tad-demm jew komponenti tad-demm mill-bank tad-demm fi sptar ikun tali li ebda demm jew komponenti tad-demm ma jkun jista' jiġi amministrat għat-trasfużjoni b'mod sigur; jew

(ċ) l-informazzjoni mogħtija mill-persuna responsabbli għat-tmexxija ta' bank tad-demm fi sptar kienet qarrieqa jew mhux kompluta f'xi fatt materjali,

l-Awtorità dwar il-Liċenzi tista' tinnotifika l-avviż lill-persuna responsabbli għat-tmexxija tal-bank fl-isptar fejn teħtieġ li l-isptar itemm milli jiġġestixxi l-attivitajiet speċifikati fl-avviż, jew li ma tibqa tamministra lill-pazjenti ebda demm jew komponenti tad-demm speċifikati fl-avviż, sakemm tintlaħaq konformità mal-kundizzjonijiet stabbiliti fl-avviż.

(2) Kull avviż li jiġi notifikat mill-Awtorità dwar il-Liċenzi konformement mas-subartikolu (1) għandu jispeċifika d-data minn meta għandha tibda ssehħ il-projbizzjoni speċifikata fl-avviż, liema perjodu ma għandux ikun ta' anqas minn sebat ijiem mid-data meta jiġi notifikat l-avviż:

Iżda meta l-Awtorità dwar il-Liċenzi tqis li dan ikun meħtieġ fl-interess tas-sigurtà, hija tista' tispeċifika fl-avviż li l-projbizzjoni għandha tibda ssehħ minnufih.

(3) L-avviż jiġi rtirat jekk:

(a) il-persuna responsabbli għat-tmexxija tal-bank tad-demm fi sptar ma tkunx għadha qegħda tikser il-ħtiġiet ta' dan l-artikolu;

(b) il-bank tad-demm fi sptar ikun jista' juri li l-attività jew il-prodott imsemmija fl-avviż mogħti konformement mas-

subartikolu (1)(b) jkunu jistgħu jiġu mwettqa, jew skond il-każ amministrati, b'sigurtà; jew

(ċ) tkun ingħatat kull informazzjoni meħtieġa lill-Awtorità dwar il-Liċenzi.

Validità tal-liċenza.

**8.** (1) Kull liċenza mogħtija taħt dan l-Att għandha, kemm-il darba din ma tkunx ġiet qabel revokata jew imġedda, tiskadi malli tintemm il-validità tagħha.

(2) Kull liċenza għandha tiġġedded, kemm-il darba din ma tkunx ġiet qabel revokata, meta ssir applikazzjoni mid-detentur mill-inqas tliet xhur qabel ma jiskadi l-perjodu ta' validità tagħha.

Importazzjoni.

**9.** Ħadd ma jista' jimporta ġewwa Malta xi demm jew komponenti tad-demm, inklużi demm jew komponenti tad-demm intiżi għall-użu bħala materjal inizjali jew materjal grezz fil-manufattura ta' prodotti mediċinali, minn xi pajjiż jew territorju li ma jinsabx fil-Komunità Ewropea jekk dan ma jkunx konformi mal-livelli ta' kwalità u sigurezza ekwivalenti għal dawk stipulati fl-Anness V tad-Direttiva 2004/33/KE u l-emendi kollha li saru fiha.

Sitwazzjonijiet epidemjoloġiċi speċifiċi.

**10.** (1) Meta l-Awtorità dwar il-Liċenzi tkun mgħarrfa b'xi sitwazzjoni epidemjoloġika speċifika, bħal meta tfaqqa' xi marda, li tista' tolqot is-sigurezza tad-donazzjonijiet tad-demm, u għaldaqstant tikkundisra li għandhom jiġu adottati kriterji speċifiċi ta' posponiment fit-teħid tad-donazzjonijiet tad-demm, hija għandha tavża:

(a) lill-postijiet ta' depożitu tad-demm li għandhom jiġu adottati dawk il-kriterji; u

(b) lill-Kummissjoni bis-sitwazzjoni epidemjoloġika u bil-kriterji ta' posponiment addizzjonali li l-postijiet ta' depożitu tad-demm ikunu meħtieġa jadottaw għar-rigward ta' dan konformement mal-paragrafu (a) ta' dan is-subartikolu.

(2) Post ta' depożitu tad-demm għandu jadotta u jkun konformi ma' kull kriterju ta' eżamijiet addizzjonali li jiġi notifikat lilhom mill-Awtorità dwar il-Liċenzi konformement mas-subartikolu (1) ta' dan l-artikolu.

TAQSIMA IV

POSTIJIET TA' DEPOŻITU TA' TESSUT U ĊELLOLI

Spezzjoni u miżuri ta' kontroll .

**11.** (1) L-ispezzjonijiet ta', u miżuri ta' kontroll fuq, postijiet ta' depożitu ta' tessut u ċelloli għandhom isiru minn persuna li tkun awtorizzata kif imiss bil-miktub mill-Awtorità dwar il-Liċenzi u wara li turi l-awtorizzazzjoni tagħha, dik il-persuna għandu jkollha l-jedd illi:

(a) tispezzjona f'kull ħin raġonevoli:

(i) kull fond li jkun jappartjeni lil jew qiegħed jiġi mmexxi minn post ta' depożitu ta' tessut, jew li fih il-post ta' depożitu ta' tessut u ċelloli ikun qiegħed jiġġestixxi xi attivitajiet għar-rigward tal-prokurazzjoni ta' tessut umani u ċelloli;

(ii) kull fond ta' persuna li twettaq xi attività minn dawk imsemmija hawn qabel għan-nom ta', u konformement ma', patt kuntrattwali ma' post ta' depożitu ta' tessut u ċelloli; u

