MEDICINE

Abortion and Sterilization Act 2 of 1975, as amended in South Africa to December 1977

Summary: This Act (RSA GG 4608) regulates abortion and sterilization. Abortion is legal only in cases of severe mental or physical risk to the woman concerned, cases where there is a serious risk that the child will suffer a severe physical or mental handicap, and cases where the child was conceived as a result of rape or incest.

Applicability to SWA: Section 11 states that "this Act and any amendment thereof shall apply also in the territory of South West Africa, including the Eastern Caprivi Zipfel."

Transfer of administration to SWA: The administration of this Act was transferred to SWA by the Executive Powers (Health) Transfer Proclamation (AG 14/1977), dated **1 December 1977**. Neither of the amendments to the Act in South Africa after the date of transfer and prior to Namibian independence – the *Abortion and Sterilization Amendment Act 38 of 1980* (RSA GG 6985) and the *Abortion and Sterilization Amendment Act 48 of 1982* (RSA GG 8107) – was made expressly applicable to SWA.

Amendments: The following pre-independence South African amendment was applicable to SWA –

- *Abortion and Sterilization Amendment Act 18 of 1976* (RSA GG 5034).

The Native Laws Amendment Proclamation, AG 3 of 1979 (OG 3898), deemed to have come into force in relevant part on 1 August 1978 (section 5 of AG 3 of 1979), amends some of the terminology in the Act.

Regulations: Regulations are authorised by section 8 of the Act. Pre-independence regulations are contained in RSA GN R.1210/1975 (RSA GG 4749).[124]

No post-independence regulations have been promulgated.

Cases:
S v Haimbodi 1993 NR 129 (HC)
S v Alweendo 1993 NR 177 (HC)
S v Iyambo 2007 (2) NR 842 (HC) (lenient sentence appropriate where a very young foetus is involved).

Commentary: Charles Ngwena, "Access to safe abortion as a human right in the African region: lessons from emerging jurisprudence of UN treaty-monitoring bodies", 29 (2) *South African Journal on Human Rights* 2013.

[124] In South Africa, subsequent regulations were issued in RSA GN R.2164/1977 (RGA GG 5779), withdrawing RSA GN R.1210/1975. This *Government Gazette* was dated 21 October 1977, prior to the date of transfer, but the relevant Government Notice came into effect only on 1 January 1978, after the date of transfer. An additional regulation was issued in South Africa in RSA GN R.2165/1977 (RGA GG 5779), which also came into effect only on 1 January 1978, after the date of transfer. These two regulations made no reference to SWA and were thus not applicable to SWA.

In South Africa, new regulations were made in RSA GN R.610/1983 (RSA GG 8617) (as corrected by RSA GN R.774/1983, RSA GG 8652) after the date of transfer and prior to Namibian independence, repealing RSA GN R.2164/1977 and RSA GN R.2165/1977. Again, these regulations made no reference to SWA and were thus not applicable to SWA.

Anatomical Donations and Post-Mortem Examinations Ordinance 12 of 1977

Summary: This Ordinance (OG 3633) covers the donation of human bodies and tissue (including flesh, organs, bones and body fluids) for therapeutic and scientific purposes. It also regulates post-mortems.

Amendments: This Ordinance is affected by the Health Act 21 of 1988 (OG 5651), which made it applicable to all of SWA.

Regulations: Anatomical Donations and Post-Mortem Examinations Regulations are contained in GN 87/1980 (OG 4114). These 1980 regulations do not repeal the similar Anatomical Donations and Post-Mortem Examinations Regulations contained in GN 275/1978 (OG 3866), but they cover identical topics and so must supersede the 1978 regulations.

Notices: AG GN 92/1981 (OG 4504), issued in terms of regulation 4 of the 1980 regulations, lists institutions which are authorised to receive, acquire, preserve or use the bodies of deceased persons for therapeutic or scientific purposes, and institutions which are authorised to perform post-mortem examinations for any of the purposes stated in regulation 2(1).

