Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Equality Screening, Disability Duties and Human Rights Assessment Template

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Guidance on completion of the template can be found on the Equality Commission website at S75 screening template 2010 (web access checked 230920) .docx

Part 1. Policy scoping

1.1 Information about the policy

Name of the policy:

Northern Ireland Marketing MHRA Authorisation Route (NIMAR)

Is this an existing, revised or a new policy?

New policy

What is it trying to achieve? (intended aims/outcomes)

To ensure the continued access to medicines by patients in NI. The DHSC & MHRA is exploring the development of a new regulatory route, to be used when clinical need cannot be met by medicines supplied to NI in compliance with their UK or NI marketing authorisations, to take effect on 1 January 2022.

NIMAR will allow certain medicines authorised for GB or UK use, to move from GB to NI. NIMAR would represent a new regulatory route that would allow a medicine to be supplied to the Northern Ireland market where there is clinical need, with full MHRA oversight and a marketing authorisation valid in GB.

Medicines with a UK wide authorisation would still be eligible for NIMAR if they could not be supplied on a licensed basis due to importation requirements under EU law. Additionally, key regulatory functions and economic operators could be located anywhere in the EU/EEA or the UK.

Over-the-counter (OTC) medicines are not prescribed by a health care professional and so would fall outside of the scope of EU legislation and therefore would not be eligible for supply via NIMAR. DHSC are currently exploring alternative options to help ensure the supply of OTC medicines in Northern Ireland.

Are there any Section 75 categories which might be expected to benefit from the intended policy?
If so, explain how.

The policy will be applicable to the whole population as it is intended to maintain the status quo access to medicines.

Who initiated or wrote the policy?

Department of Health and Social Care (DHSC) and the Medicines Healthcare Products and Regulatory Agency MHRA are developing the policy. Officials from the Department of Health have been liaising with DHSC and MHRA to design a robust contingency measure which can be operational, if necessary, to support the flow of medicines into Northern Ireland from 1 January 2022.

Who owns and who implements the policy?

DHSC and MHRA would own and implement the policy for Northern Ireland. Prescribers in Northern Ireland would prescribe the medicines that would be included in the NIMAR list of medicines and community pharmacies in NI would dispense the medicines. NIMAR medicines would also be prescribed and dispensed in a secondary care setting.

1.2 Implementation factors

Are there any factors which could contribute to/detract from the intended aim/outcome of the policy/decision?

If yes, are they (please delete as appropriate)

~~financial~~

Legislative:

NIMAR would have a legal basis in EU law by way of Article 5(1) of Directive 2001/83/EC, which makes provision about unlicensed medicines. The Directive is part of the EU pharmaceutical acquis that is applied in relation to Northern Ireland under the Northern Ireland Protocol. Article 5(1) forms the basis for the exemption (in regulation 167 of the Human Medicines Regulations 2012) from the requirement for a medicinal product to have a Marketing Authorisation.

MHRA and DHSC would create new UK legislation for NIMAR by laying a statutory instrument that complies with Article 5(1) and facilitates the supply of medicines that have been authorised in GB to meet the clinical need in NI.

To operationalise NIMAR, a list mechanism would need to be established i.e. a publicly available list of medicines eligible to be supplied to NI via NIMAR.

Other:

Over the counter medicines

Over-the-counter (OTC) medicines are not prescribed by a health care professional and so would fall outside of the scope of EU legislation and therefore would not be eligible for supply via NIMAR. DHSC is currently exploring alternative options to help ensure the supply of OTC medicines in NI.

Liability

The MHRA, DHSC and the Northern Ireland Executive are exploring options to ensure that prescribers of medicines supplied via NIMAR will not be required to take on any additional liability than they currently do when prescribing authorised medicines in NI.

3 Main stakeholders affected

Who are the internal and external stakeholders (actual or potential) that the policy will impact upon? (please delete as appropriate)

~~staff~~

service users – patients requiring the medicines.

~~other public sector organisations~~

~~voluntary/community/trade unions~~

other, please specify:

Stakeholders

The policy would involve prescribers of medicines prescribing medicines from a publicly available list of medicines eligible to be supplied to NI via NIMAR. The medicines could be dispensed in a primary care and secondary care. For example, the NIMAR medicines could be dispensed by community pharmacists or in a secondary care facility e.g. a hospital. The patient would be the recipient of the medicines.