(iii) fejn il-faċilitajiet għall-valutazzjoni u l-eżami ta' donatur ikunu fil-fond ta' xi persuna li ma jkunx post ta' depożitu ta' tessut u ċelloli, dawk il-faċilitajiet li jkunu jinsabu fil-fond ta' dik il-persuna;

(b) teħtieġ li jinġieb u li hija tispezzjona kull oġġett jew sustanza fil-fond;

(ċ) teħtieġ li jinġieb, u tispezzjona u tagħmel kopji, jew tieħu siltiet minn, kull ktieb, dokument, *data* jew reġistrazzjoni, tkun liema forma tkun li din tinżamm ġewwa l-fond, jew kull *data* jew reġistrazzjoni ta' *computer* li tkun aċċessibbli f'dak il-fond;

(d) li tieħu pussess ta' kampjuni għal eżami u analisi u kull oġġett, sustanza, ktieb, dokument, *data* u reġistrazzjoni oħra, jinżammu kif jinżammu fil-fond, jew kull *data* jew reġistrazzjoni ta' *computer* li tkun aċċessibbli f'dak il-fond;

(e) tagħmel mistoqsijiet lil kull persuna li tkun tinsab fil-fond u li jkollha tassew għaliex tifhem li dik il-persuna tista' tipprovdilha informazzjoni rilevanti;

(f) teħtieġ li persuna tagħtiha dik l-assistenza li hija tqis li tkun meħtieġa dwar kull ħaġa li tkun tinsab fil-kontroll ta' dik il-

persuna, jew li għar-rigward tagħha dik il-persuna jkollha r-responsabbiltajiet tagħha;

(ġ) teħtieġ, skond ma tqis li jkun meħtieġ, lil kull persuna tagħtiha dawk il-faċilitajiet li hija tista' raġonevolment teħtieġ lil dik il-persuna tagħtiha;

(ħ) tevalwa u tivverifika l-proċeduri u l-attivitajiet ġestiti f'post ta' depożitu ta' tessut u ċelloli u l-faċilitajiet li għandhom terzi u li huma rilevanti għall-ħtiġiet ta' dan l-Att u regolamenti magħmulin taħtu;

(i) tiġġestixxi kull attività li hija tista' tqis adatta għall-eżekuzzjoni kif imiss tad-dmirijiet u r-responsabbiltajiet tagħha skond ma hemm provdut f'dan l-Att u regolamenti magħmulin taħtu.

Superviżjoni u ħruġ ta' liċenzi.

**12.** (1) Ħadd ma jista' jiġġestixxi ebda attività li jkollha x'taqsam ma' l-eżami, ipproċessar, preservazzjoni, ħżin jew distribuzzjoni ta' tessut u ċelloli umani intiżi għal applikazzjonijiet umani ħlief skond liċenza maħruġa taħt l-artikolu 3 ta' dan l-Att.

(2) Ma tkun meħtieġa ebda liċenza –

(a) għall-ħżin u d-distribuzzjoni ta', u t-twettiq ta' eżamijiet ta' kompatibilità fuq, tessut u ċelloli li jkunu esklużivament għall-użu ġewwa faċilitajiet li jkunu jinsabu fi sptar; jew

(b) għal persuna li tkun qegħda tmexxi xi attività minn dawk imsemmija fis-subartikolu (1) ta' dan l-artikolu, meta dik il-persuna tkun qegħda tiġġestixxi dik l-attività għan-nom ta', u konformement ma' patt kuntrattwali ma' post ta' depożitu ta' tessut u ċelloli li jkollu liċenza taħt din it-Taqsima biex jiġġestixxi l-attività involuta;

(ċ) għad-distribuzzjoni diretta ta' tessut u ċelloli speċifikati għal trapjant immedjat fir-riċevitur sakemm il-provditur ikollu liċenza għal dik l-attività.

(3) L-applikazzjoni għall-għoti ta' liċenza għandha ssir lill-Awtorità dwar il-Liċenzi u magħha għandu jkun hemm il-ħlas dovut.

(4) L- applikazzjoni għandu jkollha dik l-informazzjoni li tista' tiġi ordnata li tingħata u għandha tiġi ppreżentata fl-għamla u bil-mod skond ma jista' jiġi stipulat b'regoli li jsiru mill-Awtorità dwar il-Liċenzi.

(5) Meta tiġi riċevuta applikazzjoni mill-Awtorità dwar il-Liċenzi, din tista' –

(a) tikkonċedi jew tiċħad l-applikazzjoni;

(b) tikkonċedi dik il-liċenza għar-rigward ta' postijiet jew attivitajiet partikulari biss;

(ċ) tikkonċedi dik il-liċenza bla ħsara għal kundizzjonijiet li timponi;

(d) tiċħad li tipproċessa l-applikazzjoni jekk dik l-applikazzjoni ma tkunx ġiet ippreżentata skond dan l-Att u regolamenti magħmulin taħtu;

(e) titlob lill-applikant jipprovdilha informazzjoni addizzjonali skond ma hija tqis li jkun meħtieġ.

(6) Meta l-Awtorità dwar il-Liċenzi tikkonċedi applikazzjoni for liċenza, hija għandha tinnotifika permezz ta' avviż bil-miktub lill-post ta' depożitu ta' tessut u ċelloli fejn tispeċifika xi jkunu -

(a) l-attivitajiet li l-post ta' depożitu jista' jiġġestixxi taħt dan l-Att u regolamenti magħmulin taħtu f'kull post li għar-rigward tiegħu tingħata liċenza;

(b) il-kundizzjonijiet li japplikaw għall-ġestjoni ta' dawk l-attivitajiet; u

(ċ) il-proċessi ta' preparazzjoni ta' tessut u ċelloli li l-post ta' depożitu jista' jiġġestixxi.

(7) L-Awtorità dwar il-Liċenzi tista' f'kull waqt tneħħi jew tibdel xi kundizzjoni tal-liċenza, jew tista' timponi kundizzjonijiet addizzjonali.