Namibia Institute of Pathology Act 15 of 1999

Summary: This Act (GG 2210) establishes the Namibia Institute of Pathology Limited and sets forth its duties and functions. Medical laboratory functions of the Ministry of Health and Social Services will be transferred to the Institute on a date determined by the Minister. This Act was brought into force on 1 April 2020 by GN 91/2020 (GG 7163).

Amendments: The State-owned Enterprises Governance Act 2 of 2006 (GG 3698), which was brought into force on 1 November 2006 by Proc. 13/2006 (GG 3733) and later re-named the Public Enterprises Governance Act 2 of 2006, amends section 11, 12, 13, 15, 16 and 22.

Regulations: Regulations are authorised by section 34 of the Act, but none have yet been promulgated.

Notices: The date for the transfer of medical laboratory functions from the Ministry of Health and Social Services to the Namibia Institute of Pathology Limited is set as 1 December 2000 (GN 283/2000, GG 2444).

Appointments: The Board of Directors is announced in GN 125/2000 (GG 2340), GN 140/2005 (GG 3529) and GN 206/2009 (GG 4357). The term of office of one board member is extended in GN 203/2015 (GG 5829). After the date that the Act was brought into force, the Board of Directors is announced (with effect from 7 December 2019) in GN 91/2020 (GG 7163).

Medicines and Related Substances Control Act 13 of 2003

Summary: This Act (GG 3051) provides for the establishment of a Namibia Medicines Regulatory Council, for the registration of medicines intended for human and animal use, and for the control of medicines and scheduled substances. It repeals the *Medicines and Related Substances Control Act 101 of 1965.* The Act was brought into force on 25 July 2008 by GN 177/2008 (GG 4088).

Portions of the Act were found unconstitutional by *Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others* 2017 (2) NR 544 (SC), as detailed below under "Cases".

Amendments: Act 8/2007 (GG 3968) – which was brought into force on 1 August 2008 by GN 187/2008 (GG 4091) – amends the Act substantially.

Savings: Pursuant to section 46(2), the schedules of the *Medicines and Related Substances Act 101 of 1965* continue to apply until the Minister publishes a notice in the Gazette in terms of section 29(1). Note that the notice referred to has been published: GN 180/2008 (GG 4088), as amended and as subsequently replaced (see the section on "Notices" below).

Pursuant to section 46(1A), the Medicines Control Council established under the previous legislation is to serve the functions of the new Namibia Medicines Regulatory Council until such time as the Minister appoints the new Council. A new Council was initially appointed in GN 209/2009 (GG 4367), which has been followed by subsequent appointments.

Notices, regulations, authorisations, orders, approvals, certificates made and other things done under the previous legislation survive, by virtue of section 47(2), as amended.

Regulations: Pre-independence regulations have not yet been comprehensively researched.

Proposed regulations under the current Act were published in GN 241/2004 (GG 3317).

Extensive regulations pertaining to medicines and related substances were subsequently issued in GN 178/2008 (GG 4088),[125] and amended by -

- GN 28/2015 (GG 5681) (substitution of Regulation 4 and repeal of Annexure II);
- GN 316/2015 (GG 5915) (substitution of Annexure XXXVIII, with effect from 1 April 2016);
  Note that GN 316/2015 refers to "Annexure XXXVIII of regulation 47 published in Government Notice 1 of 25 July 2008". It should refer to Annexure XXXVIII of the regulations published in Government Notice 178 of 25 July 2008.
- GN 66/2019 (GG 6868) (amendment of regulations 11 and 14);
- GN 202/2019 (GG 6958) (amendment of regulation 23; substitution of regulation 46, Annexure XXXVI and Annexure XXXVII; and insertion of Annexures XXXVI(A) and XXXVII(A));
- GN 219/2020 (GG 7321) (insertion of regulation 45A).
  Note that GN 219/2020 states that the regulations were previously amended by Government Notice No. **228** of 27 February 2015. This is incorrect and should refer to Government Notice No. **28** of 27 February 2015.
- GN 178/2021 (GG 7608) (substitution of Annexure XXXVIII)
  Note that GN 178/2021 states that the regulations were previously amended by Government Notice No. **228** of 27 February 2015. This is incorrect and should refer to Government Notice No. **28** of 27 February 2015.