1.4 Other policies with a bearing on this policy

- what are they? N/A

- who owns them? N/A

1.5 Available evidence

What evidence/information (both qualitative and quantitative[1]) have you gathered to inform this policy? Specify details for each of the Section 75 categories.

Religious belief evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care.

Political Opinion evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care.

Racial Group evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care.

Age evidence / information:

The table below comes from the General Pharmaceutical Services and Prescribing Statistics website on BSO – the link is General Pharmaceutical Services and Prescribing Statistics (hscni.net)

The table below shows the breakdown of prescribed items from community pharmacy by local government districts, gender and age. The figures reflect significant use by the 45-64 age group and those over age 65.

[1] * Qualitative data – refers to the experiences of individuals related in their own terms, and based on their own experiences and attitudes. Qualitative data is often used to complement quantitative data to determine why policies are successful or unsuccessful and the reasons for this.

Quantitative data - refers to numbers (that is, quantities), typically derived from either a population in general or samples of that population. This information is often analysed either using descriptive statistics (which summarise patterns), or inferential statistics (which are used to infer from a sample about the wider population).

Table 2.7a: Number of Prescription Items by LGD, Patient Age and Gender Breakdown, 2020/21

Gender	Age Group	Antrim & Newtownabbey (000's)	Ards & North Down (000's)	Armagh City, Banbridge & Craigavon (000's)	Belfast (000's)	Causeway Coast & Glens (000's)	Derry City & Strabane (000's)	Fermanagh & Omagh (000's)	Lisburn & Castlereagh (000's)	Mid & East Antrim (000's)	Mid Ulster (000's)	Newry, Mourne & Down (000's)	Unknown [note 10] (000's)	Northern Ireland (000's)
All Persons	**0-4**	27.1	26.5	42.8	68.8	22.8	29.4	25.8	29.4	25.0	31.6	43.4	2.7	**375.3**
	5-14	47.4	58.4	73.2	136.2	43.1	63.8	45.4	52.3	43.1	51.2	71.6	5.0	**690.7**
	15-24	84.0	91.2	119.7	233.5	80.2	104.6	72.7	78.0	82.6	81.1	119.7	8.5	**1,155.8**
	25-44	391.3	381.8	536.1	1,157.9	363.9	486.9	304.6	330.8	377.0	347.4	475.1	40.2	**5,193.1**
	45-64	926.0	984.6	1,410.9	2,688.1	943.6	1,338.0	835.8	794.3	911.7	897.9	1,265.7	88.5	**13,085.3**
	65-74	518.9	693.0	810.8	1,316.8	557.3	772.6	565.6	475.3	521.8	556.0	769.8	34.6	**7,592.6**
	75-84	444.8	611.1	723.5	1,055.2	496.9	549.5	460.1	475.0	481.2	473.3	637.4	32.6	**6,440.5**
	85+	215.4	303.4	327.5	542.6	233.9	199.7	222.3	240.5	244.4	231.4	296.7	23.1	**3,080.9**
	Unknown [note 13]												4,085.75	**4,085.7**
All Persons	**Total**	**2,654.8**	**3,150.1**	**4,044.5**	**7,199.1**	**2,741.8**	**3,544.5**	**2,532.3**	**2,475.6**	**2,686.9**	**2,669.9**	**3,679.4**	**4,320.9**	**41,699.9**
Male	**0-4**	13.6	14.1	23.5	36.9	10.9	15.1	13.7	15.9	13.5	16.2	23.9	1.4	**198.6**
	5-14	26.1	32.9	38.7	78.5	22.4	33.7	25.3	29.4	23.2	28.5	40.8	2.9	**382.5**
	15-24	33.4	36.6	46.6	97.0	30.5	42.9	30.0	31.6	31.8	32.5	48.8	3.7	**465.4**
	25-44	146.4	139.6	203.0	463.4	135.2	190.6	118.6	118.8	143.6	132.3	181.8	15.8	**1,989.1**
	45-64	403.8	424.6	630.4	1,177.5	407.1	605.8	382.4	349.0	399.8	398.1	576.9	48.8	**5,804.2**
	65-74	237.2	331.0	383.5	615.9	268.2	372.8	282.0	226.7	241.8	267.0	379.3	19.1	**3,624.5**
	75-84	188.8	279.3	316.0	436.0	218.0	244.4	210.4	200.2	204.4	209.5	288.8	13.8	**2,809.5**
	85+	68.8	103.9	107.7	162.9	79.1	72.4	79.2	78.6	76.6	79.7	106.1	8.8	**1,023.9**
Male	**Total**	**1,118.3**	**1,361.9**	**1,749.4**	**3,068.0**	**1,171.4**	**1,577.6**	**1,141.7**	**1,050.1**	**1,134.8**	**1,163.8**	**1,646.5**	**114.3**	**16,297.7**
Female	**0-4**	13.4	12.5	19.3	31.9	11.9	14.3	12.2	13.6	11.5	15.4	19.5	1.3	**176.7**
	5-14	21.3	25.5	34.5	57.6	20.7	30.0	20.1	22.9	19.9	22.7	30.8	2.1	**308.2**
	15-24	50.6	54.6	73.1	136.6	49.7	61.7	42.6	46.5	50.7	48.6	70.9	4.9	**690.4**
	25-44	244.8	242.3	333.1	694.6	228.6	296.3	186.0	212.0	233.4	215.1	293.3	24.4	**3,204.0**
	45-64	522.3	560.0	780.5	1,510.6	536.5	732.2	453.4	445.4	512.0	499.8	688.7	39.6	**7,281.1**
	65-74	281.7	362.0	427.3	700.9	289.2	399.8	283.5	248.6	280.0	289.1	390.5	15.5	**3,968.1**
	75-84	255.9	331.8	407.5	619.2	278.9	305.1	249.8	274.8	276.8	263.7	348.6	18.8	**3,631.0**
	85+	146.6	199.5	219.8	379.7	154.8	127.4	143.0	161.8	167.8	151.7	190.6	14.3	**2,057.0**
Female	**Total**	**1,536.6**	**1,788.2**	**2,295.1**	**4,131.1**	**1,570.3**	**1,966.9**	**1,390.6**	**1,425.5**	**1,552.1**	**1,506.1**	**2,032.9**	**120.9**	**21,316.4**