(8) Meta l-Awtorità dwar il-Liċenzi tneħħi jew tibdel xi kundizzjoni jew timponi kundizzjonijiet addizzjonali, hija għandha tinforma bil-miktub lill-post ta' depożitu involut filwaqt li tagħti r-raġunijiet għad-deċiżjoni tagħha.

(9) Post ta' depożitu ta' tessut u ċelloli ma jista' jagħmel ebda bidla sostanzjali fl-attivitajiet li jiġġestixxi mingħajr l-approvazzjoni bil-miktub li tingħata bil-quddiem mill-Awtorità dwar il-Liċenzi.

(10) Applikazzjoni għall-approvazzjoni biex issir bidla sostanzjali fl-attivitajiet ta' post ta' depożitu ta' tessut u ċelloli għandha ssir bil-miktub lill-Awtorità dwar il-Liċenzi, u magħha għandu jkun hemm il-ħlas dovut.

(11) Għall-finijiet ta' dan l-artikolu, bidla sostanzjali fl-attivitajiet ta' post ta' depożitu ta' tessut u ċelloli hija kull bidla -

(a) li ssir fil-postijiet minn fejn ikun jopera l-post ta' depożitu jew fl-attivitajiet li għandhom jiġu ġestiti f'kull post;

(b) li tirriżulta f'kontravenzjoni ta' dan l-Att jew regolamenti magħmulin taħtu jew ta' xi kundizzjoni speċifikata mill-Awtorità dwar il-Liċenzi; jew

(ċ) li ssir fis-sistema tal-kwalità u li x'aktarx ikollha impatt sostanzjali fuq l-imġieba ta', jew li tista' tikkomprommetti s-sigurezza ta' xi attività minn dawk li l-post ta' depożitu ikollu l-liċenza li jiġġestixxi.

(12) L-Awtorità dwar il-Liċenzi għandha tissospendi jew tirrevoka l-liċenza ta' post ta' depożitu ta' tessut jew ta' proċess ta' preparazzjoni ta' tessut jew ċelloli meta l-ispezzjonijiet jew il-miżuri ta' kontroll li jsiru jkunu juru li dak il-post ta' depożitu jew proċess ma jkunux konformi mal-ħtiġiet ta' dan l-Att u regolamenti magħmulin taħtu.

Revoka jew sospensjoni ta' liċenza.

**13.** (1) (a) L-Awtorità dwar il-Liċenzi tista' tissospendi jew tirrevoka l-liċenza ta' post ta' depożitu ta' tessut u ċelloli abbażi ta' xi raġuni waħda jew aktar minn dawn li ġejjin -

(i) li l-post ta' depożitu jkun naqas, f'xi fatt materjali, milli jkun konformi mal-ħtiġiet ta' dan l-Att jew regolamenti magħmulin taħtu;

(ii) li l-informazzjoni mogħtija mill-post ta' depożitu tad-demm kienet waħda qarrieqa jew mhux kompluta f'xi fatt materjali.

(b) B'żjieda ma' dan, l-Awtorità dwar il-Liċenzi għandha tissospendi jew tirrevoka l-liċenza ta' post ta' depożitu ta' tessut u ċelloli jew ta' proċess ta' preparazzjoni ta' tessut jew ċelloli meta l-ispezzjonijiet jew il-miżuri ta' kontroll ikunu juru li dak il-post ta' depożitu jew proċess ma jkunux konformi mal-ħtiġiet ta' dan l-Att u regolamenti magħmulin taħtu.

(2) Qabel ma tissospendi jew tirrevoka l-liċenza ta' post ta' depożitu tad-demm, l-Awtorità dwar il-Liċenzi għandha tinnotifika avviż lill-post ta' depożitu tad-demm fejn tiddikjara li tkun biħsiebha tissospendi jew tirrevoka l-liċenza ta' dak l-post b'seħħ mid-data speċifikata fl-avviż, filwaqt li tagħti r-raġunijiet għal dik id-deċiżjoni:

Iżda sospensjoni jew revoka bħal dik għandha tibda sseħħ minnufih malli l-Awtorità dwar il-Liċenzi tqis li dan ikun meħtieġ fl-interess tas-sigurtà.

(3) F'dawk il-każijiet meta -

(a) il-post ta' depożitu jkun naqas, f'xi fatt materjali, milli jkun konformi mal-ħtiġiet ta' dan l-Att jew regolamenti magħmulin taħtu; jew

(b) l-informazzjoni mogħtija mill-post ta' depożitu kienet waħda qarrieqa jew mhux kompluta f'xi fatt materjali, u l-Awtorità dwar il-Liċenzi tikkunsidra li n-nuqqas involut ma jkunx suffiċjentement gravi li fl-ewwel lok jeħtieġ is-sospensjoni jew ir-revoka tal-liċenza tal-post ta' depożitu, l-Awtorità dwar il-Liċenzi tista' tinnotifika avviż lill-persuna responsabbli għal dak il-post ta' depożitu fejn:

(i) tidentifika l-ħtiġiet li l-post ta' depożitu ikun qiegħed jikkontravjeni jew fil-każ ta' informazzjoni qarrieqa u mhux kompluta, dik l-informazzjoni ulterjuri li tkun meħtieġa;

(ii) tidentifika l-azzjoni li l-post ta' depożitu jkun meħtieġ li jieħu; u

(iii) tagħti l-perjodu li matulu l-post ta' depożitu tad-demm għandu jieħu l-azzjoni identifikata fis-subparagrafu (ii) ta' dan l-artikolu.

(4) Jekk il-post ta' depożitu jonqos milli jkun konformi mal-ħtiġiet stabbiliti fl-avviż fil-perjodu speċifikat, l-Awtorità dwar il-Liċenzi tista', b'avviż li jiġi notifikat lill-post ta' depożitu, tissospendi jew tirrevoka l-liċenza tal-post ta' depożitu.