These regulations were initially ruled invalid in *Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others*, 2010 (2) NR 660 (HC). Subsequently, *Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others* 2011 (1) NR 272 (HC) suspended the operation of sections 46(3) and (4) of the Act until such time as new regulations are made. However, these holdings were overruled by *Minister of Health and Social Services & Others v Medical Association of Namibia Ltd & Another* 2012 (2) NR 566 (SC), which found the regulations to be generally valid, with the exception of **regulation 34(3)(a), (c), (d) and (e)** which was declared invalid as being *ultra vires* the powers of the Minister under the Act. The Supreme Court and also found that it was not competent for the High Court to have suspended the operation of section 46(3) of the Act.

Exemptions: Exemptions from the application of section 29 of the Act are contained in GN 179/2008 (GG 4088), as amended by GN 43/2015 (GG 5703).

Temporary exemptions from section 18(1) of the Act are contained in GN 85/2010 (GG 4473) and GN

[125] GN 178/2008 repeals the pre-independence regulations contained in RSA GN R.352/1975 (RSA GG 4594), as amended by RSA GN R.1188/1976 (RSA GG 5209) and GN 47/2001 (GG 2485).

194/2011 (GG 4808), subject to certain conditions. Specified COVID-19 vaccines are exempted from section 18(1) of the Act, subject to certain conditions, by GN 39/2021 (GG 7479).

A temporary exemption from sections 19 and 31(5)(c) of the Act, until 31 December 2021, is contained in GN 304/2020 (GG 7402).

Certain medicines are exempted from the operation of certain regulations for specified time periods in GN 272/2008 (GG 4174), GN 49/2010 (GG 4444), GN 84/2011 (GG 4736), GN 187/2012 (GG 5003), GN 22/2014 (GG 5425), GN 29/2015 (GG 5681), GN 76/2017 (GG 6277), Certain medicines are permanently exempted from the operation of certain regulations, and portions of annexures issued pursuant to certain regulations, in GN 207/2017 (GG 6384) and GN 52/2018 (GG 6552).

Registrations and cancellations: Registrations and cancellations under the previous Act are as follows:

> GN 64/2001 (GG 2512) relates to the continued registration of medicines registered prior to independence.
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> Certain medicines are registered in GN 202/1995 (GG 1183), GN 4/1997 (GG 1480), GN 144/1997 (GG 1603), GN 210/1998 (GG 1942), GN 254/1998 (GG 1972), GN 66/1999 (GG 2083), GN 105/2002 (GG 2759), GN 240/2004 (GG 3317), General Notice 39/2005 (GG 3391), GN 131/2005 (GG 3511), GN 182/2005 (GG 3556), GN 159/2006 (GG 3704), GN 193/2006 (GG 3735), GN 138/2007 (GG 3887), GN 211/2007 (GG 3937) (which withdraws GN 138/2007), GN 220/2007 (GG 3945), GN 15/2008 (GG 3983), and GN 90/2008 (GG 4032).
>
> The registration of certain medicines is cancelled in GN 26/2006 (GG 3584), GN 203/2006 (GG 3746) and GN 137/2007 (GG 3887).