Marital Status evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care.

Sexual Orientation evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care.

Men & Women generally evidence / information:

The table above comes from the General Pharmaceutical Services and Prescribing Statistics website on BSO – the link is General Pharmaceutical Services and Prescribing Statistics (hscni.net)

The table shows the breakdown of prescribed items from community pharmacy by Health Trust, gender and age and indicates a higher number of prescription items for females

Disability evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care although it is likely to be the case that some people with a disability will rely on prescription medicines.

Dependants evidence / information:

There are no statistics readily available in order to monitor prescribed drug item use by this section 75 category across primary and secondary care.

1.6 Needs, experiences and priorities

Taking into account the information referred to above, what are the different needs, experiences and priorities of each of the following categories, in relation to the particular policy/decision?

Specify details of the needs, experiences and priorities for each of the Section 75 categories below:

The proposed policy will apply across all section 75 groups.

Religious belief

The proposed policy will apply across all section 75 groups

Political Opinion

The proposed policy will apply across all section 75 groups

Racial Group

The proposed policy will apply across all section 75 groups

Age

The proposed policy will apply across all section 75 groups although, as indicated at 1.5 above, figures reflect significant use by the 45-64 age group and those over age 65.

Marital status

The proposed policy will apply across all section 75 groups

Sexual orientation

The proposed policy will apply across all section 75 groups

Men and Women Generally

The proposed policy will apply across all section 75 groups although, as indicated at 1.5 above, the table indicates a higher number of prescription items for females.

Disability

The proposed policy will apply across all section 75 groups although, as indicated at 1.5 above, it is likely to be the case that some people with a disability will rely on prescription medicines

Dependants

The proposed policy will apply across all section 75 groups

Part 2. Screening questions

2.1 What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? minor/major/none

Although it is recorded that the impact is 'none' on all groups (because the measures are to retain the status quo), failure to ensure the continued access to medicines by patients in NI would have a detrimental impact on everyone requiring this medication.