(5) Kull sospensjoni għandha tkun għal dak il-perjodu li l-Awtorità dwar il-Liċenzi tikkunsidra li jkun meħtieġ meta tqis ir-raġunijiet għal dik is-sospensjoni.

(6) Is-sospensjoni jew ir-revoka ta' liċenza jista' jkun wieħed totali, jew limitat għal xi attività partikulari jew għal xi attività waħda jew aktar ġestita f'xi post jew postijiet partikulari, jew għal xi tessut u ċellola partikulari.

Validità ta' liċenza.

**14.** (1) Kull liċenza mogħtija taħt dan l-Att għandha, kemm-il darba ma tkunx ġiet revokata jew mġedda qabel, tiskadi fi tmiem il-perjodu ta' validità tagħha.

(2) Kull liċenza tista', kemm-il darba ma tkunx ġiet revokata qabel, tiġi mġedda wara li ssir applikazzjoni għaldaqstant mid-detentur mill-anqas tliet xhur qabel ma jiskadi l-perjodu ta' validità tagħha.

Importazzjoni jew esportazzjoni ta' tessut uman u ċelloli.

**15.** (1) Ħadd ma jista' jimporta tessut u ċelloli minn pajjiżi terzi kemm-il darba:

(a) attività bħal dik ma ssirx f'post ta' depożitu ta' tessut li jkollu liċenza;

(b) it-tessut u ċelloli importati ma jkunux jistgħu jiġu rintraċċati mingħand id-donatur u r-riċevitur u viċi-versa skond il-proċeduri stabbiliti b'regolamenti taħt dan l-Att;

(ċ) il-post ta' depożitu ta' tessut u ċelloli li jirċievi importazzjonijiet bħal dawk minn pajjiżi terzi ma jkunx jiżgura li dawn ikunu skond il-livelli ta' kwalità u sigurezza ekwivalenti għal dawk stipulati fid-Direttiva 2004/23/KE.

(2) Ħadd ma jista' jesporta tessut u ċelloli lejn pajjiżi terzi kemm-il darba:

(a) attività bħal dik ma ssirx minn xi post ta' depożitu ta' tessut u ċelloli li jkollu liċenza;

(b) dawk l-esportazzjonijiet lejn pajjiżi terzi ma jkunux jikkonformaw mal-ħtiġiet tad-Direttiva 2004/23KE.

(3) L-Awtorità dwar il-Liċenzi tista', wara li tiżgura ruħha li dawk l-importazzjonijiet u esportazzjonijiet ta' tessut u ċelloli msemmija fis-subartikolu (2) ta' dan l-artikolu jkunu konformi ma' livelli ta' kwalità u sigurezza ekwivalenti għal dawk stipulati fid-Direttiva 2004/23/KE, tawtorizza direttament:

(a) l-importazzjoni jew l-esportazzjoni ta' tessut u ċelloli msemmija fl-artikolu 12(2)(ċ);

(b) l-importazzjoni jew l-esportazzjoni ta' ċertu tessut u ċelloli f'każ ta' emerġenza.

## TAQSIMA V

## MIXXELLANJI

Setgha tal-Ministru li jagħmel regolamenti.

**16.** Il-Ministru jista', wara konsultazzjoni ma' l-Awtorità dwar il-Liċenzi, jipprovdi permezz ta' regolamenti dwar -

(a) il-ħtiġiet li għandhom jiġu sodisfatti minn postijiet ta' depożitu ta' demm u tessut;

(b) il-livelli ta' prattika tajba fil-manifattura;

(ċ) il-ħtiġiet li għandhom jiġu sodisfatti mill-banek tad-demm fi sptar;

(d) il-ħtiġiet biex tiġi stabbilita sistema effettivi ta' emoviġilanza;

(e) ordni biex isir ħlas għall-ħruġ ta' liċenza;

(f) kull ħaġ'oħra biex iġġib fis-seħħ kif imiss id-disposizzjonijiet ta' dan l-Att.

Reati u pieni.

**17.** Kull persuna li tonqos milli tkun konformi ma' xi disposizzjoni ta' dan l-Att jew ta' regolamenti jew regoli magħmulin taħtu tkun ħatja ta' reat u tista', meta tinsab ħatja, teħel multa ta' mhux iżjed minn ħamest elef lira.

Proċedura speċjali.

**18.** (1) Minkejja kull liġi oħra li tipprovdi dwar is-smigħ ta' kawżi dwar reati, meta l-Awtorità jkollha għaliex tassew taħseb li persuna tkun għamlet reat kontra dan l-Att jew regolamenti magħmulin taħtu, l-Awtorità dwar il-Liċenzi għandha tagħti avviż bil-miktub lil dik il-persuna fejn tgħid xi jkun ir-reat li dik il-persuna tkun qegħda tiġi akkużata bih, filwaqt li tindika l-passi li għandhom jittieħdu biex ikun jista' jiġi rimedjat ir-reat u l-penali li dik il-persuna stkun meħtieġa tħallas għar-rigward ta' dak ir-reat.

(2) Il-Ministru għandu jordna xi jkunu l-penali li jistgħu jintalbu mill-Awtorità dwar il-Liċenzi għar-rigward ta' xi reat speċifikat:

Iżda penali bħal dik m'għandhiex tkun ta' iżjed minn somma ta' ħamest elef lira.

(3) Meta jkun ngħata avviż taħt dan l-artikolu, il-persuna msemmija fl-avviż tista', fi żmien wieħed u għoxrin ġurnata minn notifika ta' l-avviż, taċċetta responsabbiltà għar-reat speċifikat fl-avviż u tħallas fl-istess perjodu il-piena indikata fl-avviż, filwaqt li tikkonforma ruħha mad-disposizzjoni relattiva ta' dan l-Att, jew tar-regolamenti jew regoli magħmulin taħtu u ma jkunu jistgħu jittieħdu ebda proċedimenti ulterjuri taħt dan l-Att għar-rigward ta' dak ir-reat.