Certain medicines are registered under the current Act in GN 196/2008 (GG 4103), GN 210/2009 (GG 4367), GN 50/2010 (GG 4444), GN 128/2010 (GG 4505), GN 225-226/2010 (GG 4577), GN 39-40/2011 (GG 4683), GN 47/2011 (GG 4695), GN 71/2011 (GG 4726), GN 122/2011 (GG 4761), GG 197/2011 (GG 4812), GG 188/2012 (GG 5003), GN 244/2012 (GG 5042), GN 245/2012 (GG 5042), GG 30/2013 (GG 5142), GN 212/2013 (GG 5263), GN 211/2014 (GG 5596), GN 50/2018 (GG 6551) (veterinary medicines), GN 51/2018 (GG 6552), GN 63/2018 (GG 6566) (veterinary medicines), GN 64/2018 (GG 6566), GN 305/2018 (GG 6779), GN 306/2018 (GG 6779) (veterinary medicines), GN 22/2019 (GG 6840), GN 23/2019 (GG 6840), GN 127/2019 (GG 6910), GN 128/2019 (GG 6910), GN 201/2019 (GG 6956), GN 354/2019 (GG 7052), GN 355/2019 (GG 7052), GN 356/2019 (GG 7052), GN 180/2020 (GG 7296), GN 248/2020 (GG 7353), GN 94/2021 (GG 7527), GN 181/2021 (GG 7615), GN 222/2021 (GG 7658) and GN 20/2022 (GG 7744).

The registration of certain medicines is cancelled in terms of the current Act in GN 51/2010 (GG 4444), GN 89/2012 (GG 4915), GN 186/2012 (GG 5003) and GN 31/2013 (GG 5142), GN 210/2014 (GG 5596), GN 98/2015 (GG 5758), GN 37/2018 (GG 6534), GN 80/2018 (GG 6580), GN 307/2018 (GG 6779), GN 308/2018 (GG 6779), GN 20/2019 (GG 6840), GN 21/2019 (GG 6840), GN 92/2019 (GG 6901), GN 93/2019 (GG 6901), GN 200/2019 (GG 6956), GN 353/2019 (GG 7052), GN 179/2020 (GG 7296), GN 180/2021 (GG 7615), GN 221/2021 (GG 7658) and GN 19/2022 (GG 7744).

GN 111/2011 (GG 4756) determines classes of veterinary medicines which are subject to registration under the Act.

Health care practitioners are ordered to return certain cancelled medicines to the manufacturers, suppliers or importers of those medicines in terms of GN 90/2012 (GG 4915).

Notices: Notices under the previous Act which appear to survive include the following –

> GN 154/1999 (GG 2155) is a notice requiring the return to the suppliers of certain undesirable medicines (those containing chlormezanone).

GN 105/2002 (GG 2759) is a notice concerning medicines and classes of medicines subject to registration.

GN 104/2002 (GG 2759) is a notice about inspection of the Medicines Register.

There are a number of RSA Government Notices which amended the Schedules to the previous Act. These have not been recorded here.

In terms of the current Act, GN 80/2021 (GG 7509) currently classifies certain medicines and other substances as Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5.[126]

Appointments: Members of the Namibia Medicines Regulatory Council are announced in GN 209/2009 (GG 4367), GN 195/2010 (GG 4561), GN 162/2012 (GG 4978), GN 278/2012 (GG 5076), GN 277/2013 (GG 5328), GN 278/2013 (GG 5328), GN 337/2013 (GG 5379), GN 218/2016 (GG 6125), GN 4/2017 (GG 6217), GN 17/2008 (GG 6527), GN 141/2018 (GG 6649), GN 370/2018 (GG 6816) and GN 305/2020 (GG 7402).

Note that GG 6527 was initially numbered incorrectly as GG 6528. A corrected version was subsequently issued.