Details of the likely policy impacts on Religious belief:

What is the level of impact? None

Details of the likely policy impacts on Political Opinion:

What is the level of impact? None

Details of the likely policy impacts on Racial Group:

What is the level of impact? None

Details of the likely policy impacts on Age:

What is the level of impact? None

Details of the likely policy impacts on Marital Status:

What is the level of impact? None

Details of the likely policy impacts on Sexual Orientation:

What is the level of impact? None

Details of the likely policy impacts on Men and Women:

What is the level of impact? None

Details of the likely policy impacts on Disability:

What is the level of impact? None

Details of the likely policy impacts on Dependants:

What is the level of impact? None

2.2 Are there opportunities to better promote equality of opportunity for people within the Section 75 equalities categories? No

Detail opportunities of how this policy could promote equality of opportunity for people within each of the Section 75 Categories below:

Religious Belief - ~~If Yes, provide details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

Political Opinion - ~~If Yes, provide details:~~
If No, provide reasons

No the policy is intended to maintain the status quo access to medicines for all.

Racial Group - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons

No the policy is intended to maintain the status quo access to medicines for all.

Age - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

Marital Status - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons

No the policy is intended to maintain the status quo access to medicines for all.

Sexual Orientation - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

Men and Women generally - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

Disability - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

Dependants - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

2.3 To what extent is the policy likely to impact on good relations between people of different religious belief, political opinion or racial group?

Please provide details of the likely policy impact and determine the level of impact for each of the categories below i.e. either minor, major or none.

Details of the likely policy impacts on Religious belief:

What is the level of impact? None

Details of the likely policy impacts on Political Opinion:

What is the level of impact? None

Details of the likely policy impacts on Racial Group:

What is the level of impact? None

2.4 Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?

Detail opportunities of how this policy could better promote good relations for people within each of the Section 75 Categories below:

Religious Belief - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons:

No the policy is intended to maintain the status quo access to medicines for all.

Political Opinion - ~~If Yes, provide~~ ~~details:~~
If No, provide reasons

No the policy is intended to maintain the status quo access to medicines for all.

Racial Group - ~~If Yes, provide details:~~
If No, provide reasons

No the policy is intended to maintain the status quo access to medicines for all.

2.5 Additional considerations

Multiple identity

Generally speaking, people can fall into more than one Section 75 category.
Taking this into consideration, are there any potential impacts of the policy/decision on people with multiple identities?
(*For example; disabled minority ethnic people; disabled women; young Protestant men; and young lesbians, gay and bisexual people).*

No the policy is intended to maintain the status quo access to medicines for all, although it is acknowledged that some groups, e.g. older people and females are more reliant on prescription medicines.

Provide details of data on the impact of the policy on people with multiple identities. Specify relevant Section 75 categories concerned. N/A

2.6 Was the original policy / decision changed in any way to address any adverse impacts identified either through the screening process or from consultation feedback. If so please provide details.

No the policy is intended to maintain the status quo access to medicines for all. No consultation has been carried out by DoH as this is a DHSC & MHRA led policy.

Part 3. Screening decision

3.1 Would you summarise the impact of the policy as; No Impact/ Minor Impact/ Major Impact?

No impact

3.2 Do you consider that this policy/ decision needs to be subjected to a full equality impact assessment (EQIA)?

No.

3.3 Please explain your reason.

No the policy is intended to maintain the status quo access to medicines for all. Any wider impacts uncovered with regards to supply will be a matter for DHSC and NIMAR.

3.4 Mitigation

When the public authority concludes that the likely impact is 'minor' and an equality impact assessment is not to be conducted, the public authority may consider mitigation to lessen the severity of any equality impact, or the introduction of an alternative policy to better promote equality of opportunity or good relations.

Can the policy/decision be amended or changed or an alternative policy introduced to better promote equality of opportunity and/or good relations?

The policy is intended to maintain the status quo access to medicines for all.