(4) Meta l-persuna li tkun ġiet notifikata bl-avviż taħt is-subartikolu (1) ma tkunx ħallset il-penali fi żmien wieħed u għoxrin ġurnata kif imsemmi fis-subartikolu (3) u ma tkunx, fil-perjodu speċifikat, ikkonformat ruħha mal-ħtiġiet ta' dan l-Att, jistgħu jittieħdu proċedimenti kriminali kontriha skond d-disposizzjonijiet tal-Kodiċi Kriminali, ta' dan l-Att u ta' kull liġi oħra li tkun tapplika għal dak ir-reat.

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## Għanijiet u Raġunijiet

L-għan ta' dan l-Abbozz hu sabiex jittrasponi id-Direttivi 2002/98KE, 2004/33KE u 2004/23KE u aktar espliċitament jiżgura li dawk l-attivitajiet li jkollhom x'jaqsmu mat-teħid u l-eżami ta' demm uman u komponenti tad-demm, ikun xi jkun l-iskop intiż tagħhom, u mal-preparazzjoni, il-ħżin u d-distribuzzjoni tagħhom meta dawn ikunu intiżi għat-trasfużjoni, isiru biss minn postijiet ta' depożitu tad-demm f'Malta li jkunu ġew imsemmija, awtorizzati, akkreditati jew li jkollhom liċenza mill-Awtorità dwar il-Liċenzi għal dak l-iskop. Iktar minn hekk, l-Abbozz jistabbilixxi l-livelli ta' kwalità u ta' sigurezza għat-tessut u ċ-ċelloli umani intiżi għal applikazzjonijiet umani sabiex jiġi żgurat livell għoli ta' protezzjoni għas-saħħa tal-bniedem.

**A BILL**
**entitled**

*AN ACT to regulate the collection and testing of human blood and blood components and to establish standards of quality and safety for human tissues and cells intended for human transplants.*

Title and commencement.

**1.** (1) The title of this Act is the Human Blood and Transplants Act, 2006.

(2) This Act shall come into force on such date as the Minister responsible for health may by notice in the Gazette establish, and different dates may be so established for different provisions and for different purposes of this Act.

PART I

PRELIMINARY

Interpretation.

**2.** In this Act, unless the context otherwise requires –

"allogenic use" means cells or tissues removed from one person and applied to another;

"autologous transfusion" means transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used;

"autologous use" means cells or tissues removed from and applied in the same person;

"blood" means whole blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

"blood component release" means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

"blood establishment" means any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion, but does not include a hospital blood bank;

"blood product" means any therapeutic product derived from human blood or plasma;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue;

"the Commission" means the European Commission;

"deferral" means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary;

"Directive 2004/23/EC" means the Commission Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

"Directive 2004/33/EC" means the Commission Directive 2004/33/EC of 22 March, 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components;

"distribution" means in the case of blood and blood components, the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusions. In the case

of human tissues and cells "distribution" means transportation and delivery of tissues or cells intended for human application;

"donor" means every human source, whether living or deceased, of human cells or tissues;

"donation" means donating human tissues or cells intended for human applications;

"establishment" includes a blood establishment and a tissues and cells establishment;

"haemovigilance" means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

"hospital blood bank" means a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

"human application" means the use of tissues or cells on or in a human recipient and extracorporal applications;

"inspection" means formal and objective control to identify problems in accordance with standards adopted to assess compliance with these regulations;

"the Licensing Authority" means the Superintendent of Public Health as established in article 3 (1) of this Act;

"the Medicines Authority" means the Licensing Authority established under the Medicines Act; Cap. 458.

"organ" means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

"processing" means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

"procurement" means a process by which tissues or cells are made available;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

"quarantine" means the status of retrieved tissues or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

"serious adverse event" means in the case of blood and blood components, any untoward occurrence associated with the collection, testing, processing, storage, and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity; and in the case of tissues and cells means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" in the case of blood and blood components means an unintended response in donor or in patient associated with the collection or transfusion of blood and blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity; in the case of tissues and cells it means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

"storage" means maintaining the product under appropriate controlled conditions until distribution;

"tissue" means all constituent parts of the human body formed by cells;

"tissues and cells establishment" means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;

"qualified health professional" includes a doctor, nurse and any health professional regulated by the Health Care Professions Act. Cap. 464.

## PART II

## THE LICENSING AUTHORITY

Functions of the Licensing Authority.

**3.** (1) The Superintendent of Public Health shall be the Licensing Authority for the purposes of this Act.

(2) The Licensing Authority, hereinafter referred to as the Licensing Authority, shall have the following functions:

(a) to verify that the establishments are in compliance with the requirements set out under this Act and any regulations made thereunder;

(b) to indicate to the establishment which activities it may undertake;

(c) to establish conditions applicable to establishments;

(d) to issue, renew, amend, vary, suspend or revoke any licence that may be required by or under this Act;

(e) to carry out inspections of establishments and organize control measures in such establishments regularly and in any case not less than once every two years;

(f) to conduct such additional inspections of establishments as it considers necessary for the purpose of ensuring compliance with the requirements of this Act and any regulations made thereunder;

(g) to inspect hospital blood banks to ensure that such banks and persons responsible for the management of such banks comply with the requirements of this Act and any regulations made thereunder;

(h) to organize, in the event of any serious adverse event or reaction or suspicion thereof, inspections and other control measures;

(i) to establish guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance;

(j) to establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been licensed;

(k) to do all such things as may be necessary for the purpose of ensuring compliance with any of the provisions of this Act or regulations made thereunder.