Cases:

Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others 2010 (2) NR 660 (HC) finds the proposed regulations published in GN 241/2004 (GG 3317) and the regulations published in GN 178/2008 (GG 4088) to be unlawful and *ultra vires;* it also affects the application of section 31(3)and 34(1) and suspends the application of 46(3) until such time as valid new regulations are in place; *Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others* 2011 (1) NR 272 (HC) varies the order made in the previous case, but still suspends the operation of sections 46(3) and (4) of the Act until such time as new regulations are made; and *Minister of Health and Social Services & Others v Medical Association of Namibia Ltd & Another* 2012 (2) NR 566 (SC) finds the regulations to be generally valid – with the exception of regulation 34(3)(a), (c), (d) and (e) which are invalid as being *ultra vires* the powers of the Minister under the Act – and finding that it was not competent for the High Court to suspend the operation of section 46(3) of the Act

Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others 2015 (1) NR 1 (HC) (licensing scheme for dispensing of medicines under section 31(3) – read together with sections 29(7)(b), 29(9)(b), 29(13)(b) and 29(19)(b) – is not unconstitutional; the Namibia Medicines Regulatory Council is a tribunal as envisaged by Art 12(1)(a) of the Namibian Constitution); overruled by *Medical Association of Namibia Ltd & Another v Minister of Health and Social Services & Others* 2017 (2) NR 544 (SC) (This case holds that section 31(3) is "of no force and effect", finding it unconstitutionally vague; also holding that the words ". . . . who holds a licence contemplated in section 31(3), subject to the conditions of that licence" in sections 29(7)(b), 29(9)(b), 29(13)(b), 29(19)(b) of the Act are "declared to be inconsistent with the Constitution and therefore invalid and accordingly severed from those provisions". Note that the court's order (point 1.1 at para 106) also states that these words should be severed from section 31(3), but the words in question do not appear there and section 31(3) is in any event declared entirely void.)

[126] Initially, GN 180/2008 (GG 4088), as amended by GN 163/2012 (GG 4978), GN 198/2013 (GG 5255), GN 190/2014 (GG 5582) and GN 53/2018 (GG 6552), classified certain medicines and other substances as Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5. It was published in terms of section 29(1) of the Act – and so replaces the Schedules of the Medicines and Related Substances Act 101 of 1965 which survived in terms of section 47(2) of the Act. GN 180/2008 was repealed and replaced, initially by GN 278/2018 (GG 6749) which was withdrawn by GN 7/2019 (GG 6830), and then by GN 8/2019 (GG 6830) and by GN 80/2021 (GG 7509).

SELECTED CASES

LM & Others v Government of the Republic of Namibia 2012 (2) NR 527 (HC) (unlawful sterilisations); upheld on appeal and remitted to High Court for determination of quantum of damages in *Government of the Republic of Namibia v LM & Others* 2015 (1) NR 175 (SC); see also Priti Patel, "How did we get here and where to now? The coerced sterilisation of HIV-positive women in Namibia", *Agenda,* Issue 75, 2008

Ex Parte Chingufo: In re Semente v Chingufo 2013 (2) NR 328 (HC) (patient's right to refuse treatment if sufficient mental capacity present, but requisite capacity missing in the case at hand), overturned on appeal in *ES v AC* 2015 (4) NR 921 (SC) (patient autonomy as a basic human right, notwithstanding children's right to be cared for by their parents); see also Nico Horn, "*Ex Parte Chingufo. In re E Semente; E Semente v Chingufo:* Another unfortunate victory for formalist law", *Namibia Law Journal*, Volume 5, Issue 1, 2013 and Carmen C Visser, Medical treatment vis-à-vis patient's rights", *Namibia Law Journal*, Volume 8, Issue 1, 2016.

COMMENTARY

Clever Mapaure, "Melancholic medical law: Namibian medical practitioners may get away with homicide – The story of Mr H", *Namibia Law Journal*, Volume 6, Issue 1, 2014.

See also Veterinary and Veterinary Para-Professions Act 1 of 2013 (**ANIMALS**).

See also **HEALTH**.

See also **HOSPITALS**.

See also Namibia Qualifications Authority Act 29 of 1996 (occupational standards) (**EDUCATION**).

See also **MEDICAL AID**.

See also **MENTAL HEALTH AND MENTAL DISORDERS**.

See also **SOCIAL WELFARE**.