Over-the-counter (OTC) medicines are not prescribed by a health care professional and so would fall outside of the scope of EU legislation and therefore would not be eligible for supply via NIMAR.

If so, give the reasons to support your decision, together with the proposed changes/amendments or alternative policy.

DHSC is currently exploring alternative options to help ensure the supply of OTC medicines in NI.

3.5 Timetabling and prioritising

Factors to be considered in timetabling and prioritising policies for equality impact assessment. N/A – screened out by DoH.

Is the policy affected by timetables established by other relevant public authorities?

If yes, please provide details.

Yes, DHSC developing this policy for NI.

Part 4. Monitoring

Monitoring is an important part of policy development and implementation. Through monitoring it is possible to assess the impacts of the policy / decision both beneficial and adverse.

4.1 Please detail how you will monitor the effect of the policy / decision?

DoH will liaise with the DHSC and MHRA to understand what monitoring arrangements they will put in place. DoH will be able to access the gov.uk internet site to ascertain the medicines added to the NIMAR list of medicines. Impacts of the policy in NI will be monitored by the HSC and identified to DoH.

4.2 What data will you collect in the future in order to monitor the effect of the policy / decision?

Failure to achieve continued supply of medicines will require further measures. DHSC monitor the supply of medicines and notification is provided to the HSC as required.

Part 5. Disability Duties

5.1 Does the policy/decision in any way promote positive attitudes towards disabled people and/or encourage their participation in public life?

No the policy is intended to maintain the status quo access to medicines for all, although continued availability of medicines will ensure there is no detrimental impact on those that require it, including those with a disability, thus ensuring continued participation in public life, and quality of life in general.

5.2 Is there an opportunity to better promote positive attitudes towards disabled people or encourage their participation in public life by making changes to the policy/decision or introducing additional measures?

No the policy is intended to maintain the status quo access to medicines for all.

Part 6. Human Rights

6.1 Does the policy / decision affects anyone's Human Rights?

The policy is intended to maintain the status quo access to medicines for all and, as such, we have recorded a neutral impact on all articles below. It is, however, acknowledged that, failure to ensure the continued access to medicines by patients in NI would have a detrimental impact on everyone requiring this medication and, possibly on some of the Human Rights articles. If this was to occur a further screening exercise would be required.

Details of the likely policy impacts on Article 2 – Right to life:

What is the impact? ~~Positive / Negative~~ (human right interfered with or restricted) / Neutral

Details of the likely policy impacts on Article 3 – Right to freedom from torture, inhuman or degrading treatment or punishment:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 4 – Right to freedom from slavery, servitude & forced or compulsory labour:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 5 – Right to liberty & security of person:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 6 – Right to a fair & public trial within a reasonable time:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 7 – Right to freedom from retrospective criminal law & no punishment without law: (insert text here)

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 8 – Right to respect for private & family life, home and correspondence:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 9 – Right to freedom of thought, conscience & religion:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 10 – Right to freedom of expression:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 11 – Right to freedom of assembly & association:

What is the impact? ~~Positive / Negative~~ /

Details of the likely policy impacts on Article 12 – Right to marry & found a family:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on Article 14 – Prohibition of discrimination in the enjoyment of the convention rights:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on 1st protocol Article 1 – Right to a peaceful enjoyment of possessions & protection of property:

What is the impact? ~~Positive / Negative~~ / Neutral

Details of the likely policy impacts on 1st protocol Article 2 – Right of access to education:

What is the impact? ~~Positive / Negative~~ / Neutral

6.2 If you have identified a likely negative impact who is affected and how?

N/A

6.3 Outline any actions which could be taken to promote or raise awareness of human rights or to ensure compliance with the legislation in relation to the policy/decision.

The policy is intended to maintain the status quo access to medicines for all. Any legislative changes will be led by DHSC and associated guidance to industry and stakeholders.

Part 7 - Approval and authorisation

Screened by:	**Position/Job Title**	**Date**
Eimear Smyth	Grade 5	03/02/2022
Approved by:		
Cathy Harrison	Chief Pharmaceutical Officer	03/03/2022
Copied to EHRU:		
Eimear Smyth	Grade 5	15/02/2022