(3) The Licensing Authority may by rules delegate any of the functions referred to in sub-article (2) hereof to the Medicines Authority, or any other authority or institution it deems competent.

(4) The Licensing Authority shall levy such fees as may be prescribed for the purpose of this Act.

## PART III

## BLOOD ESTABLISHMENTS AND HOSPITAL BLOOD BANKS

Inspections and control measures.

**4.** (1) The inspections and control measures of blood establishments and hospital blood banks shall be carried out by any person duly authorized in writing by the Licensing Authority and shall, on production of this authorization, have a right to:

(a) inspect at any reasonable hour:

(i) any premises owned or managed by a blood establishment or person responsible for management of a hospital blood bank, or at which the blood establishment or person responsible for management of a hospital blood bank carries out any of this Activities referred to in this Part of this Act;

(ii) any premises of any person who carries out any of this Activities referred to in this Part of this Act on behalf of, and pursuant to a contractual arrangement with, a blood establishment or a person responsible for management of a hospital blood bank; and

(iii) where any facilities for donor evaluation and testing are in the premises of any person other than a blood establishment or hospital blood bank, those facilities in that person's premises;

(b) to require the production of, and inspect any article or substance at the premises;

(c) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record, in whatever form held at the premises, or any computer data or records which are accessible thereat;

(d) to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record in whatever form held at the premises, or any computer data or records which are accessible thereat;

(e) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;

(f) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities;

(g) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him;

(h) carry out any activity he may deem appropriate for the proper execution of his duties and responsibilities as provided by this Act and any regulations made thereunder.

Licensing of blood establishments.

**5.** (1) It shall not be lawful for any person to carry out any activity listed in sub-article (2) other than in accordance with a licence issued under article 3 of this Act.

(2) The activities referred to in sub-article (1) hereof are:

(a) the collection of human blood components, whatever their intended purpose; and

(b) the testing of human blood components, whatever their intended purpose; and

(c) their preparation, storage and distribution when intended for transfusion, unless any such activity is undertaken in a blood establishment licensed for that purpose by the Licensing Authority.

(3) A licence shall not be required for –

(a) the storage and distribution of, and the performance of compatibility tests on, blood and blood components exclusively

for use within hospital facilities, including transfusion activities where such activities are performed by a hospital blood bank; or

(b) any person carrying out any of the activities referred to in sub-article (2) where that person carries out that activity on behalf of, and pursuant to, a contractual arrangement with –

(i) a blood establishment which is licenced under this Part to carry out the activity in question; or

(ii) a person responsible for the management of a hospital blood bank.

(4) The application for the grant of a licence shall be made to the Licensing Authority and shall be accompanied by the prescribed fee.

(5) The application shall contain the information as may be prescribed and shall be submitted in the form and in the manner as may by rules be laid down by the Licensing Authority.

(6) Where an application is received by the Licensing Authority, it may –

(a) grant or refuse any application;

(b) grant such licence in respect of particular sites or activities only;

(c) grant such licence subject to conditions;

(d) refuse to process the application if such application has not been submitted in accordance with this Act and regulations made thereunder;

(e) request the applicant to furnish it with additional information as it may deem necessary.

(7) When the Licensing Authority grants a licence following an application, it shall give notice in writing to the blood establishment specifying –

(a) the activities which the blood establishment may undertake under this Act and regulations made thereunder at each site in respect of which licence is granted; and

(b) the conditions which apply to the undertaking of those activities.

(8) The Licensing Authority may at any time remove or vary any of the licence conditions, or may impose additional conditions.

(9) When the Licensing Authority removes or varies any condition or imposes any additional condition the Licensing Authority shall inform in writing the blood establishment in question giving reasons for its decision.

(10) A blood establishment may not make any substantial change in the activities which it undertakes without the prior written approval of the Licensing Authority.

(11) Any application for approval to make a substantial change in its activities shall be made in writing to the Licensing Authority, and shall be accompanied by the prescribed fee.

(12) For the purpose of this article, a substantial change in a blood establishment's activities is any change -

(a) to the sites from which the blood establishment operates or to the activities to be carried out at each site;

(b) which would result in breach of this Act or regulations made thereunder or of any condition specified by the Licensing Authority; or

(c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of those activities which the blood establishment has been licensed to undertake.

Revocation or suspension of licence.

**6.** (1) The Licensing Authority may suspend or revoke the licence of a blood establishment on one or more of the following grounds -

(a) that the blood establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder;

(b) that the collection, testing, processing, storage or distribution of blood or blood components by the blood establishment cannot be carried out safely;

(c) that any blood or blood components cannot be supplied to hospital blood banks in such a state that they could be safely administered for transfusion; or

(d) that the information given by the blood establishment was false or incomplete in any material respect.

(2) Prior to suspending or revoking the licence of a blood establishment, the Licensing Authority shall serve a notice on the blood establishment stating that it intends to suspend or revoke its licence with effect from the date specified in the notice, giving reasons for such decision:

Provided that a suspension or revocation shall take effect immediately when the Licensing Authority considers that it is necessary in the interests of safety.

(3) In those cases where -

(a) the blood establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder; or

(b) the information given by the blood establishment was false or incomplete in any material respect, and the Licensing Authority considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the licence of the blood establishment in the first instance, the Licensing Authority may serve a notice on the responsible person of the blood establishment:

(i) identifying the requirements of which the blood establishment is in breach or, in the case of false and incomplete information, the further information which is required;

(ii) identifying the action which the blood establishment is required to take; and

(iii) giving the timescale within which the blood establishment shall take the action identified in the preceeding sub-paragraph.

(4) If the blood establishment fails to comply with the requirements set out in the notice within the specified timescale, the Licensing Authority may, by a notice served on the blood establishment, suspend or revoke the licence of the blood establishment.

(5) Any suspension shall be for such period as the Licensing Authority shall consider necessary having regard to the reasons for the suspension.

(6) The suspension or revocation of an licence may be total, or limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular blood component.

Notice served on hospital blood banks.

**7.** (1) If the Licensing Authority is of the opinion that -

(a) the person responsible for management of a hospital blood bank has failed, in any material respect, to comply with the requirements of these articles; or

(b) the testing, storage or distribution of blood or blood components by the hospital blood bank is such that any blood or blood components cannot be safely administered for transfusion; or

(c) the information given by the person responsible for management of a hospital blood bank was false or incomplete in any material respect, the Licensing Authority may serve a notice on the person responsible for management of the hospital bank requiring that the hospital ceases to conduct any of this Activities specified in the notice, or refrains from administering to patients any blood or blood components specified in the notice, until the conditions set out in the notice are complied with.

(2) Any notice served by the Licensing Authority pursuant to sub-article (1) shall specify the date from which the prohibition specified in the notice shall take effect, which shall be not less than seven days from the date on which the notice is served:

Provided that where the Licensing Authority considers that it is necessary in the interests of safety, it may specify in the notice that the prohibition takes immediate effect.

(3) The notice shall be withdrawn if:

(a) the person responsible for management of the hospital blood bank is no longer in breach of the requirements of these articles;

(b) the hospital blood bank is able to show that the activity or product referred to in the notice given pursuant to sub-article (1)(b) may be safely carried out or, as the case may be, administered; or

(c) all necessary information has been supplied to the Licensing Authority.

Validity of licence.

**8.** (1) Every licence granted under this Act shall, unless previously revoked or renewed, expire at the end of its period of validity.

(2) Every licence shall, unless previously revoked, be renewable upon application by the holder made at least three months before the expiry of the period of validity.

Importation.

**9.** No person shall import into Malta any blood or blood components, including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products, from a country or territory outside the European Community which does not meet standards of quality and safety equivalent to those laid down in Annex V of Directive 2004/33/EC and any amendments thereto.

Specific epidemiological situations.

**10.** (1) Where the Licensing Authority is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood donations, and as a result of which it considers that specific deferral criteria for the collection of blood donations should be adopted, it shall notify:

(a) the blood establishments that those criteria must be adopted; and

(b) the Commission of the epidemiological situation and the additional deferral criteria which blood establishments are required to adopt in relation to it pursuant to paragraph (a) hereof.

(2) A blood establishment shall adopt and comply with any criteria for additional tests notified to them by the Licensing Authority pursuant to sub-article (1) hereof.

## PART IV

## TISSUES AND CELLS ESTABLISHMENTS

Inspection and control measures.

**11.** (1) The inspections and control measures of tissues and cells establishments shall be carried out by any person duly authorized in writing by the Licensing Authority and such person shall, on production of his authorization, have a right to:

(a) inspect at any reasonable hour:

(i) any premises owned or managed by a tissues and cells establishment, or at which the tissues and cells establishment carries out any of its activities in relation to the procurement of human tissues and cells;

(ii) any premises of any person who carries out any of the activities referred to above on behalf of, and pursuant to a contractual arrangement with, a tissues and cells establishment; and

(iii) where any facilities for donor evaluation and testing are in the premises of any person other than a tissues and cells establishment, those facilities in that person's premises;

(b) to require the production of and inspect any article or substance at the premises;

(c) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record, in whatever form it is held at the premises, or any computer data or records accessible thereat;

(d) to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record, in whatever form they are held at the premises, or any computer data or records accessible thereat;

(e) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;

(f) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities;

(g) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him;

(h) to evaluate and verify the procedures and the activities carried out in tissues and cells establishments and the facilities of third parties that are relevant to the requirements of this Act and regulations made thereunder;

(i) carry out any activity he may deem appropriate for the proper execution of his duties and responsibilities as provided by this Act and regulations made thereunder.

Supervision and licensing.

**12.** (1) It shall not be lawful for any person to carry out any activity in connection with testing, processing, preservation, storage or distribution of human tissue and cells intended for human applications otherwise than in accordance with a licence issued under article 3 of this Act.

(2) A licence shall not be required for –

(a) the storage and distribution of, and the performance of compatibility tests on, tissues and cells exclusively for use within hospital facilities; or

(b) any person carrying out any of these activities referred to in sub-article (1) hereof, where that person carries out that activity on behalf of, and pursuant to a contractual arrangement with a tissues and cells establishment which is licenced under this Part to carry out the activity in question;

(c) the direct distribution of specified tissues and cells for immediate transplantation to the recipient as long as the supplier is licensed for such activity.

(3) The application for the grant of a licence shall be made to the Licensing Authority and shall be accompanied by the prescribed fee.

(4) The application shall contain the information as may be prescribed and shall be submitted in the form and in the manner as may by rules be laid down by the Licensing Authority.

(5) Where an application is received by the Licensing Authority, it may –

(a) grant or refuse any application;

(b) grant such licence in respect of particular sites or activities only;

(c) grant such licence subject to conditions;

(d) refuse to process the application if such application has not been filed in accordance with this Act and regulations made thereunder;

(e) request the applicant to furnish it with additional information as it may deem necessary.

(6) When the Licensing Authority grants an application for licence, it shall give notice in writing to the tissues and cells establishment specifying –

(a) the activities which the establishment may undertake under this Act and regulations made thereunder at each site in respect of which a licence is granted;

(b) the conditions which apply to the undertaking of those activities; and

(c) the tissues and cells preparation processes which the establishment may carry out.

(7) The Licensing Authority may at any time remove or vary any of the licence conditions, or may impose additional conditions.

(8) When the Licensing Authority removes or varies any condition or imposes any additional condition, it shall inform in writing the establishment in question giving reasons for its decision.

(9) A tissues and cells establishment may not make any substantial change in the activities which it undertakes without the prior written approval of the Licensing Authority.

(10) Any application for approval to make a substantial change in the activities of the tissues and cells establishment shall be made in writing to the Licensing Authority, and shall be accompanied by the prescribed fee.

(11) For the purposes of this article, a substantial change in a tissues and cells establishment's activities is any change -

(a) to the sites from which the establishment operates or to the activities to be carried out at each site;

(b) which would result in breach of this Act or regulations made thereunder or of any condition specified by the Licensing Authority; or

(c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the establishment has been licensed to undertake.

(12) The Licensing Authority shall suspend or revoke the licence of a tissues amd cells establishment or of a tissue or cell

preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Act and regulations made thereunder.

Revocation or suspension of licence.

**13.** (1) (a) The Licensing Authority may suspend or revoke the licence of a tissues and cells establishment on one or more of the following grounds -

(i) that the establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder;

(ii) that the information given by the blood establishment was false or incomplete in any material respect.

(b) In addition the Licensing Authority shall suspend or revoke the licence of a tissues and cells establishment or of a tissues or cells preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Act and regulations made thereunder.

(2) Prior to suspending or revoking the licence of a blood establishment, the Licensing Authority shall serve a notice on the blood establishment stating that it intends to suspend or revoke its licence with effect from the date specified in the notice, giving reasons for such decision:

Provided that such suspension or revocation shall take effect immediately when the Licensing Authority considers that it is necessary in the interests of safety.

(3) In those cases where -

(a) the establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder; or

(b) the information given by the establishment was false or incomplete in any material respect, and the Licensing Authority considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the licence of the establishment in the first instance, the Licensing Authority may serve a notice on the responsible person of the establishment:

(i) identifying the requirements of which the establishment is in breach or, in the case of false and

incomplete information, the further information which is required;

(ii) identifying the action which the establishment is required to take; and

(iii) giving the timescale within which the blood establishment shall take the action identified in sub-paragraph (ii) hereof.

(4) If the establishment fails to comply with the requirements set out in the notice within the specified timescale, the Licensing Authority may, by a notice served on the establishment, suspend or revoke the licence of the establishment.

(5) Any suspension shall be for such period as the Licensing Authority shall consider necessary having regard to the reasons for the suspension.

(6) The suspension or revocation of an licence may be total, or limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular tissue and cell.

Validity of licence.

**14.** (1) Every licence granted under this Act shall, unless previously revoked or renewed, expire at the end of its period of validity.

(2) Every licence may, unless previously revoked, be renewed upon application by the holder made at least three months before the expiry of the period of validity.

Import or export of human tissues and cells.

**15.** (1) No person shall import tissues and cells from third countries unless:

(a) such an activity is undertaken by a licensed tissues and cells establishment;

(b) the imported tissues and cells can be traced from the donor to the recipient and vice versa in accordance with the procedures established by regulations under this Act;

(c) the tissues and cells establishments that receive such imports from third countries ensures that they meet standards of quality and safety equivalent to the ones laid down in Directive2004/23/EC.

(2) No person shall export tissues and cells to third countries unless:

(a) such activity is undertaken by a licensed tissues and cells establishment;

(b) such exports to third countries complies with the requirements of Directive 2004/23EC.

(3) The Licensing Authority may, after ensuring that the that imports and exports of tissues and cells referred to in subarticle (2) hereof meet quality and safety standards equivalent to those laid down in Directive 2004/23/EC, directly authorise:

(a) the import or export of tissues and cells referred to in article 12(2)(c);

(b) the import or export of certain tissues and cells in case of emergency.

## PART V

## MISCELLANEOUS

Power of the Minister to make regulations.

**16.** The Minister may, after consultation with the Licensing Authority, by regulations provide for –

(a) the requirements to be satisfied by blood and tissues and cells establishments;

(b) standards of good practice in manufacture;

(c) the requirements to be satisfied by hospital blood banks;

(d) the requirements to establish an effective system of haemovigilance;

(e) prescription of the fee to be paid for the issue of a licence;

(f) any other matter to better put into effect the provisions of this Act.

Offences and penalties.

**17.** Any person who fails to comply with any of the provisions of this Act or any regulations or rules made thereunder, shall be guilty of an offence and shall, on conviction, be liable a fine not exceeding five thousand liri.

Special procedure.

**18.** (1) Notwithstanding any other law providing for the trial of offences, where the Authority believes that a person has committed an offence against this Act or any regulations made thereunder, the

Licensing Authority shall give notice in writing to such person describing the offence of which the person is accused, indicating the steps to be taken to remedy the offence and the penalty he is required to pay in respect of that offence.

(2) The Minister shall prescribe the penalties that may be demanded by the Licensing Authority in relation to any specified offence:

Provided that such penalty shall not exceed the amount of five thousand Malta liri.

(3) Where a notice under this article has been given, the person named in the notice may, within twenty-one days of the service of the notice, accept responsibility for the offence specified in the notice and within the same period pay the penalty indicated in the notice, and comply with the relative provision of this Act, or of the regulations or rules made thereunder and no further proceedings may be taken under this Act in respect of such offence.

(4) Where the person to whom notice is given under sub-article (1) has not paid the penalty within the twenty-one day period referred to in sub-article (3) and has not, within the time specified, complied with the requirements of this Act, criminal proceedings may be taken against him in accordance with the provisions of the Criminal Code, of this Act and of any other law applicable to the offence.

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## Objects and Reasons

The object of the Bill is to transpose Directives 2002/98EC, 2004/33EC and 2004/23EC and more explicitly to ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage and distribution when intended for transfusion, are undertaken only by blood establishments in Malta which have been designated, authorized, accredited or licensed by the Licensing Authority for that purpose. Furthermore, the Bill lays down the standards of quality and safety for human tissues and cells intended for human applications in order to ensure a high level of protection of human health.